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SECRETARY

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# Correspondence Memorandum

Date: August 14, 2018

To: Group Insurance Board

From: Renee Walk, Strategic Health Policy Advisor Office of Strategic Health Policy

Subject: Transgender Services Coverage

This memorandum provides a review of the history related to the Group Insurance Board's (Board) coverage of transgender services, recent developments and relevant considerations. The primary purpose of this memo is to ensure that the Board has updated information to make an informed decision regarding coverage, should it choose to do so.

# **Background & Recent Developments**

In July of 2016, ETF staff recommended, and the Board approved removing the exclusion of benefits and services related to gender reassignment or sexual transformation, following guidance from the federal Department of Health and Human Services (HHS)<sup>1</sup>. The language was removed from Uniform Benefits at that time.

On December 30, 2016, the Board convened a special meeting to consider the reinstatement of the exclusion of transgender services to the 2017 Uniform Benefits. At this meeting, the Board established four contingencies that, once satisfied, would trigger the reinstatement of the exclusion to Uniform Benefits. Those contingencies were:

1. A court ruling or an administrative action that enjoins, rescinds, or invalidates the rules set by the federal Department of Health and Human Services (HHS); 2. Compliance with state law, Section 40.03(6)(c);

3. Renegotiation of contracts that maintain or reduce premium costs for the state; and

4. A final opinion of the Wisconsin Department of Justice (DOJ) that the action taken does not constitute a breach of the Board's fiduciary duties.<sup>2</sup>

Reviewed and approved by Eileen K Mallow, Director, Office of Strategic Health Policy

Board	Mtg Date	Item #
GIB	8.22.18	6A1

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<sup>&</sup>lt;sup>1</sup> Pray, T. June 22, 2016. *Guidelines Contract and Uniform Benefit Changes for 2017.* Department of Employee Trust Funds Correspondence Memorandum. <u>http://etf.wi.gov/boards/agenda-items-2016/gib0712/item3a.pdf</u>.

<sup>&</sup>lt;sup>2</sup> Conlin, R.J. January 30, 2017. *Uniform Benefits and Services Related to Gender Reassignment*. January 30, 2017. Department of Employee Trust Funds Correspondence Memorandum. http://etf.wi.gov/boards/agenda-items-2017/gib0208/item4.pdf.

The last of the contingencies was deemed to be met on February 1, 2017.

The exclusion remains in the 2018 health program agreement. However, in the two years since the Board first reviewed removing the exclusion, developments in this arena have continued. The legal landscape regarding transgender health care and transgender rights generally has developed further. In addition, coverage by other employers has changed, and the Board has received a considerable amount of correspondence regarding the lack of coverage. For these reasons, ETF felt it important to update the Board with a summary of new developments, and options for consideration moving forward.

# Legal Landscape in Brief

Caselaw continues to develop that broadens transgender legal protections, in Wisconsin as well as other parts of the country<sup>3,4</sup>

More recently in Wisconsin, Judge Conley of the United States District Court for the Western District of Wisconsin granted a motion for a preliminary injunction enjoining the State of Wisconsin Department of Health Services from enforcing an exclusion under Wisconsin's Medicaid program that denies coverage for "transsexual surgery" and related drugs<sup>5</sup>.

While the *Boyden* litigation continues, it is important to note that the 7<sup>th</sup> Circuit Court of Appeals, which covers Wisconsin, has not issued a decision addressing whether health insurance plans that exclude gender dysphoria treatment constitute discrimination on the basis of sex.

Meanwhile, an additional Equal Employment Opportunity Commission (EEOC) complaint based on the exclusion in the State of Wisconsin Group Health Insurance Program Uniform Benefits has also been filed with the EEOC<sup>6</sup>.

# **Employer Request for Coverage**

In an August 8, 2018 letter to the Board, the Chancellor of the University of Wisconsin-Madison and Chancellors of five other UW-System schools requested that the Board add transgender health insurance benefits to the State Group Health Insurance Program. The letter indicates that the lack of coverage "jeopardizes our ability to attract top academic and research talent and puts us at a serious disadvantage retaining our LGBTQ employees" (See GIB Item 10C). The letter states that four of the University's Big 10 competitors offer coverage for transgender surgery or therapy. The correspondence suggests that the number of people who would use the services would be smaller than "the goodwill and recruiting impact this coverage would have for a broader range of sympathetic current and prospective employees." The letter cites a

<sup>&</sup>lt;sup>3</sup> Hively v. Ivy Tech Cmty. Coll. of Indiana, 853 F.3d 339, 340-41 (7th Cir. 2017)

<sup>&</sup>lt;sup>4</sup> Whitaker v. Kenosha Unified School District, 858 F.3d 1034 (7th Cir. 2017)

<sup>&</sup>lt;sup>5</sup> Flack v. Wis. Dept. of Health Serv's, No. 18-CV-309, 2018 WL 3574875 (W.D. Wis. July 25, 2018)

<sup>&</sup>lt;sup>6</sup> EEOC Charge No. 443-2018-01712

specific example at the University of Wisconsin-Milwaukee, where a highly specialized researcher left that institution after learning that it did not cover transgender health services.

# Correspondence

Item 10C in the Board packet contains approximately 23 pieces of correspondence urging the Board to remove the transgender services exclusion. Similar correspondence has been received by the Board in the past. Approximately 108 pieces of correspondence on this topic have been received by the Board since January 2017.

# Medicare Advantage Plan

During implementation with UnitedHealthcare® (UHC) of the Board's Medicare Advantage program, UHC raised the issue of the exclusion in its current state. According to UHC, in emails exchanged with ETF:

"...the Uniform Benefit exclusion regarding transgender benefits is in conflict with their responsibilities as a Medicare Advantage Organization (MAO). In the CMS [Centers for Medicare and Medicaid Services] Final Decision Memorandum dated August 30, 2016, CMS provided direction to both Medicare Administrative Contractors (MACs) and MAOs. The Memorandum stated: "The result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans." UHC has stated that the surgical services exclusion in Uniform Benefits would cause UHC to be out of compliance with the CMS required obligation to make such coverage determinations on a case-by-case basis and in accordance with the reasonable and necessary standard."7

# **Current Uniform Benefits Coverage/Exclusion**

The Board's current Uniform Benefits certificate excludes, "Procedures, services, and supplies related to surgery and sex hormones associated with gender reassignment"<sup>8</sup>. Coverage for gender dysphoria is limited under this certificate to mental health services, as long as those services do not meet the criteria above. Other medical services would be prohibited under the exclusion. Removing this or any exclusion, however, does not result in automatic service coverage; rather, the certificate language defaults to the health plan's judgment of medical necessity. Each plan is required to have a medical policy in place for determining medical necessity.

<sup>&</sup>lt;sup>7</sup> Weikel, K. Email correspondence, August 13, 2018.

<sup>&</sup>lt;sup>8</sup> State of Wisconsin Group Health Insurance Program. *Certificate of Coverage 2018 Benefit Year.* <u>http://etf.wi.gov/publications/18et2107cc.pdf</u>

# **Affected Population**

In considering the impact of a programmatic change, it is important to determine the population who will be affected by the change. Recent efforts have been made to capture the prevalence of transgender identification in the population at large. The Behavioral Risk Factor Surveillance System (BRFSS), a monthly telephone survey of American adults managed by the federal Centers for Disease Control and Prevention (CDC), made optional questions available to states regarding gender identification starting in 2014. Wisconsin is one of 19 states that has added this question set to its interview. The Wisconsin BRFSS data reports that 0.43% of the entire state population identifies as transgender, or approximately 19,150 people<sup>9</sup>. In their January 23, 2017 memo to the Board, Segal used the BRFSS figures to estimate that between two and five people in ETF's population would be anticipated to need transgender-related services in any given year<sup>10</sup>.

# **State of Clinical Literature**

According to the American Psychiatric Association (APA), gender dysphoria, "involves a conflict between a person's physical or assigned gender and the gender with which he/she/they identify."<sup>11</sup> APA notes that this presentation is different than gender non-conformity, where a person may dress or behave in a way that does not align with norms or stereotypes of their gender. The *Diagnostic and Statistical Manual of Mental Disorders* (DSM) is the handbook for diagnosing mental health conditions, maintained by the APA. The DMS includes specific clinical criteria for diagnosing gender dysphoria.

Treatment practices related to gender dysphoria have been developing rapidly over the past 40 years. The first guidelines for clinical treatment were developed by the World Professional Association for Transgender Health (WPATH) in 1979 and are in their seventh revision. The American Medical Association and the APA have endorsed the current WPATH standards, and several other professional organizations (e.g., the American College of Obstetrics and Gynecology, the Endocrine Society, etc.) have developed concurrent standards that pertain to their fields of specialty. These standards encourage providers to be ready to treat transgender individuals, acknowledging how patients may be different while asserting how treating them in the office setting will be in many ways the same as treating any other patient.

The volume of literature available to practitioners to determine a proper course of treatment for transgender people has grown significantly in recent years. Organizations like UpToDate, a clinical reference and decision support tool used nationally by private practitioners and by agencies within the state of Wisconsin who provide services, include extensive reviews of the appropriate courses of treatment for transgender

<sup>&</sup>lt;sup>9</sup> Flores, A.R., Herman, J.L., Gates, G.J., & Brown, T.N.T. (2016). *How Many Adults Identify as Transgender in the United States*? Los Angeles, CA: The Williams Institute.

<sup>&</sup>lt;sup>10</sup> Schatten, K.R., Viera, K.C. January 23, 2017. *Transgender Cost Estimate.* Segal Consulting Memorandum. <u>http://etf.wi.gov/boards/agenda-items-2017/gib0208/item4.pdf</u>.

<sup>&</sup>lt;sup>11</sup> Parekh, R. February 2016. *What is Gender Dysphoria*? <u>https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria</u>.

people. In their guidance to clinicians, UpToDate reviewers indicate in their summary of the standards of care that they agree with the clinical guidelines issued by the above-referenced professional organizations. In their statement of outcomes, they note, "…treatment that includes hormonal therapy results in significant improvement in quality-of-life and psychosocial outcomes"<sup>12</sup>.

Older clinical guidelines once raised concerns regarding the outcomes of individuals who undergo gender-affirming surgical procedures. This was the basis for a 1981 National Coverage Determination (NCD) by the Centers for Medicare and Medicaid Services (CMS). In 2014, the Health and Human Services Departmental Appeals Board reviewing a challenge to this NCD stated in their decision that overwhelming evidence invalidated the NCD. Experts testifying as a part of this appeal stated that a combination of surgeon experience and development of new procedures indicates that surgical interventions for transgender patients are safe and effective. Further, the experts noted that many of the procedures used as gender-affirming surgical treatments are routinely used to treat non-transgender patients and are covered for those patients by health plans<sup>13</sup>.

Due to the small size of this population, data is limited on the number of people who progress to surgical interventions (see next section for employer coverage experience). In the case of treatment for gender dysphoria, not only does evidence support the effectiveness of medical treatments, but it also indicates a danger to affected individuals who are not treated. According to the American College of Obstetricians and Gynecologists published care guidelines, untreated gender dysphoria, "can result in psychologic dysfunction, depression, suicidal ideation, and even death"<sup>14</sup>.

Not all experts agree, however. CMS, in its Final Decision Memorandum of August 30, 2016 stated: "We are not issuing a (NCD) [National Coverage Determination] at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery" (page 25). In the same Memorandum, CMS stated: "Of the 33 studies reviewed by CMS, published results were conflicting—some were positive; others were negative. Collectively, the evidence was inconclusive for the Medicare population." (page 29).

ETF asked the DOJ for copies of the five (5) expert reports that were submitted during the pending litigation, so that GIB will have all the pertinent information available. Those reports are included as Attachments A, B, C, D, and E.

<sup>&</sup>lt;sup>12</sup> Tangpricha, V., Safer, J.D. (2018) *Transgender women: Evaluation and management*. UpToDate. Wolters Kluwer. <u>www.uptodate.com</u>. Date Accessed: July 20, 2018.

<sup>&</sup>lt;sup>13</sup> Department of Health and Human Services Departmental Appeals Board. May 30, 2014. *NCD 140.3 Transsexual Surgery*. Docket No. A-13-87. Decision No. 2576.

<sup>&</sup>lt;sup>14</sup> American College of Obstetricians and Gynecologists. December 2011. *Health care for transgender individuals, Committee Opinion No 512*. Obstet Gynecol 2011;118:1454-8.

# State of Coverage in the Insurance Market and Costs

The most recent surveys of employee benefits programs show that most employers do not offer trans-inclusive health plans; however, the proportion of those who do has been steadily rising. A 2018 employer survey done by the International Foundation of Employee Benefit Plans showed that 22% of all employer respondents now offer coverage for gender affirmation surgery. The proportion is much larger for employers with more than 10,000 employees; 52% of those respondents indicated that they cover trans-inclusive benefits<sup>15</sup>.

An earlier study by the Williams Institute at the UCLA School of Law surveyed 34 employers in 2013 who had previously indicated they offer transgender-inclusive benefits. Survey respondents included Fortune 1000 and AmLaw 200 firms. The most common reasons these employers reported for adding transgender-inclusive benefits were that these benefits made them more competitive in recruitment (60%), reflected their values (60%), improved overall employee satisfaction and morale (48%), and demonstrated a commitment to inclusion and diversity (44%). Twenty-six of the surveyed employers also provided cost information; of those, 22 reported no costs associated with adding the benefit. Three employer respondents reported projected and not actual costs since the employer had no utilization at the time of the report<sup>16</sup>.

Actual cost data for employers adding services is scarce. The same Williams Institute study obtained specific cost information from three public employers in detail: the City and County of San Francisco and the University of California.

San Francisco originally collected an additional \$4.3M in premium (or \$1.70 per member per month) when their transgender benefits were added to their self-funded plan in 2001. During the first year the group spent \$156,000 on services. Over the following five years, the group collected an additional \$5.4M in premium and paid a total of \$386,417. In 2006, the plan chose to drop the additional premium share for these services since it was not necessary to fund the benefit<sup>17</sup>.

The University of California added their transgender inclusive benefit to their employee plan in 2005. Their program is a mix of self-insured, fully-insured and managed care benefits. At the outset, their insurers charged no additional premium to add the benefits. At the close of the first year, the plans estimated costs to be less than \$0.20 per member per month, or less than 0.05% of total premium<sup>18</sup>.

<sup>16</sup> Herman, J.L., Cooper, P.J. (September 2013). *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans.* The Williams Institute. <u>https://williamsinstitute.law.ucla.edu/research/transgender-issues/costs-benefits-providing-transition-related-health-care-coverage-herman-2013/</u>

<sup>&</sup>lt;sup>15</sup> Patterson, A. June 20, 2016. *Transgender-Inclusive Health Benefits on the Rise.* <u>https://blog.ifebp.org/index.php/transgender-inclusive-health-benefits-on-the-rise</u>

<sup>&</sup>lt;sup>17</sup> *Ibid.* P. 5

State employee programs in Wisconsin's neighboring states cover transgender-related medical services. Minnesota's State Employee Group Insurance Program (SEGIP) benefits document indicates that coverage is based on medical necessity and the most recent published expert standards<sup>19</sup>. Illinois' state employee program defers to the policies of their insurers; of the policy documents available for review, all indicated that exclusions for transgender persons were not allowed under the policy. Indiana's state employee plan requires authorization before reassignment surgeries<sup>20</sup>; Michigan and Iowa's publicly-available policy documents are silent though Iowa's acknowledges that sex-specific services deemed appropriate by a transgender person's physician will be eligible for an exception process for coverage<sup>21</sup>. In Wisconsin, ETF's three largest participating health plans (Dean, WEA Trust, and Quartz) have removed their exclusions for other non-state lines of business.

The costs of coverage have also been studied more recently for military service members. According to a study in the New England Journal of Medicine, an estimated 12,800 service personnel identify as transgender. The author notes that there is a twofold higher proportion of transgender people serving in the military than are present in the general population. Even with the increased numbers, the author calls the costs of providing coverage, "too low to warrant consideration"<sup>22</sup>.

Other studies do find a cost attributable to covering transition-related services. A study in the Journal of General Internal Medicine examined the cost-effectiveness of health insurance coverage for transgender people. The study was completed for the Massachusetts Group Health Insurance Commission to analyze the clause in its coverage certificate that excluded coverage for transgender-related services. The study found that, "compared to no health benefits for transgender patients...insurance coverage for medically necessary services came at a greater cost and effectiveness," and that the added expense held "good value for reducing the risk of negative endpoints—HIV, depression, suicidality, and drug abuse"<sup>23</sup>. The study noted in its conclusions that services would have a low budget impact on U.S. society.

While it is challenging to predict the costs of care averted for any condition, there is some evidence that the costs associated with providing transgender-inclusive plans is met with reduced costs related to comorbidities. A larger number of transgender people postponed general preventive care (33%) than the non-transgender population. In

<sup>21</sup> Wellmark Health Plan of Iowa. January 8, 2018. *Iowa Choice Benefit Booklet*.
 <u>https://das.iowa.gov/sites/default/files/hr/benefits/documents/hlthcerts/2018.SOI.Iowa.Choice.pdf</u>
 <sup>22</sup> Belkin, A. September 17, 2015. *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care*. N Engl J Med 373;12.

<sup>&</sup>lt;sup>19</sup> Minnesota Management and Budget. May 1, 2018. *Summary of Benefits 2018-2019*. <u>https://mn.gov/mmb-stat/segip/doc/SoB\_current\_AHP.pdf</u>

<sup>&</sup>lt;sup>20</sup> Indiana State Personnel Department. 2018. *Medical Benefit Booklet*. <u>https://www.in.gov/spd/files/2018-Medical-Benefit-Booklet-Wellness-CDHP-Plan.pdf</u>

<sup>&</sup>lt;sup>23</sup> Padula, W.V., Heru, S., Campbell, J.D. October 19, 2015. Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis. J Gen Intern Med 31(4):394-401. DOI: 10.1007/s11606-015-3529-6.

addition to care avoidance, it is well-documented that transgender people have a higher rate of HIV infection, alcohol and drug use, and smoking. The rate of lifetime suicide attempts among transgender people in one study was 41%, versus 1.6% in the general population<sup>24</sup>.

Attention should be paid to the costs associated with transgender services, as they should in any emerging field, to ensure that billing is not abusive. Despite treatments for gender dysphoria being clinically well established, the same may not be said in billing departments, depending upon how familiar the market is in paying for a service; in one case recently in Wisconsin, estimates for the cost of a single gender confirmation surgery ranged from \$19,000 to \$100,000. The hospital's statement indicated that the price quotes ranged because the hospital, "did not know how much it would be reimbursed by the insurance company"<sup>25</sup> It is critical to note, however, that these types of billing issues are not isolated to gender-confirmation surgeries; rather they are endemic in health care generally, so much so that the referenced article is a part of a regular series on egregious health care bills. It will be incumbent upon health programs and plans to monitor billing and possibly consider reference pricing strategies.

# Options

Considering the above-noted recent developments, a number of options present themselves should the Board wish to revisit the transgender-related exclusion in Uniform Benefits. The options include, but are not limited to the following:

Option 1: Remove the exclusion and defer to medical necessity language within Uniform Benefits. This approach is consistent with other parts of Uniform Benefits that defer to the medical necessity of a treatment and the administering health plan's authorization criteria. The approach would be the same as the revised transplant language that the Board approved at the May 2018 Board meeting. Similar to transplants or any other service requiring prior authorization, patients must progress through a treatment protocol and meet clinical criteria before a service is provided. This rigor is to protect all parties: the plan, the provider, and the patient.

# Option 2: Revise the exclusion to provide incremental coverage.

Option 2.1: Remove the exclusion related to a limited subset of benefits. For example, the Board could begin with coverage of hormones and certain surgeries only, and modify in future years on review.

*Option 2.2: Remove the exclusion for the Medicare Advantage program only.* This would preserve the exclusion for other populations.

 <sup>&</sup>lt;sup>24</sup> Stroumsa, D. March 2104. *The State of Transgender Health care: Policy, Law, and Medical Frameworks*. Am J Public Health. 2014;104:e31-e38. DOI:10.2105/AJPH.2013.301789.
 <sup>25</sup> Huetteman, E. July 26, 2018. *Bill of the Month: A Plan For Affordable Gender-Confirmation Surgery Goes Awry*. <u>https://www.npr.org/sections/health-shots/2018/07/26/630619038/bill-of-the-month-a-plan-for-affordable-gender-confirmation-surgery-goes-awry</u>.

<u>Option 3: Request additional information from ETF</u>. Under this option, the Board would provide specific, additional questions to ETF staff for research and future presentation.

<u>Option 4: Maintain the exclusion (status quo)</u>. This option would preserve the exclusion in its current state.

Staff will be at the Board meeting to answer questions.

Attachment A: Expert Report #89 Attachment B: Expert Report #90 Attachment C: Expert Report #91 Attachment D: Expert Report #104 Attachment E: Expert Report #105

# 6A1. Attachments A-E Transgender Services Coverage

Portions of the following attachments include information that constitutes a medical record as defined in Wis. Admin. Code ETF s. 10.01 (3m) and protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA).

Information that is covered under the definition stated above has been redacted to ensure compliance and privacy.

#### **EXPERT WITNESS REPORT OF STEPHANIE BUDGE, Ph.D.**

I, Stephanie Budge, Ph.D., a licensed psychologist, have prepared this expert report pursuant to Fed. R. Civ. P. 26(a)(2) in the case of Boyden v. Wisconsin Dep't of Employee Trust Funds. I was retained as an independent consultant with expertise on issues related to gender dysphoria and the medical necessity of transition-related medical care (e.g., hormone therapy, gender confirmation surgery, facial feminization surgery) for transgender individuals. I was retained by the American Civil Liberties Union Foundation, the American Civil Liberties Union of Wisconsin Foundation, and Hawks Quindel, S.C., who represent the Plaintiffs Shannon Andrews and Alina Boyden, who are seeking insurance coverage for transition-related care and challenging the state of Wisconsin's blanket exclusion of such coverage for state employees.

Based on my training, research and clinical experiences, it is my professional opinion that if transgender individuals do not receive appropriate transition-related health care, there are often significant physical and mental health consequences, thus showing the medical necessity of such care for many transgender individuals. In alignment with my professional experiences, there is a substantial body of literature indicating that transition-related medical care is medically necessary for many transgender individuals. In addition, there is no evidence to support a policy of excluding coverage for all transition-related care for transgender individuals. As well, the evidence indicates that the cost to insurance plans of covering transition-related care for transgender individuals is minimal and may well be offset by reductions in other health care expenses that arise from failure to provide such care.

#### **A. Professional Qualifications and Experience**

I am a licensed psychologist who has been specializing in issues of gender identity and gender transition processes for over 10 years. I received a master's degree in educational psychology from the University of Texas at Austin in 2006 and a Ph.D. in counseling psychology in 2011 from the University of Wisconsin-Madison. My Ph.D. concentration specifically focused on transgender individuals, with a broader focus on lesbian, gay, and bisexual issues. I also received a minor in psychological assessment as part of my Ph.D. degree program. I have been a mental health professional since 2006 and I am currently licensed to practice psychology in the state of Wisconsin (license # 3244-57).

I have expertise working with individuals whose gender assigned at birth is different from their gender identity (hereafter referred to as transgender or trans individuals). I have been a mental health provider to transgender individuals since 2007. Transgender individuals have comprised the majority of my clinical caseload since 2011, and I have worked clinically with over 100 transgender clients (through individual therapy, group therapy, psychological evaluations, and providing supervision of clinical work of transgender individuals). Many of these individuals have met the Diagnostic and Statistical Manual 5 (DSM-5) criteria for gender dysphoria, a psychiatric diagnosis that signifies distress caused by incongruence between a person's assigned gender at birth and their gender identity.

I am currently an assistant professor in counseling psychology at the University of Wisconsin-Madison, where I teach courses that focus on training master's and doctoral students skills to become mental health professionals and psychological researchers. My courses

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primarily focus on counseling skills, conducting psychological assessments, and research design. My faculty appointment has included clinical work at the Counseling Psychology Training Clinic (CPTC), which has included providing pro bono therapy to transgender individuals and training students in best practices in clinical work with transgender clients. As part of my faculty appointment, I direct the Trans Research Lab (TRL). As director of the lab, I design research projects that focus on transgender individuals' mental health. Of note, one of the current research projects is a clinical trial focusing on the efficacy of psychotherapy for transgender individuals. As part of this project, I trained all of the therapists in assessing gender dysphoria and writing letters for transition-related medical care for transgender clients. I also hold an appointment as a part-time (summer) clinical health psychologist at UW Health, where I conduct evaluations of transgender adolescents to determine if they require medically necessary treatments (e.g., psychological, social, and medical interventions) related to their gender identity.

I have published 62 invited and peer-reviewed journal articles and book chapters, with the majority of these focusing on transgender individuals. Notably, several of these publications are focused on evaluating transgender individuals to assess their eligibility for transition-related care, including hormone treatment and surgery; how to engage in clinical decision-making related to mental health care for transgender individuals; and effective psychotherapeutic treatment for transgender individuals. I have been involved in more than 100 academic presentations (internationally, nationally, and locally). The majority of these presentations have been focused on transgender individuals. I am an associate editor for the journal *Psychotherapy*. I am also on the editorial board for two peer-reviewed academic journals: *Psychology of Sexual Orientation and Gender Diversity* and the *International Journal of Transgenderism*. Researchers

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in the United States and internationally have sought my assistance as an expert reviewer for research focused on transgender individuals.

I have received several awards for my work in the science and clinical practice of working with transgender individuals. Most recently, (along with colleagues) I received the 2017 paper award for *The Counseling Psychologist* related to a major contribution on *Research on Transgender People and Issues*. I received the 2015 American Psychological Association Early Career Award for work with LGBT populations from the Society for Counseling Psychology and I was the first recipient of the APA Transgender Research Award in 2010. Locally, I am also a member of the Wisconsin Trans Health Coalition, which is an organization focused on improving health care for transgender individuals throughout Wisconsin. My primary role on the coalition is to consult on research projects and collect data about transgender individuals in Wisconsin to tailor health care interventions for local community members.

I am also a member of the Society for Lesbian, Gay, Bisexual, and Transgender Issues within the American Psychological Association (APA) (of which I am also a member). I am cochair of the Science Committee for the Society. The Science Committee is charged with ensuring that the most relevant and up-to-date research regarding LGBT individuals is disseminated through the Society and to full membership of the APA. We provide programming at the annual APA convention to disseminate cutting edge research on the best psychological practices and evidence-based treatments with LGBT individuals. At the 2018 APA annual convention, I will be disseminating up-to-date information about evidence-based treatments for transgender individuals. I am also member of the World Professional Association of Transgender Health (WPATH). WPATH (formerly known as the Harry Benjamin International Gender Dysphoria Association) is an interdisciplinary professional and educational organization of individuals

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worldwide specializing in research and practice in transgender health. As a WPATH member, I attend conferences that focus on transgender individuals and present my own research to provide trainings to other professionals.

I am attaching a copy of my current C.V., which lists my qualifications, experience, and publications, as Appendix A to this report.

#### **Prior Expert Witness Experience**

I have previous experience as an expert psychologist in an immigration case that was focused on a transgender woman seeking asylum in the United States. Her case was heard by the United States Department of Justice Executive Office for Immigration Review. I prepared an expert report for that case in May 2015. I was also hired as an expert witness in the case *Whitaker v. Kenosha Unified School District.* As part of my role in the case, I prepared and wrote a declaration and expert report describing my psychological assessments of a transgender youth who had reported experiencing discrimination at his high school. I was not deposed and I did not testify in this case.

#### Compensation

I am being compensated at an hourly rate of \$200/hour for actual time devoted for my expert services and testimony in this case, as well as expenses and costs. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

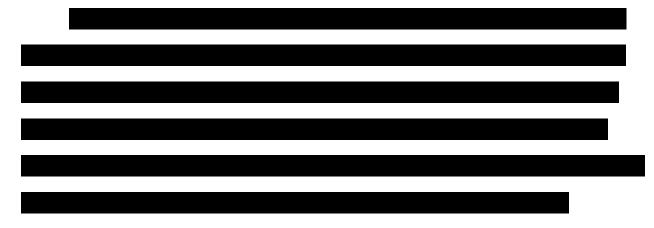
#### **BASIS FOR OPINIONS**

In this report, I use my clinical and academic expertise to provide an overview and discussion of gender identity, the psychological processes surrounding gender identity development for transgender individuals, and the appropriate clinical standards for gender transition and treatment of gender dysphoria in transgender adults. I then discuss the medical

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necessity of gender transition-related medical and psychological care for transgender individuals, as informed by authoritative research, prevailing medical and psychological standards, and ethical standards for psychological practice with transgender clients. I also provide reasons why blanket exclusions for transition-related care are not supported by research or policy and why transition-related care is cost-effective treatment.

In preparing this report, I reviewed the formative and influential psychological and public health research on transgender individuals published over the past decade, including in-press research and recently published studies. I have included a bibliography in Appendix B to this report. The majority of these publications come from highly-respected, peer-reviewed journals on LGBT and/or psychological issues. I also reviewed: the Plaintiffs' Amended Complaint; State Defendants' Responses to Plaintiffs' Requests to Admit, Interrogatories and for Production of Documents; documents produced by the State Defendants concerning insurance coverage of transition-related care; and documents related to appeals of denials of the Plaintiffs' requests for coverage of transition-related care.



Based on my review of these materials and these evaluations, I render the opinions contained in this report, with a reasonable degree of professional certainty in my field of psychology. I understand that investigation and discovery is continuing in this case and may result in additional materials for me to review. I may, if necessary, supplement or amend my opinions based on such materials.

#### GENDER IDENTITY AND TRANSGENDER INDIVIDUALS

#### A. Definitions and Key Concepts

The following are several of the most up-to-date definitions and concepts related to transgender identity:

**Sex:** Sex refers to one's classification as male, female, or neither male or female. The term refers a person's chromosomes, hormones, reproductive organs, secondary sex characteristics, and gender identity (i.e., internal sense of gender) (Singh & dickey, 2016). The majority of individuals born with penises, testes, and XY chromosomes will identify as men and experience themselves as male. As well, the majority of individuals born with vaginas, clitorises, vulvas, ovaries, uteruses, and XX chromosomes will identify as women and experience themselves as female. Transgender individuals and those with intersex conditions and sex chromosome conditions (e.g., Turner Syndrome, Klinefelter Syndrome) will likely experience a different path with their sex (Morselli et al., 2016). There is no single sex-based characteristic that defines an individual's sex; that being said, gender identity is one of the primary factors when defining an individual's sex. When sex-related characteristics such as internal or external genitalia, reproductive capacity, chromosomes, or gender identity are inconsistent—as with many transgender people and people with intersex conditions—it is most appropriate to define sex based on the person's gender identity (Singh & dickey, 2016).

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**Gender:** Gender refers to an individual's social, cultural, and psychological characteristics that are considered masculine or feminine based on cultural stereotypes, norms, and traits. (Gilbert & Scher, 2009).

**Gender identity:** Gender identity is understood in the psychological and medical professions to mean a person's internal sense of one's own sex, as it is privately experienced in one's behavior and self-awareness of being female, male, or at a defined point along a gender continuum (Singh & dickey, 2016). All human beings have a gender identity. Gender identity is innate and generally considered an immutable characteristic. Gender identity for human beings usually begins to become clear around the age of three (with some variation around this age), although many transgender individuals may not begin to recognize or express their gender identity until later in life. Neuroimaging data demonstrate strong evidence to indicate biological causes for transgender identity (see Sanchez & Pankey, 2017 for a review; Spizzirri et al., 2018). Recent neuroimaging data show that transgender women's brains are similar to cisgender women's brains (Rametti et al., 2011) and that transgender men's brains are similar to cisgender men's brains (Luders et al., 2009; Savic & Arvor, 2011).

**Gender expression**: Gender expression is defined as the behaviors associated with a public expression of stereotyped masculinity and/or femininity, or a rejection of these stereotypes (Brierley, 2000).

Gender assigned at birth: Gender assignment is usually based on either an assessment of an infant's external genitals or a chromosome analysis. This language is also sometimes referred to as "sex assigned at birth" in the literature, but gender assignment is considered more accurate based on gender socialization and gender expectations that occur from infancy.

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**Transgender:** Transgender identity is indicated by incongruence between a person's gender assigned at birth (male assigned at birth or female assigned at birth) and their gender identity (Singh & dickey, 2016).

**Cisgender:** Conversely, individuals are considered cisgender if they identify with the gender identity that corresponds with their gender assigned at birth (Singh & dickey, 2016).

**Gender Transition:** For most transgender individuals, a gender transition or "transitioning" is considered psychologically and medically necessary, as will be noted in the report below. Transition can take either or both of two forms: (a) social transition, and (b) medical transition (American Psychological Association, 2015).

**Social Transition:** A social transition is considered any aspect of identifying and expressing one's gender identity and usually does not encompass medical interventions—a social transition is considered to be medically necessary, given the psychosocial benefits of social transition (Coleman et al., 2012). An individual will typically, among other things, tell others of their gender identity (also known as coming out), use a different name than their birth name, use pronouns congruent with their gender identity, wear clothing typically associated with their gender identity, change their hairstyle, and use restrooms that fit their gender identity. This list of aspects of social transition is not exhaustive, nor are all of these steps necessary for all transgender persons.

**Medical transition:** A medical transition usually includes any medical procedure to assist a transgender individual with achieving primary or secondary sex characteristics that are closely aligned with their gender identity. Examples of medical transition can include hormone therapy and/or surgeries (for example, chest/breasts, internal/external genitalia, facial features, and/or body contouring). Not all transgender individuals will desire or need medical

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interventions and some medical interventions, including surgeries, may not be developmentally or socially appropriate for some individuals (APA, 2015; Singh & dickey, 2016).

**Hormone Therapy:** Hormone therapy (HT) for transgender individuals includes the administration of feminizing or masculinizing hormones to induce changes in physical appearance (White-Hughto & Reisner, 2016). Hormone therapy is considered medically necessary for many transgender individuals due to its efficacy in relieving psychological distress associated with gender dysphoria and improving quality of life (Coleman et al., 2012; White-Hughto & Reisner, 2016). Hormone therapy is also referred to as hormone replacement therapy (HRT) in the literature.

Gender confirmation surgery: Gender confirmation surgery (GCS) includes any surgery to alter or adjust an individual's primary or secondary sex characteristics to align with their current gender identity. The most common surgeries include changes to the chest, genitals, and face/neck (Coleman et al., 2012). Gender confirmation surgery is considered medically necessary for many transgender individuals due to its efficacy in relieving psychological distress associated with gender dysphoria and improving quality of life (Coleman et al., 2012). Gender confirmation surgery (GCS) is also commonly referred to as sex reassignment surgery (SRS) or gender affirmation surgery (GAS) in the literature.

#### **Prevalence of Transgender Individuals**

Most recent population-based estimates indicate that 0.38% (approximately 1,000,000 people; Meerwijk & Sevelius, 2017) to 0.6% (approximately 2,000,000 people; Flores et al., 2016) of the United States population identifies as transgender. The Flores et al. (2016) report estimated that transgender adults comprise approximately 0.43% of the population in Wisconsin.

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However, the authors of these recent publications indicate that these estimates are likely low due to population-based survey instruments that constrain the definition of transgender identity, which can have limitations on how transgender people are defined or recognized in public policy and public health.

#### Statistics Regarding Medical Interventions for Transgender Individuals

Many transgender people have undergone some form of medical transition, though many more may need such transition-related care than actually receive it. There have been several nation-wide publications estimating the prevalence of transgender individuals seeking or undergoing transition-related care in the United States. In the first nationwide survey of its kind, Grant et al. (2011) surveyed 6,456 participants. They reported that for medical transition-related care, 62% of participants used hormone therapy and an additional 23% planned to use hormone therapy in the future (for a total of 5,487 participants using or planning to seek hormone therapy). Transgender women reported the following information regarding gender confirmation surgery: 20% had had a vaginoplasty (surgical creation of vagina and vulva) and 60% planned to have it someday; 21% had had an orchiectomy (surgical removal of the testes) and 59% planned to have it someday; and 18% had had chest surgery and 54% planned to have it someday. Transgender men reported that 41% had had chest surgery and 51% planned to have chest surgery someday. Regarding additional surgeries for transgender men, fewer men indicated they had genital surgery (2% reported having had a phalloplasty [surgical creation of a penis]), with 26% indicating they planned to have it someday. The authors hypothesize that the difference between the number of people having had surgery and the number who plan to have it in the future might be due to financial barriers or other social barriers. Non-binary individuals' data were not analyzed in the 2011 report.

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In 2016, a new report based on a survey of 27,715 transgender respondents from the United States described the health care and discrimination experiences of transgender people (James et al., 2016). In this report, 95% of transgender men and women reported they had or planned to have hormone therapy; only 49% of all respondents had had hormone therapy, despite the large numbers of individuals desiring hormone therapy. Twelve percent of transgender women indicated they had had a vaginoplasty and an additional 54% planned to have the procedure someday (with an additional 22% reporting that they were unsure about the procedure). Eleven percent of trans women had had an orchiectomy and an additional 47% planned to have the procedure someday (with an additional 22% reporting that they were unsure about the procedure). Percentages for transgender men and non-binary individuals are listed in the report on pages 101 and 102.

#### **Clinical Diagnosis and Treatment Standards for Gender Dysphoria**

Gender dysphoria (GD) is the medical and psychiatric term for the psychological distress caused by the incongruence between a transgender person's gender assigned at birth and gender identity. This psychiatric diagnosis is codified within the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The DSM-5 is widely used within psychiatry and psychology. Formal clinical training is necessary to understand and apply the manual in diagnosing psychological conditions (Black & Grant, 2014). The most recent version of the World Health Organization's International Classification of Diseases (ICD-10) uses the term gender identity disorder (GID) to describe the condition the DSM-5 calls gender dysphoria. Gender identity disorder was first identified as a mental health disorder in the DSM-III in 1973 (Zucker & Spitzer, 2005). After several iterations, GID was updated to GD in the DSM-5 in 2013 to account for recent developments in understanding and reflecting that gender

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identity is not a disorder, but that the distress related to the incongruence is what leads to a diagnosis (Fraser, 2015; Regier, Kuhl, & Kupfer, 2013).

Individuals who present with gender dysphoria will likely report a variety of symptoms, but with a theme of an intense need to experience themselves as their affirmed gender identity, present themselves in accordance with their affirmed gender identity, and be viewed by others in accordance with their affirmed gender identity. When individuals diagnosed with gender dysphoria do not obtain competent and necessary treatment, serious and debilitating psychological distress (depression, anxiety, self-harm, suicidal ideation/attempts, etc.) often occurs (Bockting et al., 2016; Coleman et al., 2012; Wilson, Chen, Arayasirikul, Wenzel, & Raymond, 2015).

Under the DSM-5, the symptoms under Criterion A for identifying Gender dysphoria in adolescents and adults (302.85) include a marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

- A marked incongruence between one's experienced/expressed gender and primary and or/secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics);
- (2) A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
- (3) A strong desire for the primary and/or secondary sex characteristics of the other gender.

- (4) A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- (5) A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- (6) A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

According to the DSM-5 Criterion B, a diagnosis of gender dysphoria also requires a finding of clinically significant distress or impairment in social, occupational, educational, or other important areas of functioning.

#### Standards of Care

The World Professional Association for Transgender Health (WPATH) publishes the Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People ("SOC"), which are considered the international standards for medical and mental health treatment for transgender individuals. The foremost medical and mental health organizations within the United States, and internationally, recognize the SOC as the authoritative standards for treatment of gender dysphoria. These standards are considered authoritative because the foremost experts in the field of transgender health articulate professional consensus regarding the most up-to-date evidence-based research on transgender health. WPATH is the largest transgender health organization in the world and is committed to promoting "evidence based care, education, research, advocacy, public policy, and respect in transgender health" (wpath.org, 2017). WPATH (originally called the Harry Benjamin International Gender Dysphoria Association) has published the SOC since 1979. The seventh and most current version of the SOC was published in 2012. The professional medical and mental health organizations

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recognizing the authority of the WPATH SOC include the American Psychological Association, the American Psychiatric Association, the American Counseling Association, and the American Medical Association.

The SOC provide evidence-based protocols for mental health and medical providers to follow in determining the specific treatment regimen that will best fit the needs of the transgender individual. It has been well-established from the SOC and experts in the health care of transgender individuals that each transgender person has their own specific transition needs and that not every transition will look the same. Treatment generally consists of social, psychological, and/or medical support, as needed, which allows the individual to live and be integrated into society in accordance with their gender identity, thus relieving the distress that results from gender incongruence. Interventions are not used to change a person's gender identity; instead, they help to bring the person's external appearance and gender expression in alignment with their gender.

#### **Medical Necessity for Treatment**

To date, "every major expert medical association in the United States recognizes the medical necessity of transition-related care for improving the physical and mental health of transgender people and has called for health insurance coverage for treatment of gender dysphoria" (p. 1801, Baker, 2017). Research confirms not only the medical necessity of transition related care, but also that the procedures are safe and have high post-surgical satisfaction rates (Hess et al., 2014; Tran et al., 2018).

The WPATH Standards of Care (SOC v.7; Coleman et al., 2012) outline the specific reasons for the medical necessity of transition-related care for transgender individuals. The SOC first note the medical necessity of masculinizing hormones (for individuals assigned a female

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gender at birth) and feminizing hormones (for individuals assigned a male gender at birth) to alleviate or decrease dysphoria. As noted by the SOC, the medical regimen will be individualized to each patient. The SOC note that gender confirmation surgery for transgender individuals is considered reconstructive, not cosmetic or aesthetic, "with unquestionable therapeutic results" (p. 58). As well, the SOC indicate that gender confirmation surgery has been found to alleviate gender dysphoria in many people. Specifically, for many transgender individuals "relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity" (p. 55).

According to the WPATH SOC, the primary reason for the medical necessity of hormone therapy and gender confirmation surgery is demonstrated in the psychosocial benefits of the treatments. The SOC v.7 outline 37 years of data that focus on the beneficial psychosocial outcomes of hormone therapy and gender confirmation surgery. The SOC indicate that the majority of studies demonstrate an irrefutable beneficial effect of gender confirmation surgery on postoperative outcomes (e.g., well-being and sexual functioning)." (p. 107). One of the first major retrospective studies focused on gender confirmation surgery indicated that 80.7% of transgender men reported positive outcomes (improved social and emotional adjustment) and 71.4% of transgender women reported positive outcomes (Pauly, 1981). Kuiper & Cohen-Kettenis (1988) reported that 88.6% of the sample (N = 141) reported feeling very/moderately happy with the results of their surgery.

Since standards of care were released in 1996, the research overwhelmingly indicates that transgender patients are satisfied with surgery and experience positive psychosocial outcomes post-hormones and post-surgery. See bibliography included as Appendix B. There are many studies that are indicative of the positive outcomes of medical treatment, such as general

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satisfaction with surgery, satisfaction with sexual functioning, and improved quality of life (e.g., De Cuypere et al., 2005; Krege et al., 2001; Rehman et al., 1999; Wierckx et al., 2011).

Since the most recent version of the SOC were published in 2012, numerous other studies have been published showing even stronger treatment benefits and more specific information about the outcomes of surgery. The most up-to-date research confirms what previous research has shown regarding positive outcomes gender confirmation surgery. These studies indicate that quality of life and mental health outcomes only continue to improve after surgery and that patients do not experience regret related to the procedures (Glynn et al., 2016; van de grift, 2018).

Additional longitudinal studies have noted the importance of hormone-related care on mental health outcomes. For example, Heylens et al. (2014) indicated that hormone therapy was associated with a significant decrease in anxiety, depression, interpersonal sensitivity, and hostility. Additionally, psychopathology scores for transgender people who had received hormone therapy were compared with general population outcomes; after initiating hormones, transgender individuals reported similar levels of functioning to cisgender individuals. Similarly, Colizzi, Costa, & Todarello (2014) reported in a longitudinal study that hormone therapy was associated with lowered anxiety, depression, and general psychological symptoms.

In addition to the substantial body of literature noting the positive psychosocial outcomes of hormone therapy and gender confirmation surgery, research also shows that *failure* to provide transition-related medical care can lead to significant harm. For example, Glynn et al. (2016) report that some transgender women may engage in harmful behaviors, such as self-surgery or use of non-prescribed hormones, primarily if they are denied access to medical care and/or cannot afford the treatment(s). If individuals engage in self-prescribing hormones or in selfsurgeries, serious side effects and physical health concerns can occur as a result (Rotandi et al.,

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2013)—leading to additional health complications that will require additional medically necessary treatments.

#### Ethical Standards and Guidelines for Medical and Psychological Care

Within the medical and mental health care fields, gender-related transition care is considered medically necessary. Lambda Legal recently published a document outlining 12 United States major medical and mental health organizations' resolutions and statements documenting the medical necessity of transition-related medical care (Lambda Legal, 2017). Notably, the document indicates that the American Medical Association (AMA) has released at least 10 statements regarding accessibility of medical care for transgender individuals and as early as 2008, AMA Resolution 122, A-08 stated: "An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID... Therefore, be it RESOLVED, that the AMA supports public and private health insurance coverage for treatment of gender identity disorder; and be it further RESOLVED, that the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician" (p. 2).

The American Psychiatric Association's Task Force on Treatment of Gender Identity Disorder (GID) (Byne et al., 2012) indicates: "This resolution concludes that medical research demonstrates the effectiveness and necessity of mental health care, hormone therapy and SRS [sex reassignment surgery] for many individuals diagnosed with GID" (p. 768). As well, the American Psychological Association's Task Force on Gender Identity and Gender Variance (2009) report indicates: "For individuals who experience such distress, hormonal and/or surgical sex reassignment may be medically necessary to alleviate significant impairment in interpersonal

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and/or vocational functioning. Indeed, when recommended in clinical practice, gender confirmation surgery is almost always medically necessary, not elective or cosmetic (Bockting & Fung, 2005; Meyer et al., 2001)" (p. 32).

Several years after the release of this Task Force report, the American Psychological Association released guidelines for psychological practice with transgender and gender nonconforming people (APA, 2015). This report also highlights the medical necessity of transitionrelated care. In addition, the report outlines 16 guidelines for ethical psychological practice with transgender and gender non-conforming people (TGNC). Guideline 5 indicates that psychologists should be able to recognize how discrimination and stigma affect the health and well-being of TGNC. The guidelines indicate: "psychologists are encouraged to provide written affirmations supporting TGNC people and their gender identity [as appropriate] so that they may access necessary services (e.g., hormone therapy)" (p. 841). Finally and relatedly, Guideline 11 states that psychologists should "recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care" (p. 846). This guideline indicates that psychologists should be aware of the evidence indicating the positive outcomes in research literature that specifically focus on hormones and surgery and that psychologists may play an essential role in the process of facilitating access to these medically necessary treatments.

In response to some individuals and practitioners who believe that transgender people should adjust or change their gender identity to remain in their gender assigned at birth, several health organizations have indicated that this practice is harmful and unethical. For example, the WPATH Standards of Care (SOC) note that "treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been

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attempted in the past without success...such treatment is no longer considered ethical" (p. 175, Coleman et al., 2012).

The American Psychological Association's statement on gender diversity and transgender identity in adolescents indicates: "attempts to force gender diverse and transgender youth to change their behavior to fit into social norms may traumatize the youth and stifle their development into healthy adults" (p. 2, Mizock, Mougianis, Meier, & Moundas, 2015).

In their *Position Statement on Attempts to Change Sexual Orientation, Gender Identity, or Gender Expression,* the American Psychoanalytic Association (2012) indicates that any attempts to convert, change, or "repair" an individual's gender identity or gender expression "often results in substantial psychological pain by reinforcing damaging internalized attitudes."

The American Counseling Association's report on competencies for counseling with transgender clients (Burnes et al., 2010) indicates that counselors must: "understand that attempts by the counselor to alter or change gender identities and/or the sexual orientation of transgender clients across the lifespan may be detrimental, life-threatening, and are not empirically supported" (p. 144). As such, these organizations report that it is harmful (and thus unethical) to attempt to change a person's transgender identity.

#### Well-being and Mental Health

In addition to the research that shows specific positive effects on mental health and wellbeing directly related to hormone therapy and gender confirmation surgery, research also links the overall transition process to better outcomes in well-being. Budge, Adelson, & Howard (2013) found that transgender men and transgender women (N = 351) who are further along in their transition process use less avoidant coping mechanisms and have lower levels of anxiety and depression. As well, being further along in the transition process (i.e., "stage of identity")

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predicted better well-being in a large community sample (N = 571) of transgender individuals (Barr, Budge, & Adelson, 2016).

In addition to improving well-being, several qualitative studies have noted the importance of the transition process on increasing civic engagement, such as becoming educators, activists, volunteers, and creating systems for support and connection (e.g., Budge, Thai, & Orovecz, 2015; Budge, Chin, Minero, 2017; Budge, Katz-Wise, Tebbe, Howard, Schneider, & Rodriguez, 2013).

#### **Blanket Exclusions for Transition-Related Care**

In the above sections, I discuss the substantial body of literature indicating the medical necessity of transition-related care for transgender individuals and have listed citations for that literature in Appendix B. As noted in the Plaintiffs' Amended Complaint and in the Employee Trust Funds (ETF) *Uniform Benefits: Exclusions and Limitations* document, ETF excludes all "procedures, services, and supplies related to surgery and sex hormones associated with gender reassignment." Padula, Heru, & Campbell (2016) report that, even though many insurance policies prohibit coverage for transgender individuals for transition-related care, in 2014 the U.S. Department of Health and Human Services lifted a ban on these exclusions for the Centers for Medicare and Medicaid Services (CMS) beneficiaries for two reasons: (1) that the literature demonstrates gender confirmation surgery is efficacious, safe, and effective, and that (2) because it is efficacious, safe, and effective, "exclusions of coverage are not reasonable" (p. 395).

Instead of excluding all procedures, services, and supplies related to transgender care, the WPATH SOC indicate that all treatment plans for transgender individuals should be individualized to the patient (Coleman et al., 2012). In the most recent iteration of their guidelines, the Center of Excellence for Transgender Health at the University of California-San

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Francisco released recommendations based on their *Guidelines for the Primary and Gender-Affirmation Care of Transgender and Nonbinary People* (2016). Specifically, these guidelines outline how providers can create individualized treatment plans with transgender patients, noting specific health care concerns that might interact with transition-related care and how to best approach treatment plans with patients. Given the overwhelming evidence and precedent for offering transition-related care pursuant to individualized plans, there is no evidence to support insurance policies that exclude coverage for all transition-related care for transgender individuals.

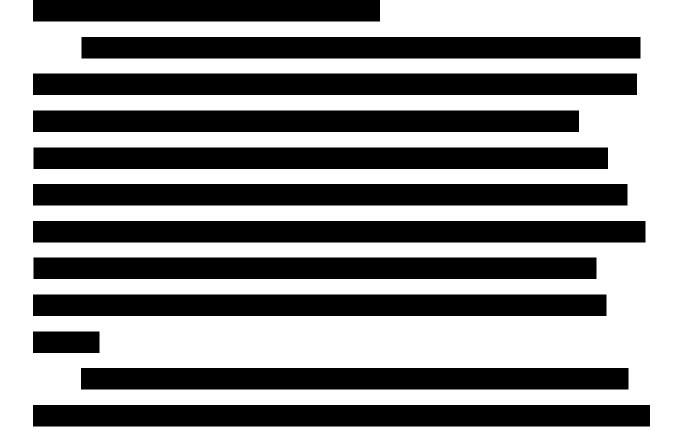
#### **Costs of Transition-Related Care**

Along with transition-related care being considered medically necessary by medical and mental health experts, it is also considered cost effective for insurance companies to cover transition-related care. Padula et al. (2016) analyzed the Grant et al. (2011) dataset that sampled over 6,000 transgender individuals in the United States. Their statistical analysis indicates that it is cost-effective for the patient, the other persons insured, and the insurance company itself to cover transition-related care. They found that coverage would cost members approximately \$0.016 a month. When comparing this data to the current case, the differences appear negligible. In a memo dated 9/28/2005, ETF was provided with the cost impact of covering "all surgical procedures and hormone therapies" for the state insurance. The cost impact per paying member was estimated to be \$0.05 per month, indicating that the costs estimated per member are similar.

Regarding the cost to the insurance company, results also indicate that it is in the insurance company's financial interest to cover transition-related care. Padula et al. (2016) note that a reason to consider transition-related care cost-effective is that denial of coverage could be costly to payers due to morbidity of failing to provide the care. Padula & Baker (2017) note that it is more costly to deny coverage to transgender patients because denial of care is associated

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with increased disparities in depression, drug abuse, HIV, and additional conditions that are costly to treat. In fact, analyses indicate that without transition-related care, the costs related to treating depression, anxiety, drug abuse, etc. are estimated to be \$10,712 a year (Beck, 2015) indicating the economic benefit of insurance companies covering transgender-related care. In our study (dickey, Budge, Katz-Wise, & Garza, 2016) we discuss the disparities in health insurance coverage between transgender and cisgender individuals; we found that transgender individuals will often avoid seeking health care when they need it because they are worried about discrimination by providers or that their insurance will deny certain claims (Grant et al., 2011) and thus some health issues may be exacerbated by the lack of preventative or immediate care. This avoidance of health care has been shown to have deleterious health effects in marginalized populations (Becker, 2004)—which in turn would likely have economic consequences.



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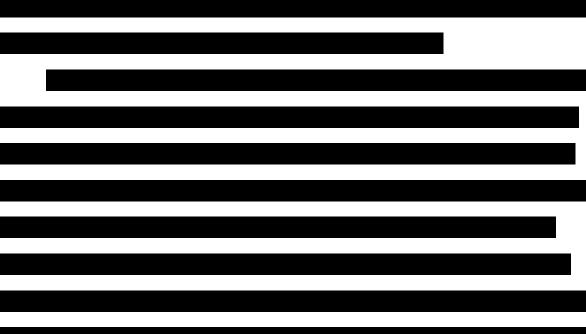
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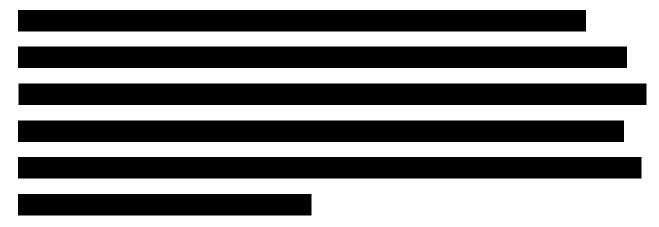
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2017). The preeminent international organization (World Professional Association for Transgender Health) focused on transgender related care has outlined the wide basis of evidence indicating why these treatments are considered medically necessary (see Coleman et al., 2012) and this report outlines more recent evidence that continues to support the necessity and efficacy of these treatments. In addition, there is no evidence to support ETF excluding coverage for all transition-related care for transgender individuals. As well, the evidence indicates that the cost of covering transition-related care for transgender individuals is minimal.



Respectfully submitted,

Fophanie Budge

Stephanie Budge, Ph.D.

DATE:\_\_\_\_02/19/2018\_\_\_\_

# Appendix A

#### Stephanie L. Budge, PhD, Licensed Psychologist Curriculum Vitae

Department of Counseling Psychology, School of Education, Room 305, University of Wisconsin-Madison, Madison, WI 53706, 608-262-4807, <u>budge@wisc.edu</u>

### **EDUCATION**

Doctor of Philosophy	8/2006 - 8/2011
University of Wisconsin-Madison APA Accredited Counseling Psychology Program	
Minor: Psychological Assessment	
Dissertation Title: Distress in the transition process for transgender indiv	iduals. The role of loss
community, and coping.	<i>iuuuis. The fole of loss</i>
Master of Science	8/2004 - 5/2006
University of Texas at Austin	
Educational Psychology	
Thesis Title: Sexual pressure in gay, lesbian, and bisexual relationships.	
Bachelor of Science	1/2003 - 12/2003
University of Utah	
Major: Psychology	
Pace University	9/2000 - 12/2002
Major: Psychology	
Minor: Women's and Gender Studies	
POSITIONS HELD	
Health Psychologist	6/2017 - current
University of Wisconsin Hospital & Clinics	
American Family Children's Hospital	
Assistant Professor, tenure-track,	8/2016 - current
Department of Counseling Psychology,	
University of Wisconsin-Madison	
Assistant Professor, visiting,	8/2014 - 7/2016
Department of Counseling Psychology,	
University of Wisconsin-Madison	
Postdoctoral Clinical Training	7/2013 - 6/2014

University of Louisville Trans Project	
Assistant Professor, tenure-track, Department of Educational and Counseling Psychology, University of Louisville	8/2011 - 8/2014
<b>Postdoctoral Clinical Training,</b> University of Louisville Counseling Center	9/2011 - 8/2012
<b>Predoctoral Internship</b> , University of Minnesota, University Counseling and Consulting Services, APA-Accredited, APPIC listed predoctoral internship	8/2010 - 8/2011
PROFESSIONAL LICENSE	
Licensed Psychologist in Wisconsin - 3244-57	2/2015 - current
Licensed Psychologist in Kentucky - 2012-42 (under supervision to gain hours for Health Service Provider status)	8/2011 - 6/2014
SPECIAL HONORS AND AWARDS	
<b>Outstanding Paper Award</b> American Psychological Association Division 17 (Counseling Psychology) major contribution published in <i>The Counseling Psychologist</i>	<b>6/2017</b> ) award for a 2016
American Psychological Association Division 17 (Counseling Psychology)	) award for a 2016 7/2015
<ul> <li>American Psychological Association Division 17 (Counseling Psychology) major contribution published in <i>The Counseling Psychologist</i></li> <li><b>Division 17 Early Career Award</b></li> <li>American Psychological Association Division 17 (Counseling Psychology)</li> </ul>	) award for a 2016 7/2015 ) award for social 5/2015
<ul> <li>American Psychological Association Division 17 (Counseling Psychology) major contribution published in <i>The Counseling Psychologist</i></li> <li><b>Division 17 Early Career Award</b> American Psychological Association Division 17 (Counseling Psychology) justice work and research with LGBT populations</li> <li><b>Division 29 Early Career Award</b> American Psychological Association Division 29 (Society for the Advance)</li> </ul>	) award for a 2016 7/2015 ) award for social 5/2015 ment of 1/2014 ment of
<ul> <li>American Psychological Association Division 17 (Counseling Psychology) major contribution published in <i>The Counseling Psychologist</i></li> <li><b>Division 17 Early Career Award</b></li> <li>American Psychological Association Division 17 (Counseling Psychology) justice work and research with LGBT populations</li> <li><b>Division 29 Early Career Award</b></li> <li>American Psychological Association Division 29 (Society for the Advance Psychotherapy) award for psychotherapy research</li> <li><b>Most Valuable Paper Award (Runner Up)</b></li> <li>American Psychological Association Division 29 (Society for the Advance</li> </ul>	) award for a 2016 7/2015 ) award for social 5/2015 ment of 1/2014 ment of

<b>Outstanding Graduate Student Award</b> American Psychological Association Division 17 (Counseling Psychology) LGBT award for community contributions with the LGBT population during my doctoral studies	<b>7/2010</b> given
<b>Graduate Student Research Award</b> American Psychological Association Division 17 (Counseling Psychology) Society for Vocational Psychology/ACT for career research regarding transgender individuals	7/2010
<b>Transgender Research Award</b> Recipient of the inaugural American Psychological Association Division 44 (Society for the Psychological Study of Lesbian, Gay, Bisexual, and Transgender Issues) award for research with transgender populations	6/2010
APA Student Travel Award	5/2010
APA Student Travel Award John W. M. Rothney Memorial Research Award University of Wisconsin-Madison Counseling Psychology Department award provided to outstanding doctoral student excelling in research	2/2010
John W. M. Rothney Memorial Research Award University of Wisconsin-Madison Counseling Psychology Department award provided to	2/2010
John W. M. Rothney Memorial Research Award University of Wisconsin-Madison Counseling Psychology Department award provided to outstanding doctoral student excelling in research Outstanding Student Poster Award	<b>2/2010</b> D an

#### RESEARCH

#### JOURNAL PUBLICATIONS

<u>Underlining</u> denotes student, \* denotes peer reviewed publication, ° denotes invited publication

- 1. \*Budge, S.L., <u>Orovecz, J.</u>, Owen, J.J., & Sherry, A.R. (In Press). The relationship between conformity to gender norms, sexual orientation, and gender identity for sexual minorities. *Counselling Psychology Quarterly*. (Available online ahead of print.)
- 2. \*Salkas, S., Conniff, J. & Budge, S.L. (In Press). Provider quality and barriers to care for transgender people: An analysis of data from the Wisconsin transgender community health assessment. *International Journal of Transgenderism*. (Available online ahead of print.)
- \*Katz-Wise, Budge, S.L. Fugate, E., Flanagan, K., Touloumtzis, C., Rood, B...Leibowitz, S. (In Press). Transactional pathways of transgender identity development in transgender and gender nonconforming youth and caregiver perspectives from the Trans Youth Family Study. *International Journal of Transgenderism*. (Available online ahead of print.)

- \*<u>Nienhuis, J. B.</u>, Owen, J., Valentine, J. C., <u>Black, S. W., Halford, T. C.</u>, <u>Parazak, S.</u> <u>E.</u>, **Budge, S.**, & Hilsenroth, M. J. (in press). Therapeutic alliance, empathy, and genuineness in individual adult psychotherapy: A meta-analytic review. *Psychotherapy Research*. (Available online ahead of print.)
- 5. **\*Budge, S.L.,** Israel, T., Merrill, C. (2017). Improving the lives of sexual and gender minorities: The promise of psychotherapy research. *Journal of Counseling Psychology, 64*, 376-384.
- 6. \*Budge, S.L., <u>Chin, M.Y., & Minero, L.P.</u> (2017). Trans individuals' facilitative coping: An analysis of internal and external processes. *Journal of Counseling Psychology, 64, 12-25*.
- 7. <sup>o</sup> Imel, Z.E., **Budge, S.L.**, & Owen, J. (2017). Introduction to special section on advanced methodology: Counseling the dog to wag its methodological tail. *Journal of Counseling Psychology*, *64*, 601-603.
- \*Katz-Wise, S. L., Williams, D. N., Keo-Meier, C. L., Budge, S. L., Pardo, S., & Sharp, C. (2017). Longitudinal associations of sexual fluidity and health in transgender men and cisgender women and men. *Psychology of sexual orientation and gender diversity*, 4, 460-471
- 9. ° Matsuno, E. & **Budge, S.L.** (2017). Non-binary/genderqueer identities: A critical review of the literature. *Current Sexual Health Reports*, *9*, 116-120.
- 10. \*Katz-Wise, S.L., Reisner, S.L., White, J.M., & **Budge, S.L.** (2017). Self-reported changes in attractions and social determinants of mental health in transgender adults. *Archives of Sexual Behavior, 46*, 1425-1439.
- 11. \*Budge, S.L. & dickey, l.m. (2017). Barriers, challenges, and decision-making in the letter writing process for gender transition. *Psychiatric Clinics*, 40, 65-78.
- 12. \*Katz-Wise, S.L., **Budge, S. B.,** <u>Orovecz, J.O.</u>, Nguyen, B., & Thompson, K. (2017). Imagining the Future: Qualitative findings of future orientation from the Trans Youth Family Study. *Journal of Counseling Psychology*, *64*, *26-40*.
- 13. ° **Budge, S.L.** (2016). To err is human: An introduction to the special issue on clinical errors. *Psychotherapy*, *53*, 255-256.
- \*<u>Sinnard, M., Raines, C.</u>, & Budge, S.L. (2016). The association between geographic location and anxiety and depression in transgender individuals: An exploratory study of an online sample. *Transgender Health*, 1, 181-186.
- 15. \*Budge, S.L. & Pankey, T.L. (2016). Ethnic differences in gender dysphoria. *Current Psychiatry Reviews, 12,* 175-180.
- 16. \*dickey, l.m., **Budge, S.L.,** Katz-Wise, S.L., & Garza, M.V. (2016). Health disparities in the transgender community: Exploring differences in insurance coverage. *Psychology of Sexual Orientation and Gender Diversity*, *3*, 275-282.
- \*Barr, S.M., Budge, S.L., & Adelson, J.L. (2016) Transgender community belongingness as a mediator between strength of transgender identity and well-being. *Journal of Counseling Psychology*, 63, 87-97.
- \*Budge, S.L., <u>Thai, J.L.</u>, Tebbe, E., & Howard, K.H. (2016) The intersection of socioeconomic status, race, sexual orientation, transgender identity, and mental health outcomes. *The Counseling Psychologist, 44,* 1025-1049.
- 19. \*Tebbe, E.A. & **Budge, S.L.** (2016) Research with transgender communities: Applying a process-oriented approach to methodological considerations and research recommendations. *The Counseling Psychologist, 44,* 996-1024.

- \*Moradi, B., Tebbe, E., Brewster, M., Budge, S.L., Lenzen, A., Enge, E...<u>Painter, J.</u> (2016). A content analysis of trans people and issues: 2002-2012. *The Counseling Psychologist, 44,* 960-995.
- 21. \*Tebbe, E.A., Moradi, B., & **Budge, S.L.** (2016). Enhancing scholarship focused on trans people and issues. *The Counseling Psychologist, 44,* 950-959.
- 22. \*Budge, S.L. (2015). Psychotherapists as gatekeepers: An evidence-based case-study highlighting the role and process of letter-writing for transgender clients. *Psychotherapy*, *52*, 287-297.
- \*Kopta, M., Owen, J.J., & Budge, S.L. (2015). Measuring psychotherapy outcomes with the Behavioral Health Measure-20: Efficient and comprehensive. *Psychotherapy*, 52, 442-448.
- 24. \*Watkins, C.E., Budge, S.L., & Callahan, J.L. (2015). Common and specific factors converging in psychotherapy supervision: A supervisory extrapolation of the Wampold/Budge psychotherapy relationship model. *Journal of Psychotherapy Integration, 25,* 214-235.
- \*Owen, J.J., Adelson, J.L., Budge, S.L., Wampold, B.E., Kopta, M., Minami, T., & Miller, S.D., (2015). Trajectories of change in short-term psychotherapy. *Journal of Clinical Psychology*, *71*, 817-827.
- 26. \*Budge, S.L. (2015). The effectiveness of psychotherapeutic treatments for personality disorders: A review and critique of current research practices. *Canadian Psychology*, *56*, 191-196.
- 27. \*Owen, J.J., Adelson, J.L., Budge, S.L., Reese, R.J., & Kopta, M.M. (2015). Good-Enough Level and Dose-Effect models: Variation among outcomes and therapists. *Psychotherapy Research*, 26, 22-30.
- \*Katz-Wise, S.L. & Budge, S.L. (2015). Cognitive and interpersonal identity processes related to mid-life gender transitioning in transgender women. *Counselling Psychology Quarterly, 28,* 150-174.
- 29. \*Budge, S.L., <u>Orovecz, J., & Thai, J.L.</u> (2015). Trans men's positive emotions: The interaction of gender identity and emotion labels. *The Counseling Psychologist, 43,* 404-434.
- \*Budge, S. L., <u>Keller, B.L.</u>, & Sherry, A. (2015) A qualitative investigation of lesbian, gay, bisexual, and queer women's experiences of sexual pressure. *Archives of Sexual Behavior, 44*, 813-824.
- \*Budge, S.L. (2014). Navigating the balance between positivity and minority stress for LGBTQ clients who are coming out. *Psychology of Sexual Orientation and Gender Diversity, 1,* 350-352.
- 32. \*Budge, S.L., <u>Rossman, H.K.</u>, & Howard, K.H. (2014). Coping and psychological distress among genderqueer individuals: The moderating effect of social support. *Journal of LGBT Issues in Counseling*, *8*, 95-117.
- 33. \*Budge, S.L., Moore, J.T., Del Re, A.C., Wampold, B.E., Baardseth, T.P., & <u>Nienhuis</u>, J.B. (2013). The effectiveness of evidence-based treatments for personality disorders when comparing treatment-as-usual and bona fide treatments. *Clinical Psychology Review*, 33, 1057-1066.
- 34. **\*Budge, S.L.** (2013). Interpersonal psychotherapy with transgender clients. *Psychotherapy*, 50, 356-359.

- \*Katz-Wise, S.L., Budge, S.L., & Hyde, J.S. (2013). Individuation or identification? Self-objectification and the mother–adolescent relationship. *Psychology of Women Quarterly*, 37, 366-380.
- 36. \*Budge, S.L., Adelson, J.L., & Howard, K.H. (2013). Anxiety and depression in transgender individuals: The roles of transition status, loss, social support, and coping. *Journal of Consulting and Clinical Psychology*, 81, 545-557.
- 37. \*Budge, S.L., Owen, J.J., Kopta, S.M., Minami, T., Hanson, M.R., & Hirsch, G (2013). Differences among trainees in client outcomes associated with the Phase Model of Change. *Psychotherapy*, 50, 150-157.
- 38. **\*Budge, S. L.,** Katz-Wise, S. L., Tebbe, E., Howard, K.A.S., Schneider, C. L., & Rodriguez, A. (2013). Transgender emotional and coping processes: Use of facilitative and avoidant coping throughout the gender transition. *The Counseling Psychologist, 41,* 601-647.
- 39. \*Valdez, C. R. & Budge, S.L. (2012). Addressing adolescent depression in schools: Effectiveness and acceptability of an in-service training for school staff in the United States. *International Journal of Educational Psychology*, 1, 228-25.
- 40. \*Wampold, B.E., & **Budge, S.L.** (2012). The relationship—and its relationship to the common and specific factors of psychotherapy. *The Counseling Psychologist, 40,* 601-623.
- 41. \*Wampold, B.E., Budge, S.L., Laska, K. M., Del Re, A.C., Baardseth, T.P., Fluckiger, C., Minami, T., Kivlighan, M., & Gunn, W. (2011). Evidence-based treatments for depression and anxiety versus treatment-as-usual: A meta-analysis of direct comparisons. *Clinical Psychology Review*, 31, 1304-1315.
- 42. \*Valdez, C. R., Dvorscek, M., **Budge, S.L.,** & Esmond, S.L. (2011). Provider perspectives of Latino patients: Determinants of care and implications of treatment. *The Counseling Psychologist, 39,* 497-526.
- 43. \*Wampold, B.E., Benish, S.G., Imel, Z.E., Miller, S.D., Laska, K., Del Re, A.C., Baardseth, T.P., & **Budge, S.L.** (2010).What works in the treatment of PTSD? A response to Ehlers et al. *Clinical Psychology Review, 30,* 269-276.
- 44. **\*Budge, S. L.,** Tebbe, E. N. & Howard, K. A. S. (2010). The work experiences of transgender individuals: Negotiating the transition and coping with barriers. *Journal of Counseling Psychology*, *57*, 377-393.
- 45. \*Howard, K. A. S., **Budge, S. L.,** Gutierrez, B., Lemke, N. T., & Owen, A. D. (2010) Future plans of urban youth: Influences, perceived barriers, and coping strategies. *Journal of Career Development, 37*, 655-676.
- 46. ° **Budge, S. L.,** Baardseth, T. P., Wampold, B. H., & Fluckiger, C. (2010). Researcher allegiance and supportive therapy: Pernicious affects on results of randomized clinical trials. *European Journal of Counselling and Psychotherapy*, *12*, 23-39.
- 47. \*Howard, K. A. S., **Budge, S. L.,** & McKay, K. M. (2010). Youth exposed to violence: The role of protective factors. *Journal of Community Psychology, 38,* 63-79.
- 48. \*Budge, S. L. (2006) Peer mentoring in post-secondary education: Implications for research and practice. *Journal of College Reading and Learning*, *37*, 71-85.

#### **BOOK CHAPTERS**

- 1. ° Budge, S.L. & Orovecz, J.J. (2017). Gender fluidity. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 660-662). Thousand Oaks, CA: SAGE.
- Budge, S.L. & <u>Pankey, T. L.</u> (2017). Interpersonal therapies and gender. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 961-964). Thousand Oaks, CA: SAGE.
- 3. ° **Budge, S.L.** & <u>salkas, s.</u> (2017). Experiences of transgender people within the LGBT community. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1073-1075). Thousand Oaks, CA: SAGE.
- 4. ° **Budge, S.L.** & <u>Thai, J.L. (2017)</u>. Coming out processes for transgender people. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 357-360). Thousand Oaks, CA: SAGE.
- 5. ° Budge, S.L. & <u>Sinnard, M.</u> (2017). Trans. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1685-1685). Thousand Oaks, CA: SAGE.
- <sup>o</sup> <u>Akinniyi, D.</u> & Budge, S.L. (2017). Biological sex and mental health outcomes. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 161-165). Thousand Oaks, CA: SAGE.
- ° Lam, J. & Budge, S.L. (2017). Help-seeking behaviors and men. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 832-834). Thousand Oaks, CA: SAGE.
- 8. <sup>o</sup> Jones, T., Chin, M.Y., & **Budge, S.L.** (2017). Sororities. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1611). Thousand Oaks, CA: SAGE.
- 9. ° <u>Sun, S.</u> & **Budge, S.L.** Women's group therapy. (2017). In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1829-1830). Thousand Oaks, CA: SAGE.
- <sup>o</sup> Sun, S., Minero, L., & Budge, S.L. (2017). Multiracial people and gender. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1208-1212). Thousand Oaks, CA: SAGE.
- 11. ° <u>Alexander, D., Hunter, C., & Budge, S.L.</u> (2017). Experiences of women in religious leadership. In K. Nadal (Ed.) *The SAGE Encyclopedia of Psychology and Gender* (pp. 1813-1815). Thousand Oaks, CA: SAGE.
- 12. ° **Budge, S.L.** (2017). Genderqueer. In A. Goldberg (Ed.) *The SAGE Encyclopedia of LGBTQ Studies* (pp. 460-463). Thousand Oaks, CA: SAGE.
- <sup>o</sup> Budge, S.L. & Snyder, K.E. (2016). Sex-related differences research. In A. Goldberg (Ed.) *The Wiley Blackwell Encyclopedia of Gender and Sexuality Studies* (pp. 2125-2129). Thousand Oaks, CA: SAGE.
- 14. °Budge, S. L., & Wampold, B. E. (2015). The relationship: How it works. In O. C. G. Gelo, A. Pritz, & B. Rieken (Eds.), *Psychotherapy research: Foundations, process, and outcomes* (pp. 213-228). Dordrecht: Springer.

#### **PUBLICATIONS IN REVISION AND UNDER REVIEW**

- 1. **Budge, S.L**. & Moradi, B. (Under Review). *A meta-analytic approach to studying psychotherapy outcomes focused on transgender affirmative therapies and power dynamics.*
- 2. Moradi, M. & Budge, S.L. (Under Review). A meta-analytic approach to studying psychotherapy outcomes for LGBTQ affirmative therapies.

- 3. Budge, S.L. & Moradi, B. (Under Review). Gender Identity.
- 4. Moradi, B. & Budge, S.L. (Under Review). Sexual Orientation.
- 5. Rossman, K., Sinnard, M., & **Budge, S.L.** (Under Review). *A qualitative examination of consideration and practice of consensual non-monogamy among sexual and gender minority couples.*
- 6. **Budge, S.L.,** Katz-Wise, S.L., Conniff, J., <u>Braden, T., Belcourt, W.S., Parks, R.</u> L. (Under Review). *Coping processes for transgender youth*.
- 7. **Budge, S.L.,** Katz-Wise, S. L., & Owen, J.J. (Under Review) *Sexual minorities' sexual communication, internalized homophobia, and conformity to gender norms.*
- 8. Goldberg, A.E., Kuvalanka, K.A., **Budge, S.L.,** Benz, M. & Smith J. (Under Review). *Mental health and health care experiences of trans students in higher educational settings: a mixed methods study.*
- 9. Hambrick, M., Cintron, A., Apegoraro, L., & **Budge, S.L.** (Under review). *I Am Cait: An analysis of the top-down and bottom-up framing of Caitlyn Jenner's ESPY Awards speech.*
- 10. <u>Thai, J.L.</u>, **Budge, S.L.**, & Adelson, J. L. (Under review) *The impact of family and identity on suicidality and substance abuse in trans Asian and Pacific Islander individuals.*
- 11. Walinsky, D. & Budge, S.L. (Under Review) Gender binaries, workplace discrimination and satisfaction, and delayed gender transition.

#### MANUSCRIPTS IN PROGRESS

- 1. Budge, S.L., <u>Sinnard, M.T.</u>, & <u>Rossman, H.K.</u> *Queering emotions: A content analysis of non-binary and genderfluid individuals' experiences of affect.*
- 2. **Budge, S.L.,** <u>Rossman, H.K., & Sinnard, M.T.</u> *A grounded theory analysis of the relationship between emotions and internal identity processes for non-binary and genderfluid individuals.*
- 3. <u>Rossman, H.K.</u>, <u>Sinnard, M.T.</u>, <u>salkas, s.</u>, & **Budge**, **S.L.** Genderfluid and non-binary individuals' experiences of external identity processes and emotion labels.
- 4. Budge, S.L., Orovecz, J.O., Barr, S.M., & Keller, B.L. Affirmative emotional processes for

transgender women: A qualitative analysis.

- 5. **Budge, S.L.,** <u>Stahl, A., Alexander, D., salkas, s., Orovecz, J.</u>. *The identity formation of genderqueer individuals.*
- 6. **Budge, S.**L., <u>Akinniyi, D., Alexander, D., Stahl, A., salkas, s., Orovecz, J.</u> *Analyzing the understanding of multiple identities for genderqueer individuals.*
- 7. **Budge, S.L.** <u>Barr, S.M.</u>, & Snyder, K. & *A dynamic systems approach to exploring the development of transgender identity.*
- 8. <u>Rossman, H.K., Eleazer, J., Gervasi, C.</u>, & Budge, S.L. *A qualitative analysis of transgender individuals' perceptions of privilege.*
- 9. <u>Hunter, C.</u> & **Budge, S.L.** *The moderating effect of race related to discrimination for transgender individuals.*
- 10. <u>Alexander, D.</u> & **Budge, S.L.** *The impact of partner support on symptoms of anxiety for trans women, trans men, and genderqueer individuals.*

- 11. <u>Eleazer, J.</u> & **Budge, S.L.** *Transgender military service-members' experiences of identity and vocational integration.*
- 12. Solberg, V.S., **Budge, S.L.,** Phelps, A., Durham, J., Haakenson, K., & Timmons, J. *The perceived utility and value of Individualized Learning Plans: Parent, educator, and student perspectives.*
- 13. Solberg, V.S., **Budge, S.L.,** & Halverson, E. *Identifying the nature of career decisionmaking patterns and their impact on career, academic and social/emotional outcomes: A mixed methods approach.*

#### MINOR PUBLICATIONS AND TECHNICAL REPORTS

- Solberg, V. S., Gresham, S. L., & Budge, S. L. (2009, December). *ECDM validation* study-II. Center on Education and Work (CEW), University of Wisconsin – Madison. Submitted to Guidance Branch, Singapore Ministry of Education.
- Solberg, V. S., Gresham, S. G., Budge, S. L., Phelps, A. L., Haakenson, K., & Durham, J. (2009, September). *NCWD/Youth research and demonstration project on Individualized Learning Plans*. Center on Education and Work (CEW), University of Wisconsin-Madison. Submitted to the National Collaborative on Workforce and Disability/Youth.
- Solberg, V. S., Lindwall, J., Budge, S. L., Schneider, C. L., Deloya, J., Halley, K., & Hatfield, P. (2009, August). *Report on the Mental Health Concerns among the Students in the Madison Metropolitan School District*. Center on Education and Work (CEW), University of Wisconsin– Madison. Submitted to the Madison Metropolitan School District.
- Solberg, V. S., Budge, S. L., Phelps, L. A. (2009, August). *Phase II Portal: Focus Group Discussion*. Center on Education and Work (CEW), University of Wisconsin Madison. Submitted to Guidance Branch, Singapore Ministry of Education
- 5. Valdez, C. R., & Budge, S. L. (2008). *Program evaluation of "It's Time! Adults Addressing Youth and Teen Depression."* InHealth Wisconsin, Milwaukee, WI.
- 6. Lin, M. & **Budge**, S. (2007). Exploring the impact of race and class on the First Year in Counseling Psychology 115. *Our First Year Experience*, *2*, 3-4.

#### **RESEARCH SUPPORT**

#### **Fall Research Competition**

University of Wisconsin-Madison \$34,000 - **funded** Research project determining the effectiveness of psychotherapy interventions focused on minority stressors for transgender clients. Role: PI

#### National Institute of Health

NICHD, R01, \$500,000 - submitted

Study focused on promoting well-being among transgender and gender non-conforming youth and identifying salient contextual factors. Role: Collaborator

#### 6/2018 - 6/2019

1/2018 - current

#### 50

#### UW Institute for Clinical Research (ICTR) Health Equity and Diversity (AHEAD) research pilot award \$10,000 - funded

Research project determining the effectiveness of psychotherapy interventions focused on minority stressors for transgender clients. Role: PI

#### National Institute of Health

Structured pubertal suppression readiness assessment for gender dysphoric youth. NICHD, R21, \$206,028 Role: Collaborator

### Fall Research Competition

University of Wisconsin-Madison \$60,000 - **funded** Supplemental research project for the NIH grant (listed below) focusing on pubertal suppression for transgender youth. Role: PI

#### National Institute of Health

NICHD, K23, \$666,769 - **scored**, unfunded Study focusing on the effects of pubertal suppression on affect and emotion regulation for transgender youth. Role: PI

#### Wisconsin Partnership Program

\$10,000 - **funded** 

**UW Institute for Clinical Research (ICTR)** 

Health Equity and Diversity (AHEAD) research pilot award

Community Opportunity Grant \$50,000 - funded A grant that assists with opportunities focused on transgender health and equity in health care. Role: Collaborator

#### Research project advancing the Wisconsin Survey of Trans Youth: An Assessment of Resources and Needs. Role: Co-investigator

# Patient Centered Outcome Research Initiative (PCORI)

Engagement Award \$250,000 - scored, unfunded Creating a collective for integrating psychological health, education, and research for LGBTQ therapies (CIPHER LGBTQ) Role: Co-PI

# 1/2017 – 1/2019

5/2017 - 9/2018

6/2017 - 6/2018

11/2016

6/2016 - 6/2018

5/2016

6/2016 - 6/2018

#### Faculty Research Development Grant

College of Education and Human Development University of Louisville \$2,200 - funded Research project testing psychotherapy process and outcomes for transgender individuals. Role: PI

#### **Faculty Research Development Grant**

College of Education and Human Development University of Louisville \$2,200 - **funded** Research project regarding positive experiences of transgender identity and intersectionality of identities with genderqueer individuals. Role: PI

#### Charles J. Gelso Research Grant

American Psychological Association (Division 29) \$2,000 - **funded** Meta-analysis project focusing on personality disorders and treatment effectiveness. Role: PI

#### **INTERNATIONAL PRESENTATIONS**

°Invited; <u>Underlining</u> denotes student;

- 1. **Budge, S.L.** & Katz-Wise, S.L. (2016, July). *Emotional expression of trans youth and their families: A cross-comparison of familial cultures for gender and emotions*. Paper presented at the International Congress of Psychology Conference, Yokohama, Japan.
- <u>Chin, M.Y., Minero, L., & Budge, S.L. (2016, July). "This is me, and I am happy. I love it": Understanding Internal Coping Processes of Trans-identified Individuals using Grounded Theory.</u> Paper presented at the International Congress of Psychology Conference, Yokohama, Japan.
- 3. **Budge, S.L.,** Katz-Wise, S.L., <u>Conniff, J., Belcourt, S., & Parks, R.</u> (2016, July). *Developmental processes of coping for trans youth: Results from the Trans Youth and Family Study (TYFS)*. Paper presented at the World Professional Association for Transgender Health Biannual Conference, Amsterdam, The Netherlands.
- 4. <u>Sinnard, M., Raines, C.,</u> & **Budge, S.L.** (2016, July). *Effects of location and transition status on anxiety and depression in trans individuals.* Paper presented at the World Professional Association for Transgender Health Biannual Conference, Amsterdam, The Netherlands.
- 5. **Budge, S.L.** & <u>salkas, s.</u> (2016, July). *An overview of non-binary gender identities in the National Transgender Discrimination Survey*, Paper presented at the World Professional Association for Transgender Health Biannual Conference, Amsterdam, The Netherlands.
- 6. <u>Orovecz, J., salkas, s.,</u> & **Budge, S.L.** (2016, July). *External identity processes for individuals with non-binary identities*. Paper presented at the World Professional Association for Transgender Health Biannual Conference, Amsterdam, The Netherlands.

6/2010 - 6/2012

9/2011-9/2012

10/2012 - 10/2013

- 7. <u>Rossman, K., Sinnard, M.</u>, & **Budge, S.L.** (2016, July). *The externalization of affect for individuals with non-binary gender identities*. Paper presented at the World Professional Association for Transgender Health Biannual Conference, Amsterdam, The Netherlands.
- 8. <u>Hase, C.N</u>., Reiland, M.T., **Budge, S.L**. (2015, August). "*Omitting none:*" *Experience of people of color in a primarily white meditation community*. Poster presented at American Psychological Association. Toronto, ON.
- <u>Akinniyi, D.A.</u> & Budge, S.L. (2015, August). Genderqueer individuals' conceptualizations of multiple identities: A qualitative investigation using identity maps. Paper presented at the Annual Meeting for the American Psychological Association, Toronto, Canada.
- 10. <u>Sinnard, M.</u> & **Budge, S.L.** (2015, August). *Effects of location and transition status on anxiety and depression in trans individuals.* Poster presented at the Annual Meeting for the American Psychological Association, Toronto, Canada.
- 11. Watkins, C.E., **Budge, S.L., &** Wampold, B.E. (2015, August). *Extrapolating the Wampold/Budge psychotherapy relationship model to psychotherapy supervision.* Paper presented at the Annual Meeting for the American Psychological Association, Toronto, Canada.
- 12. **Budge, S.L.** (2014, February). *Developmental processes of positive emotions for trans individuals: The interplay of interpersonal emotions and transition appraisal.* Paper presented at the World Professional Association for Transgender Health Biannual Conference, Bangkok, Thailand.
- 13. Budge, S.L., Adelson, J.L., & Howard, K.A.S. (2014, February). Transgender and Genderqueer individuals' mental health concerns: A moderated mediation analysis of social support and coping. Paper presented the World Professional Association for Transgender Health Biannual Conference, Bangkok, Thailand.

#### **NATIONAL PRESENTATIONS**

°Invited; <u>Underlining</u> denotes student;

- 1. **Budge, S.L.** (2018, August). *The feasibility of a clinical trial focusing on trans individuals' minority stress.* Paper to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 2. **Budge, SL.,** Allen, B., <u>Andert, B.</u>, Botsford, J., & Rehm, J. (2018, August). *Resources contributing to psychological well-being for trans youth: A CBPR Approach*. Paper to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 3. <u>Dillard, S., Sinnard, M.T.</u>, **Budge, S.L.**, & Katz-Wise, S.L. (2018, August). *Triadic analysis of concordance and discordance in families of trans youth*. Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 4. <u>Mauk, E., Guo, E., Stock, C., Eck, M.,</u> & **Budge, S.L.** (2018, August). *Minority stress interventions in a psychotherapy pilot trial for transgender clients.* Paper to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 5. <u>Orzechowski, M.</u>, **Budge, S.L.**, <u>Lavendar, A.</u>, <u>Onsgard, K.</u>, <u>Schamms, S.</u>, Liebowitz, S., & Katz-Wise, S.L. (2018, August). *Emotions of transgender youth.* Poster to be presented

at the Annual Meeting for the American Psychological Association, San Francisco, California.

- 6. <u>Raines, C.R</u> & **Budge, S.L.** (2018, August). *Measuring masculine sexual entitlement: Subscales of a new instrument.* Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- Sinnard, M.T., Orzechowski, M., Budge, S.L., Belcourt, S., Conniff, J., Orovecz, J., Parks, <u>R., Sun, S., & Sutton, J.</u> (2018, August). *Depression and anxiety among transgender compared to cisgender Individuals: A meta-analysis*. Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 8. <u>Sinnard, M.T., Lewis, K.,</u> & **Budge, S.L.** (2018, August). *The effectiveness of psychotherapy for transgender clients: A randomized controlled trial.* Paper to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 9. <u>Sun, S.,</u> Hoyt, W.T., & **Budge, S.L.** (2018, August). *Minority stress, HIV risk behaviors, and mental health among Chinese men who have sex with men (MSM): A qualitative analysis.* Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 10. <u>Thomas, K.A., Andert, B., Ibarra, N.,</u> **Budge, S.L.,** & dickey, l. (2018, August). *Nonsuicidal self-injury in transgender individuals*. Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 11. <u>Dyer, R.</u>, **Budge, S.L.**, Rehm, J., Botsford, J., <u>Andert, B.</u>, & Allen, B. (2018, August). *Rural-urban differences in perceived safety at school for Wisconsin trans youth.* Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 12. <u>Raines, C.R</u> & **Budge, S.L.** (2018, August). *Understanding the relationships between masculine sexual entitlement, masculinity, and violence.* Poster to be presented at the Annual Meeting for the American Psychological Association, San Francisco, California.
- 13. Rehm, J., Botsford, J., Budge, S.L, <u>Andert, B.</u>, & Allen, B. (2017, September). *Initial results of needs assessment for trans and gender expansive youth in Wisconsin*. Poster presented at the International Joint Meeting of Pediatric Endocrinology, Washington, D.C.
- 14. <u>Minero, L.M.</u> & Budge, S.L. (2017, February). *Experiences of exclusion and discrimination among undocutrans (undocumented and transgender) individuals in the united states and implications for mental health professionals.* Paper presented at the meeting for the United States Professional Association for Transgender Health, Los Angeles, California.
- 15. **Budge, S.L.** (2017, February). *Evaluating the effectiveness of psychotherapy with trans clients: using the working alliance inventory.* Paper presented at the meeting for the United States Professional Association for Transgender Health, Los Angeles, California.
- Budge, S.L. (2016, August). Psychotherapy interventions, process, and outcome with transgender and gender non-conforming clients. Chair of invited symposium for Division 29 at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 17. **Budge, S.L.** (2016, August). *The impact of minority stress interventions on psychotherapy outcomes with a trans client*. Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.

- 18. <u>Minero, L.M., Chin, M.Y.</u>, & **Budge, S.L.** (2016, August). *Transgender clients' reports* of characteristics of effective and trans-competent therapists. Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 19. **Budge, S.L.** (2016, August). *The state and future of psychotherapy research with transgender clients.* Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 20. <u>Minero, L.M., Chin, M.Y.</u>, & **Budge, S.L.** (2016, August). *Understanding external coping processes of trans-identified individuals using grounded theory*. Poster presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 21. <u>Salkas, S.</u> & **Budge, S.L.** (2016, August). *An overview of US population-based data on individuals with non-binary gender identities*. Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 22. <u>Alexander, D., Orovecz, J., Salkas, S., Stahl, A.,</u> & **Budge, S. L.** (2016, August). *Internal identity processes for individuals with non-binary identities*. Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 23. <u>Rossman, K., Sinnard, M.,</u> & **Budge, S.L.,** (2016, August). *The "queering" of emotions--using non-binary gender identity to label emotional processes.* Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 24. <u>Barr, S. M.</u> & **Budge, S.L.** (2016, August). *Experiences of self esteem and well-being for individuals with non-binary gender identities*. Paper presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 25. <u>Chase, A., Lam, J.</u>, & **Budge, S.L.** (2016, August). *Culture and masculine ideology: measuring masculinity among japanese american men*. Poster presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 26. <u>Akinniyi, D.</u> & **Budge, S.L.** (2016, August). *The student-athlete experience: Multiple minority statuses and discrimination*. Poster presented at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 27. **Budge, S.L**. (2016, August). *Identity processes, well-being, and emotional processes for individuals with non-binary identities.* Chair of symposium at the Annual Meeting for the American Psychological Association, Denver, Colorado.
- 28. <u>Hase, C.N.</u>, Meadows, J.D., Budge, S.L. (2016, June). *Inclusion and exclusion in the white space: An investigation of the experiences of people of color in a primarily white american meditation community*. Poster presented at Mind & Life Summer Research Institute. Garrison, NY.
- 29. **Budge, S.L.** (2015, June). *The effectiveness of psychotherapeutic treatments for personality disorders: A review and critique of current research practices.* Paper presented at the Annual Meeting for the Society for Psychotherapy Research, Philadelphia, PA.
- Kring, M. & Budge, S.L. (2015, June). *Re-evaluating outcomes in psychotherapy: Considerations beyond self-report.* Paper presented at the Annual Meeting for the Society for Psychotherapy Research, Philadelphia, PA.
- 31. Owen, J. J., Wampold, B.E., Miller, S.D., Budge, S.L., & Minami, T. (2015, June). *Trajectories of change in short-term psychotherapy: Lessons from growth curve mixture modeling*. Paper presented at the Annual Meeting for the Society for Psychotherapy Research, Philadelphia, PA.

- 32. Katz-Wise, S.L. & **Budge, S.L.** (2015, April). *Imaging the future: qualitative findings of future orientation from trans youth and parents/caregivers in the Trans Youth Family Study.* Paper presented at the Annual Transgender Health Summit, Oakland, CA.
- 49. **Budge, S.L.** (2014, August). *The other side of the story: trans individuals' experiences of positivity and resilience.* Symposium chair for the Annual Meeting for the American Psychological Association, Washington, DC.
- 50. **Budge, S.L.** (2014, August). *Lessons learned from NIH-grant submission for LGBTQ research*. Invited panelist for the Annual Meeting for the American Psychological Association, Washington, DC.
- 33. **Budge, S.L.** & Katz-Wise, S.L. (2014, August). *Emotional and interpersonal experiences of trans youth and their caregivers.* Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 34. <u>Eleazer, J.L., Nguyen, Y.</u>, **Budge, S.L.** (2014, August). "*I'm afraid of my therapist": Military policy and access-to-care for transgender US service members*. Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 35. <u>Thai, J.L.</u> & Budge, S.L. (2014, August). *Mental health outcomes for trans Asian American, Asian, and Pacific Islander populations*. Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 36. <u>Alexander, D.</u> & Budge, S.L. (2014, August). *The impact of partner support on symptoms of anxiety for trans women, trans men, and genderqueer individuals.* Poster presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 37. <u>Barr, S.M.</u> & Budge, S.L. (2014, August). *Trans identity salience as a predictor for well-being and body control beliefs for trans individuals*. Poster presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 38. <u>Keller, B.L., Barr, S.M.</u>, & **Budge, S.L.** (2014, August). *Trans women's emotional resilience: Reactions to the intersection of sexism and transphobia.* Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 39. <u>Rossman, H.K., Sinnard, M.</u>, **Budge, S.L.** (2014, August). *Adapting a three-tiered model of emotions to genderqueer individuals' identity processes*. Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 40. <u>Thai, J.L., Orovecz, J.</u>, **Budge, S.L.** (2014, August). *Trans men's experiences of positive emotions: An examination of gender identity and emotion labels*. Paper presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 41. Tebbe, E.N., Brewster, M., **Budge, S.L.** (2014, August). *A content analysis of transgender psychological literature.* Poster presented at the Annual Meeting for the American Psychological Association, Washington, DC.
- 42. <u>Thai, J.L.</u> & **Budge, S.L.** (2014, March). *Family relationships and outness for transgender Asian Pacific Islander individuals*. Paper presented at the Society of Counseling Psychology Conference, Atlanta, GA.
- 43. <u>Hunter, C.</u> & **Budge, S.L.** (2014, March). *The moderating effect of race related to discrimination for transgender individuals.* Paper presented at the Society of Counseling Psychology Conference, Atlanta, GA.
- 44. <u>Alexander, D.</u> & **Budge, S.L.** (2014, March). *The impact of partner support on symptoms of anxiety for trans women, trans men, and genderqueer individuals.* Paper presented at the Society of Counseling Psychology Conference, Atlanta, GA.

- 45. <u>Barr, S.M.</u> & **Budge, S.L.** (2014, March). *Validation of the Objectified Body Consciousness Scale for transgender individuals.* Paper presented at the Society of Counseling Psychology Conference, Atlanta, GA.
- 46. **Budge, S.L.** (2013, October). *Addressing grief and role transitions for transgender clients experiencing gender identity incongruence.* Paper presented at the Biennial North American Society for Psychotherapy Research Conference, Nashville, TN.
- 47. **Budge, S.L.,** <u>Barr, S.M.,</u> Katz-Wise, S.L., <u>Keller, B.L.,</u> & <u>Manthos, M.</u> (2013, June). *Incorporating positivity into psychotherapy with trans clients.* Workshop presented at the Annual Philadelphia Transgender Health Conference, Philadelphia, PA.
- 48. **Budge, S.L.** & <u>Barr, S.M.</u> (2013, April). *Emotional and identity processes of trans youth: A developmental approach.* Paper presented at the Biennial Society for Research on Child Development Conference, Seattle, WA.
- 49. **Budge, S.L.,** <u>Thai, J., Rossman, H.K.</u> (2012, August) *Intersecting identities and mental health outcomes for transsexual, cross-dressing, and genderqueer individuals.* Poster presented at the Annual Meeting for the American Psychological Association, Orlando, Florida.
- 50. **Budge, S.L.** & <u>Keller, B.L.</u> (2012, August). "She felt pressured, I felt neglected": LGBQ individuals' experiences of sexual pressure in relationships. Poster presented at the Annual Meeting for the American Psychological Association, Orlando, Florida.
- 51. **Budge, S.L.,** <u>Moore, J., Neinhuis, J.,</u> Baardseth, T., & Wampold, B.E. (2012, June). *The relative efficacy of bona-fide psychological treatments for personality disorders: A meta-analysis of direct comparisons*. Paper presented at the Annual Meeting for the Society for Psychotherapy Research, Virginia Beach, Virginia.
- 52. **Budge, S.L.** & Katz-Wise, S.L. (2012, February). *Trans-affirmative therapy: Focusing* on emotional and coping processes throughout gender transitioning. Workshop presented at the Transgender Spectrum Symposium, Annual Meeting of the Gay and Lesbian Affirmative Psychotherapy Association, New York, New York.
- 53. **Budge, S.L.** & Katz-Wise, S.L. (2011, November). *Transgender emotional and coping processes: Facilitative and avoidant coping throughout the gender transition.* Paper presented at the Annual Meeting for the Society for the Scientific Study of Sexuality, Houston, Texas.
- 54. **Budge, S.L.** & Howard, K.H. (2011, August). *Gender socialization and genderqueer individuals: The impact of assigned sex on coping and mental health concerns.* Paper presented at the Annual Meeting for the American Psychological Association, Washington, D.C.
- 55. Tebbe, E.L., **Budge, S.L.,** & Fischer, A. (2011, March). *Transforming the research Goliath: Reflections on research with transgender communities.* Roundtable presented at the Bi-Annual Meeting of the Association for Women in Psychology, Philadelphia, Pennsylvania.
- 56. **Budge, S.L.** & Howard, K.A.S. (2010, August). *Coping, social support, and well-being in the transition process for transgender individuals*. Paper presented at the Annual Meeting for the American Psychological Association, San Diego, California.
- 57. Baardseth, T.P., **Budge, S.L.,** & Wampold, B.E. (2010, August). *Allegiance and psychotherapy research: The effectiveness of supportive therapy as a control.* Poster presented at the Annual Meeting for the American Psychological Association, San Diego, California.

- 58. Solberg, V.S., Gresham, S.L., **Budge, S.L**., & Phelps, A.L. (2010, August). *Impact of learning experiences on students with disabilities career development*. Poster presented at the Annual Meeting for the American Psychological Association, San Diego, California.
- 59. Katz-Wise, S.L., **Budge, S.L.,** & Hyde, J.S. (2010, August). *Individuation or identification? Objectified body consciousness*. Poster presented at the Annual Meeting for the American Psychological Association, San Diego, California.
- 60. Solberg, V.S., Gresham, S.L., **Budge, S.L**., & Phelps, A.L. (2010, August). *Impact of exposure to quality learning experiences on career development*. Paper presented at the Annual Meeting for the American Psychological Association, San Diego, California.
- 61. **Budge, S.L.** & Fluckiger, C. (2010, June). *Comparison of evidence-based-treatments versus treatment as usual: A meta-analysis.* Paper presented at the Annual Meeting for the Society for Psychotherapy Research, Asilomar, California.
- 62. **Budge, S.L**. & Howard, K.A.S. (2010, April). *Career decision-making in the transgender population: The role of barriers and discrimination*. Paper presented at the Annual Meeting for the American Educational Research Association, Denver, Colorado.
- 63. **Budge, S.L.**, Solberg, V.S., Phelps, L.A., Haakenson, K., & Durham, J. (2010, April). *Promising practices for implementing Individualized Learning Plans: Perspectives of teachers, parents, and students.* Paper presented at the Annual Meeting for the American Educational Research Association, Denver, Colorado.
- 64. Solberg, V.S., Gresham, S.L., Phelps, L.A., & **Budge, S.L.** (2010, April). *Identifying decision-making patterns and its impact on career development and workforce readiness.* Paper presented at the Annual Meeting for the American Educational Research Association, Denver, Colorado.
- 65. Katz-Wise, S.L., **Budge, S.L.,** & Hyde, J.S. (2010, March). *Objectified body consciousness and the mother-adolescent relationship.* Poster presented at the Biennial Meeting for the Society for Research on Adolescence, Philadelphia, Pennsylvania.
- 14. Budge, S. L., Tebbe, E. N., Katz-Wise, S. L., Schneider, C. L., & Howard, K. A. (2009, August). Workplace transitions: Work experiences and the impact of transgender identity. Paper presented at the Annual Meeting of the American Psychological Association, Toronto, Ontario, Canada.
- 15. Katz-Wise, S. L., **Budge, S. L.**, & Schneider, C. L. (2009, August). *Navigating the gender binary: A qualitative study of transgender identity development*. Paper presented at the Annual Meeting of the American Psychological Association, Toronto, Ontario, Canada.
- Nelson, M. L., Thompson, M. N., Huffman, K. L., & Budge, S. L. (2009, August). Development and further validation of the social class identity dissonance scale. Paper presented at the Annual Meeting of the American Psychological Association, Toronto, Ontario, Canada.
- 66. Dvorscek, M., **Budge, S. L.**, Bluemner, J. L., & Valdez, C. R. (2009, August). *Health care provider perspectives on Latino patients with depression*. Poster presented at the Annual Meeting of the American Psychological Association, Toronto, Ontario, Canada.
- 67. Neumaier, E. R., Budge, S. L., Bohlig, A. J., Doolin, E. M., & Nelson, M. L. (2009, August). *I feel masculine but they think I'm feminine: Toward measuring experienced gender role*. Poster presented at the Annual Meeting of the American Psychological Association during the Division 17 Social Hour, Toronto, Ontario, Canada.

- 68. Doolin, E. M., Graham, S. R., Hoyt, W. T., **Budge, S. L.**, & Bohlig, A. J. (2009, January). *Out and about in the South: Defining lesbian communities.* Poster presented at the National Multicultural Conference and Summit, New Orleans, LA.
- 69. **Budge, S. L.**, Tebbe, E. N. & Howard, K. A. S. (2009, January) *Transgender individuals' work experiences: Perceived barriers, discrimination, and self-efficacy.* Paper presented at the Annual Meeting of the Career Conference, Madison, WI.
- 70. Howard, K. A. S., Budge, S. L., Jones, J., & Higgins, K. (2009, January). Future plans of urban youth: A qualitative analysis of influences, barriers, & coping strategies. Paper presented at the Annual Meeting of the Career Conference, Madison, WI.
- 71. Budge, S., Schneider, C., Rodriguez, A., Katz-Wise, S., Tebbe, E., & Valdez, C. (2008, August). *The emotional roller coaster: Transgender experiences of positive and negative emotions*. Poster presented at the Annual Meeting of the American Psychological Association, Boston, MA.
- 72. Nelson, M. L., Huffman, K. & **Budge, S. L.**, (2008, August). *Initial validation of the Social Class Identity Dissonance Scale*. Poster presented at the Annual Meeting of the American Psychological Association, Boston, MA.
- 73. **Budge, S. L.,** Schneider, C., Rodriguez, A., & Howard, K. A. S. (2008, January) *What about the "T"?: Career counseling with transgender populations.* Paper presented at the Annual Meeting of the Career Conference, Madison, WI.
- 74. Howard, K. A.S., McKay, K. M., & Budge, S. L. (2007, August) Adolescents' use of SOC strategies: The interaction with low-income and high violence contexts. Poster presented at the Annual Meeting of the American Psychological Association, San Francisco, CA.
- 75. **Budge, S. L.** & Sherry, A. (2007, August) *The influence of gender role on sexual compliance: A preliminary investigation of LGB relationships.* Poster presented at the Annual Meeting of the American Psychological Association, San Francisco, CA.
- 76. Howard, K. A. S., Solberg, V. S., & Budge, S. L. (2007, August). Designing culturally responsive school counseling career development programming for youth. Paper presented at the Annual Meeting of the American Psychological Association, San Francisco, CA.
- 77. Howard, K. A. S., Jones, J. E., Budge, S., Gutierrez, B., Lemke, N., Owen, A., & Higgins, K. (2007, April). *Academic and career goals of high school youth: processes and challenges*. Paper presented at the Annual Meeting of the American Educational Research Association, Chicago, IL.

#### **REGIONAL PRESENTATIONS**

°Invited; <u>Underlining</u> denotes student;

- 1. **Budge, S.L.** (2017, September). *Transgender individuals and minority stress: The past, present, and future.* Research talk presented for the UW Department of Psychology Diversity series.
- 2. **Budge, S.L.** and Karcher, O. (2017, May). *Supporting trans youth and their mental health needs, Part 2.* Paper presented at the Supporting Trans and Gender Expansive Youth conference, Madison, Wisconsin.

- 3. **Budge, S.L.** (2016, October). *Supporting trans youth and their mental health needs.* Paper presented at the Supporting Trans and Gender Expansive Youth conference, Madison, Wisconsin.
- 4. **Budge, S.L.** (2013, November). *Incorporating an IPT approach with transgender clients*. Paper presented at the Annual Kentucky Psychological Association Conference, Lexington, Kentucky.
- 5. **Budge, S.L.** (2013, April). *Using interpersonal therapy with transgender clients.* Workshop provided at the Annual University of Florida Interdisciplinary Conference on LGBT Issues.
- 6. <u>Barr, S. M.</u> & **Budge, S. L.** (2013, April). *The role of identity integration in the emotional well-being of post-transition individuals*. Poster presentation at the Kentucky Psychological Association Student Research Conference, Louisville, Kentucky.
- 7. <u>Orovecz, J., Thai, J.L.,</u> & Budge, S.L. (2013, April). "*I'm stoked about life": The emotional processes of trans men through a qualitative lens*. Poster presented at the Spring Research Conference, Lexington, Kentucky.
- 8. <u>Rossman, K.</u> & **Budge, S.L.** (2013, April). *Genderqueer individuals' mental health concerns: The relationship between social support and coping*. Paper presented at the Spring Research Conference, Lexington, Kentucky.
- 9. <u>Barr, S. M.</u> & **Budge, S. L.** (2013, April). *The role of identity integration in the emotional well-being of post-transition individuals*. Poster presented at the Spring Research Conference, Lexington, Kentucky.
- 10. <u>Rossman, K.</u> & **Budge, S.L.** (2013, June). *Just the fact that I commanded that respect I got the privilege: Qualitative examination of privilege in the trans community.* Paper presented at the Spring Research Conference, Lexington, Kentucky.
- 11. <u>Keller, B.L., Barr, S.M.</u>, & **Budge, S.** L. (2013, April). "For every bad, there's 40 good things that happen": A qualitative approach to understanding the positive emotional experiences of trans women. Poster presentation at the Spring Research Conference, Lexington, Kentucky.
- 12. <u>Orovecz, J., Thai, J.L.</u>, & **Budge, S.L.** (2013, April). "*I'm stoked about life": The emotional processes of trans men through a qualitative lens.* Presented at the Spring Research Conference, Lexington, Kentucky.
- Orovecz, J., Thai, J.L., & Budge, S.L. (2013, March). "I'm me, and I'm proud to be me": A grounded theory analysis of trans men's emotional processes. Presented at the Kentucky Psychological Association Foundation Spring Academic Conference, Louisville, Kentucky.
- 14. <u>Eleazer, J. R.</u> & **Budge, S. L.** (2013, March). *"It would be better for them to have a dead hero for a father than a freak:" Suicidality and trans military service.* Poster presented at the Kentucky Psychological Association Spring Academic Conference, Louisville, Kentucky.
- 15. <u>Sinnard, M., Rossman, K.,</u> & **Budge, S. L.** (2013, March). *Positive emotional experiences of gender non-binary identified individuals*. Poster presentation at the Kentucky Psychological Association Student Research Conference, Louisville, Kentucky.
- 16. <u>Barr, S.M., Stahl, A., Manthos, M.,</u> & Budge, S.L. (2012, November). "It means there aren't rules and you don't have to ascribe to a specific binary": A qualitative examination of genderqueer identity. Paper presented at the Chicago LGBTQ Health and Wellness Conference, Chicago, Illinois.

- 17. <u>Thai, J.L., Orovecz, J.</u>, & **Budge, S.L.** (2012, November). *Trans men and positivity: Emotional processes related to identity.* Paper presented at the Chicago LGBTQ Health and Wellness Conference, Chicago, Illinois.
- 18. Budge, S.L., <u>Barr, S.M., Orovecz, J., & Rossman, H.K.</u> (2012, November). *Clinical work with LGBT youth*. Workshop provided at the Annual Kentucky Psychological Association Conference, Louisville, Kentucky.
- Budge, S.L., Lee, S., & Monahan-Rial, V. (2011, February). Bridging institutional gaps: Utilizing transgender-affirmative therapy with college students. Workshop presented at the Annual Meeting for the Big 10 College Counseling Center Conference, Minneapolis, Minnesota.
- Lee, J., Budge, S.L., Wilson, J.L., & Roper, J.M. (2011, February). *The Korean Conundrum: Managing stigma in the recruitment of group counseling members.* Workshop presented at the Annual Meeting for the Big 10 College Counseling Center Conference, Minneapolis, Minnesota.
- 21. **Budge, S.L.** & Katz-Wise, S.L. (2010, February). *Transition to adulthood: Developmental steps for transgender individuals.* Workshop presented at the Conference on Transgender and Gender Variant Youth, Madison, Wisconsin.
- 22. **Budge, S.L.** (2009, October). *Individualized Learning Plans: Parent, student, and educator focus groups*. Paper presented at the Fall Institute for the National Collaborative on Workforce and Disability/Youth, Charleston, South Carolina.

# **KEYNOTE AND INVITED PRESENTATIONS**

- 1. **Budge, S.L.** & <u>Mauk, E.</u> (2017, May). *Health and well-being of LGBTQ students: Lessons learned and recommendations for educators*. Invited presentation at the CESA Conference, Madison, Wisconsin.
- 2. **Budge, S.L.** (2016, March). *The construction of gender identity as "disordered": A critical examination of mental health using trans narratives.* Invited presentation at the Women's and Gender Studies Forum at the University of Florida, Gainesville, Florida.
- 3. **Budge, S.L.** (2016, March). *Understanding, acknowledging, and responding to LGBTQ microaggressions in health care settings.* Keynote provided at the Florida Area Health Education Center, Gainesville, Florida.
- 4. **\*Budge, S.L.** (2014, September). *Positivity in trans populations: Implications for vocational psychology*. Boston University, Boston, Massachusetts.
- 5. **Budge, S.L.** (2013, April). *Future directions for research and therapy with trans and gender diverse individuals*. Keynote provided at the Annual University of Florida Interdisciplinary Conference on LGBT Issues.
- 6. **°Budge, S.L.** (2013, March). *The psychology of sexual orientation and gender identity: future directions and implications*. Keynote provided at the East Texas Psi Chi Student Research Conference, Tyler, Texas.

## **NATIONAL RESEARCH BRIEFINGS**

1. **Budge, S.L.,** & Solberg, V.S., (2010, March) *Career exploration and the use of career narrative data for high school students' career exploration processes: A United States sample.* Research briefing presented at the Department of Labor, Washington, D.C.

2. **°Budge, S.L.,** Solberg, V.S., & Phelps, A.L. (2010, March) *Individualized Learning Plans within a community-oriented approach: The usefulness of focus group data with parents, teachers, and students.* Research briefing presented at the Department of Labor, Washington, D.C.

#### **INTERNATIONAL RESEARCH BRIEFINGS**

- 1. **°Budge, S.L.,** & Solberg, V.S., (2010, February) *A three-tiered approach to analyze the career decision making processes using focus group data with Singaporean parents, students, and staff.* Research briefing presented at the Ministry of Education, Singapore.
- 2. **Budge, S.L., &** Solberg, V.S., (2010, February) *Use of narrative analysis for high school students' career exploration processes: A Singapore Sample*. Research briefing presented at the Ministry of Education, Singapore.

#### **TEACHING EXPERIENCE**

#### University of Wisconsin-Madison Courses (Fall 2014 - Fall 2017)

#### Fall 2017

CP 951: Research in Individual Interventions (graduate): enrollment = 12

CP 999: Independent Study (graduate): enrollment = 1

CP 990: Independent Research (graduate): enrollment = 2

CP 699: Independent Research (undergraduate): enrollment = 3

#### Summer 2017

CP 699: Independent Research (undergraduate): enrollment = 1

#### Spring 2017

CP 903: Advanced Practicum (graduate): enrollment = 8

CP 900: Foundational Practicum (graduate): enrollment = 5

CP 890: Advanced Assessment Techniques (graduate): enrollment = 10

CP 999: Independent Study (graduate): enrollment = 1

CP 990: Independent Research (graduate): enrollment = 1

CP 699: Independent Research (undergraduate): enrollment = 8

#### Fall 2016

CP 805: Helping Relationships & Techniques (graduate): enrollment = 15 CP 990: Independent Research (graduate): enrollment = 2 CP 699: Independent Research (undergraduate): enrollment = 8

#### Summer 2016

CP 699: Independent Research (undergraduate): enrollment = 1

#### Spring 2016

 $\overrightarrow{CP}$  903: Advanced Practicum (graduate): enrollment = 4

CP 900: Foundational Practicum (graduate): enrollment = 9 CP 810: Professional Development/Clinical Practice (graduate): enrollment = 8 CP 699: Independent Research (undergraduate): enrollment = 1 Counseling Psychology Training Clinic Supervision (n = 7)

#### Fall 2015

CP 805: Helping Relationships & Techniques (graduate): enrollment = 10 CP 999: Independent Study (graduate): enrollment = 10

#### Spring 2015

Master's Pre-Practicum (enrollment: 17) Counseling Psychology Training Clinic Supervision (n = 12) CP 990: Independent Research (graduate): enrollment = 8 CP 901: Counseling Psych Practicum (graduate): enrollment = 1 CP 699: Independent Research (undergraduate): enrollment = 1

#### Fall 2014

CP 805: Helping Relationships & Techniques (graduate): enrollment = 17 CP 999: Independent Study (graduate): enrollment = 5

#### Course or Curriculum Development at UW-Madison From 2014-current

Individual Interventions (new course)	2017
Advanced Assessment Techniques (new curriculum)	2017
LGBT Psychology (new curriculum)	2016
Advanced Doctoral Clinical Practicum (new course)	2016
Foundational Doctoral Clinical Practicum (new course)	2016
Master's Pre-Practicum (new course)	2015
Helping Relationships & Techniques (new course)	2014

#### **Previous Teaching**

#### **University of Louisville Courses**

ECPY 780: Advanced Practicum ECPY 648: Intellectual Assessment ECPY 663: Multicultural Issues ECPY 629: Theories and Techniques of Counseling ECPY 621: Differential Diagnosis ECPY 793: Gender and Queer Issues In Psychology ECPY 793: Advanced Multicultural Psychotherapy ECPY 700: Supervised Research

#### **Graduate-Student Teaching:**

University of Wisconsin-Madison (2006-2009) CP 804: Research Methods CP 994: Personality Assessment CP 650: Interviewing Skills CP 115: First Year Experience

# University of Texas at Austin (2005-2006)

PSY 301: Introduction to Psychology

# Supervision of Clinical Work at UW-Madison

## Provision of Supervision at the Counseling Psychology Training Clinic

I was the on-site licensed psychologist and supervisor for one clinic night per week. Provided individual clinical supervision to 7 masters and doctoral students (1 hr. per week of individual clinical supervision for each student in addition to administration [feedback on notes and watching video-recordings of sessions]). Provided one hour of group supervision on the night I was on-site at the clinic.

#### Provision of Supervision to students in the Pre-Practicum course (CP 806).

Provided individual supervision (above and beyond class duties, due to low staffing in the department) to masters and doctoral students for the CP 806 course in the Spring of 2015.

# SERVICE ACTIVITIES

# **PUBLIC SERVICE (From 2014- current)**

# Wisconsin Transgender Health Coalition (WTHC)

I have been involved in the organization since its inception. I have mainly been involved in the "data and dissemination" team, where I provide my expertise as researcher helping community members establish their own research projects and write grants to support personnel within the coalition. As a part of this team, I have given presentations to community members about population-based data within Wisconsin that can influence access to more medical and mental health care. I have also assisted team members with creating surveys and recruiting individuals to be a part of a Wisconsin needs assessment of transgender youth. We meet once per month to focus on the larger data team and have smaller meetings throughout the month to focus on community outreach and training to disseminate research in a fashion that is most helpful for individuals who are not involved in academia.

# **Co-Coordinator and Co-Chair for the Transgender**

8/2014 - 5/2016

1/2015 - 5/2015

5/2015-current

#### and Gender Expansive Youth Conference

Attend meetings for an ongoing planning committee to coordinate semi-annual conferences about the concerns of transgender youth. Helped develop an agenda for the conferences, planned speakers, coordinated a budget, and decided on special topics for the conference. Introduce the keynote speaker at the conference and provide project management during the day of the conference. Provided three one-hour long sessions to educate teachers, school staff, mental health professionals, and community members.

#### **Pro-Bono Psychotherapy**

Provided 1.5 hours of pro-bono weekly group psychotherapy to transgender and gender expansive youth at the Counseling Psychology Training Clinic. Provided group therapy training to a doctoral student to conduct co-therapy with me as part of the group.

#### **Community Presentations and Trainings**

Group Health Cooperative Insurance	12/2017
Goodman Community Center and UW Health	9/2017
Marquette University	8/2017
Madison Metropolitan School District	5/2017
Wisconsin Department of Public Safety	4/2017
Psychiatric Services	2/2017
FORGE	1/2017
Wisconsin Department of Public Instruction	12/2016
Madison Metropolitan School District	10/2016
Marquette University	5/2016
PROFESSIONAL SERVICE	
Associate Editor Psychotherapy	1/2014 - current
<b>Guest Editor of Special Sections</b> <i>Psychotherapy</i> <i>Journal of Counseling Psychology</i> <i>Psychology of Sexual Orientation and Gender Diversity</i>	9/2016 12/2017 12/2017

#### 2/2016-current

8/2015 - 5/2016

#### **Editorial Board**

Archives of Sexual Behavior *Psychology of Sexual Orientation and Gender Diversity* International Journal of Transgenderism

1/2016 – current 1/2016 - current Ad Hoc Reviewer: Journal of Consulting and Clinical Psychology, Clinical Psychology Review, Journal of Counseling Psychology, The Counseling Psychologist, Feminism and Psychology,

Psychology of Religion and Spirituality, Psychology of Women Quarterly, Journal of GLBT Family Issues, BioMed Central Journal, The Cognitive Behavior Therapist, Psychotherapy Research, Routledge Publishers, Harvard University Press, Family Process

#### Leadership in Professional Organizations

#### **Co-Chair of Science Committee**

8/2011 - current

1/2014 - 12/2016

Society for the Psychological Study of Lesbian, Gay, Bisexual, and Transgender Issues (Division 44)

#### **Membership in Professional Organizations**

American Psychological Association (APA)

- Society of Counseling Psychology (Division 17)
- Division of Psychotherapy (Division 29)
- Society for the Psychology of Women (Division 35)
- Society for the Psychological Study of Lesbian, Gay, Bisexual, and Transgender Issues (Division 44)
- Society of Clinical Child and Adolescent Psychology (Division 53) •

World Professional Association for Transgender Health (WPATH) Society for Psychotherapy Research (SPR)

#### **UNIVERSITY SERVICE**

University Committee Faculty Senate (alternate) Attended 2 faculty senate meetings GLBTQ Committee	5/2016 – current 5/2017 - current
School of Education Committee Information Technology Policy Advisory Committee	8/2014 – current
<b>Department Committee</b> Doctoral Training Committee Doctoral Admissions Chair	8/2015 – current 8/2017 - current

Social Justice Committee (chair) Salary and Promotion Committee Masters Training Committee 8/2016 - current 8/2016 - current 8/2014 - 8/2015

#### **Doctoral Dissertation Committees**

Kinton Rossman (University of Louisville; Chair, Defended) Danielle Alexander (University of Louisville; Chair) Jayden Thai (University of Louisville; Proposed) Jake Nienhuis (University of Louisville; Defended) Kelley Quirk (University of Louisville; Defended) Keldric Thomas (University of Louisville; Defended) Johanna Strokoff (University of Louisville; Defended) Elise Romines (University of Louisville; Defended) Julia Benjamin (University of Wisconsin-Madison; Defended) Craig Hase (University of Wisconsin-Madison; Defended) Sarah McArdell Moore (University of Wisconsin-Madison, Defended) Noah Yulish (University of Wisconsin-Madison, Defended) Nick Frost (University of Wisconsin-Madison, Defended) Lindsey Houghton (University of Wisconsin-Madison, Proposed) Shufang Sun (University of Wisconsin-Madison, Defended) Joe Orovecz (University of Wisconsin-Madison, In preparation) Andrew Wislocki (University of Wisconsin-Madison, Proposed) Dustin Brockberg (University of Wisconsin-Madison, Proposed) Christo Raines (University of Wisconsin-Madison, Proposed) Alyssa Ramirez Stege (University of Wisconsin-Madison, Proposed)

#### **Undergraduate Thesis Committees**

Morgan Sinnard (University of Louisville; Chair, defended)

#### **Appendix B**

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# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

# ALINA BOYDEN and SHANNON ANDREWS,

Plaintiffs,

v.

Case No. 17-CV-264

STATE OF WISCONSIN DEPARTMENT OF EMPLOYEE TRUST FUNDS, et al.,

Defendants.

# EXPERT REPORT OF DR. LAWRENCE S. MAYER SUBMITTED ON BEHALF OF THE STATE DEFENDANTS

Lawrence S. Mayer, MD, MS, PhD 4 Via Corsica Dana Point, CA 92629 lsmmdphd@gmail.com

April 19th , 2018

While retained as a private consultant in this matter, I currently serve as a Visiting Fellow in Integrative Knowledge and Human Flourishing at Harvard University.

I have been asked to provide my opinion on the efficacy, safety, and optimality of hormonal and surgical interventions for the treatment of gender dysphoria.

#### **QUALIFICATIONS**

- I am a research physician, epidemiologist and biostatistician and one of the few physicians with training in clinical epidemiology and a M.S. and Ph.D. in Mathematics and Statistics.
- 2. I have served as a tenured (and nontenured) professor at major universities for over four decades. My professorial (and research) appointments have been at Arizona State University, Johns Hopkins University, The Ohio State University, The Mayo Clinic, Princeton, Stanford, University of Michigan, University of Pennsylvania, and Virginia Tech. I am currently a Visiting Fellow at Harvard University where my research focuses on the integration of the quantitative methods of the social sciences with more classical biostatistical and epidemiological methods.
- 3. My full-time and part-time appointments have been in 23 disciplines including statistics, biostatistics, epidemiology, public health, social methodology,

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psychiatry, mathematics, sociology, political science, economics and biomedical informatics. My primary focus has been on the intersection among biostatistics, medicine and public health.

- 4. I have reviewed as a biostatistician, epidemiologist, physician and social methodologist hundreds of manuscripts submitted for publication to many of the major medical, statistical and public health journals such as *The New England Journal of Medicine, The Journal of the American Statistical Association* and *The American Journal of Public Health.* I have served as an associate editor for *The Journal of the American Statistical Association* and *Social Methods and Research.* I am a founding member of the editorial board of the journal *Social Methodology* and the Sage series on Social Methodology.
- 5. I am a Fellow of the Royal Statistical Society
- 6. I attach a copy of my current Professional Vita, which lists my education, appointments, publications, research, and other professional experience.

#### SUMMARY OF OPINIONS

- 1. Sex is a biological trait and gender is a cultural construct.
- 2. Gender develops over time.
- 3. There is no evidence that gender is innate, immutable, or present at birth.
- 4. Gender dysphoria is the distress associated with incongruence between sex and gender.
- 5. Gender dysphoria is a serious medical condition that deserves treatment.

6. Medical and surgical treatments have not been demonstrated to be safe and effective for gender dysphoria.

#### **OPINIONS**

- Since the publication of Sexuality and Gender, Findings from the Biological, Psychological, and Social Sciences in Fall of 2016, which I co-authored, there have been no new publications which have changed my understanding of gender. Mayer and McHugh (2016). Scientific and other sources that support my current understanding of gender are cited in that publication.
- 2. Scientific findings since the publication of Sexuality and Gender have reinforced my understanding of gender. See, for example, Mueller (2017).
- Gender is almost uniformly defined as a cultural construct while sex is a biological trait. An excerpt from my Sexuality and Gender publication explains this idea in more detail:

To clarify what is meant by "gender" and "sex," we begin with a widely used definition, here quoted from a pamphlet published by the American Psychological Association (APA):

> Sex is assigned at birth, refers to one's biological status as either male or female, and is associated primarily with physical attributes such as chromosomes, hormone prevalence, and external and internal anatomy. Gender refers to the socially constructed roles, behaviors, activities, and attributes that a given society considers appropriate for boys and men or girls and women. These influence the ways that people act, interact, and feel about themselves.

While aspects of biological sex are similar across different cultures, aspects of gender may differ. This definition points to the obvious fact that there are social norms for men and women, norms that vary across different cultures and that are not simply determined by biology. But it goes further in holding that gender is wholly "socially constructed" — that it is detached from biological sex. This idea has been an important part of a feminist movement to reform or eliminate traditional gender roles. In the classic feminist book The Second Sex (1949), Simone de Beauvoir wrote that "one is not born, but becomes a woman." This notion is an early version of the now familiar distinction between sex as a biological designation and gender as a cultural construct: though one is born, as the APA explains, with the "chromosomes, hormone prevalence, and external and internal anatomy" of a female, one is socially conditioned to take on the "roles, behaviors, activities, and attributes" of a woman.

Mayer and McHugh (2016) at 87. I go on to explain that:

In biology, an organism is male or female if it is structured to perform one of the respective roles in reproduction. This definition does not require any arbitrary measurable or quantifiable physical characteristics or behaviors; it requires understanding the reproductive system and the reproduction process. Different animals have different reproductive systems, but sexual reproduction occurs when the sex cells from the male and female of the species come together to form newly fertilized embryos. It is these reproductive roles that provide the conceptual basis for the differentiation of animals into the biological categories of male and female. There is no other widely accepted biological classification for the sexes.

Mayer and McHugh (2016) at 90. I further explore this concept in my amicus brief for the *Gloucester County School Board v*. *G.G.* U.S. Supreme Court case, at page 7:

> Sex is thus innate and immutable. The genetic information directing development of male or female gonads and other primary sexual traits, which normally are encoded on chromosome pairs "XY" and "XX," are present immediately upon conception. As early as eight

weeks' gestation, endogenously produced sex hormones cause prenatal brain imprinting that ultimately influences postnatal behaviors. *See* Francisco I. Reyes et al., Studies on Human Sexual Development, 37 J. of Clin. Endocrinology & Metabolism 74-78 (1973); Michael Lombardo, Fetal Testosterone Influences Sexually Dimorphic Gray Matter in the Human Brain, 32 J. of Neuroscience 674-80 (2012); Geneva Foundation for Medical Education and Research, "Human Sexual Differentiation" (2016), *available at* http://www.gfmer.ch/Book&'Reproductive\_health/Huma n\_sexual\_differentiation.html. It is therefore not the reproductive system alone that carries one's sexual identity. Every cell in the body is marked with a sexual identity by its chromosomal constitution XX or XY.

Thus, sex is not "assigned" at birth, as Respondent suggests; rather, it "declares itself anatomically in utero and is acknowledged at birth." Michelle A. 8 Cretella, Gender Dysphoria in Children and Suppression of Debate, 21 J. of Am. Physicians & Surgeons 50, 51 (2016). A baby's sex – male or female – is recognized and recorded at birth.

4. Definitions of sex which include gender as a part of sex do not contribute to our

understanding of either sex or gender.

5. There is an emerging theory that gender identity is innate and immutable.

Components of this theory are described in the report of Dr. Budge. It makes no

sense.

6. For example, the following is a fundamental error in the Budge report:

Sex refers to one's classification as male, female, or neither male or female. The term refers a person's chromosomes, hormones, reproductive organs, secondary sex characteristics, *and gender identity (i.e., internal sense of gender)*.

Budge (2018) at 7 (emphasis added).

- 7. Beyond any doubt, sex is biological and, as such, cannot depend on cultural constructs.
- 8. Budge compounds her error by stating with emphasis:

[G]ender identity is one of the primary factors when defining an individual's sex.

Budge (2018) at 7.

- 9. Not only is this definition of sex inconsistent with fundamental biology as taught in every Biology 101 course across the country, but to say that a cultural construct ought to be the "primary factor" in the definition of a biological concept is wholly inconsistent with basic scientific principles.
- 10. There is no evidence to support the idea that gender identity is a latent or innate trait present at birth. See, for example, Mayer, et al. Amicus Brief (2017) at 10 n.4.
- 11. The formation of gender identity is a developmental process. Budge's report suggests that gender identity is a process of discovery of a latent variable, present at birth, and revealed around the age of three, rather than developed over time. There is not a scintilla of scientific support for this idea.
- 12. Gender dysphoria is the distress associated with an individual's identification with a non-conforming gender. It is not the same as being transgendered.
- 13. Transgenderism is not a disease, disorder, or diagnosis. As such it cannot be treated. Many fought long and hard to remove the diagnosis of Gender Identity Disorder as a diagnosis for all transgendered people.

- 14. Transgenderism is neither necessary nor sufficient for a diagnosis of gender dysphoria.
- 15. There is evidence that transgender individuals may benefit from supportive measures but these measures cannot be viewed as "treatments" for being transgendered.
- 16. Gender dysphoria, unlike transgenderism, is a serious medical condition that deserves to be treated.
- 17. Treatment for gender dysphoria must be borne of medical necessity and address the medically relevant portion of this condition, which is *distress* associated with the conflict between an individual's gender and their sex.
- 18. Treatment interventions on behalf of gender dysphoric individuals must be held to the same scientific standards as other medical treatments. These interventions must be optimal, efficacious, and safe.
- 19. Any treatment which alters biological development must be used with extreme caution.
- 20. A variety of medical and surgical procedures have been proposed for treating gender dysphoria.
- 21. The evidence that these interventions are safe, effective, and optimal is minimal. The bases for this opinion with respect to both children and adults, along with the studies on which this opinion relies, can be found in both my Sexuality and Gender publication and my amicus brief. Mayer and McHugh (2016) at 106–13; Mayer, et al. Amicus Brief (2017) at 15–21. This opinion is supported by the

Centers for Medicare and Medicaid Services (Decision Memo for Gender Dysphoria and Gender Reassignment Surgery) which reviews many available studies and found "inconclusive" clinical evidence regarding gender reassignment surgery.

- 22. Optimality requires that the procedures employed in the treatment of a condition effectively address the underlying features of that condition. For transgendered patients, the idea that they require treatment for being transgendered is dated, offensive, and mistaken.
- 23. Optimality considerations for the treatment of gender dysphoria, the distress associated with have a non-conforming gender, should aim at reducing or eliminating this distress.
- 24. In body dysmorphic disorders, such as anorexia nervosa, we do not give patients interventions to alter their physical appearance. We treat the distress caused by the conflict between their perception of themselves and the reality of themselves. In other words, treatment of the <u>distress associated with the disorder</u> is what is medically appropriate and medically necessary.
- 25. If we disregard the principle of optimality, problems of equity arise: If a transgendered woman is entitled to feminization procedures to reduce her distress, surely a cis-gendered woman, similarly distressed, should be entitled to the same procedure.
- 26. Neither patient as presented above is entitled to the procedure as a medical necessity.

- 27. It is particularly difficult for me to imagine a world in which we might favor one category of person over another when considering the allocation of medical resources as a public good.
- 28. Suppose identical twins are both bothered by the masculinity of their face. However, the twins differ in their gender identity. If we accept treatment suggestions as proposed by Budge, one but not the other would be entitled to surgery. Why should one twin be treated but the other not, when neither twin presents a medical necessity for treatment?
- 29. Furthermore, since feminization or masculinization of transgender individuals is defined by concepts of femininity or masculinity which are cultural constructs, then the treatments for these individuals varies by culture.
- 30. Suppose in a particular society small hands is part of the archetypal female gender. Would a transgendered woman in that society be entitled to hand reduction surgery? What if she moves to a different culture?
- 31. Since gender affirming medical and surgical procedures depend on cultural values, the medical necessity of these interventions would vary depending upon the cultural traits of an individual, in a given place, at a given time.
- 32. Suppose a transgendered woman chooses, after a period of time, to adopt a male gender identity. Would she be entitled to surgery to re-masculinize her face?
- 33. According to Budge, transgender women are women from birth and are entitled to procedures that reduce the impact of biology on their development as a transgendered person.

34. According to the ideas presented in Budge's report not only does culture dominate biology, but biology is interpreted as being dependent upon culture. In essence, who you believe you are is more important than who you are.

#### **CONCLUSION**

Sex is a biological trait while gender is a cultural construct that develops over time and varies across cultures. There is no evidence that gender is innate, immutable, or present at birth. Some patients develop gender dysphoria, a serious condition that deserves treatment. There is little evidence that medical and surgical interventions reduce the incidence and prevalence of gender dysphoria. There is even less evidence that they would be cost effective compared to social and psychological interventions.

Lawrence S. Mayer, MD, MS, PhD

Date

# **Appendix A: Testimony in Last Four Years**

1. Court Appearances:

*Elenza, Inc. v. Alcon Laboratories*, Superior Court of the State of Delaware, No. N14-03-185 MMJ CCLD, May 8, 2017

2. Depositions:

*Sowards v. Las Cruces Medical Center*, Third Judicial District Court, County of Dona Ana, State of New Mexico, no. D-307-CV-2009-02563, July 15, 2014

*Hilverding v. Steptodont, Inc. and Novocol Pharmaceutical of Canada, Inc.*, Court of Fulton County, State of Georgia, No. 13EV018074B, January 15, 2015

*Hilverding v. Steptodont, Inc. and Novocol Pharmaceutical of Canada, Inc.*, State Court of Fulton County, State of Georgia, No. 13EV018074B, February 10, 2015 in

Prelas v. Mercedes Benz, USA, LLC, Circuit Court, Boone County, State of Missouri, O9BA-CV2409, April 17, 2015

*Hilverding v. Septodont, et al.*, State Court of Fulton County, State of Georgia, Civil Action NO. 13EV018074B, August 31, 2015

*Hyoung v. Target Corporation*, Los Angeles County Superior Court, State of California, No. NC0580059, January, 6 2016

*Environmental Research Center Aloe Vera of America*, San Francisco County Superior Court, State of California, January 20, 2016

*Elenza, Inc v. Alcon Laboratories*, Superior Court of the State of Delaware, No. N14-03-185 MMJ CCLD, October 25, 2016

*Ball v. Bukeirat*, Circuit Court of Monongalia County, West Virginia, CA 14-C-37, November 4, 2016

*Cheney v. Falcon Safety Products*, Circuit Court of the 15th Judicial Court, Palm Beach County, FL, NO: 02013CA007140XXXMBAN, December 27, 2017

### **Appendix B: Professional Vita**

# LAWRENCE S. MAYER, MD, MS, PhD

Professional Vita

#### February 2018

Primary interests: The biostatistical foundations, methods and interpretations used in the analysis of epidemiological and social science data. Development implementation and evaluation of statistical methods for assessing health effects of preventive interventions and environmental exposures including life-style variables. Analysis of statistical and epidemiological issues arising from applying evidence-based medicine in a clinical or policy environment. Analysis of the statistical issues arising from applying epidemiological models in the diagnosis, treatment, and prognosis of disease. Particularly interested in the intersections among social methodology, biostatistics and epidemiology.

#### Address:

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### **Previous Offices:**

Johns Hopkins Medicine Department of Psychiatry 5300 Alpha Commons Drive Baltimore, MD 21224-2764 410-336-2100

Mayo Clinic Samuel C. Johnson Research Building 13212 East Shea Boulevard Scottsdale, AZ 85259 480-884-0221

Arizona State University Department of Economics Tempe, AZ 85258 480-965-6528

# **Current Position:**

Visiting Fellow, Harvard University

# **Education:**

Undergraduate: Arizona State University (1963-64) and Ohio State University: Psychology (Pre-med), BS, 1967, Phi Beta Kappa, *magna cum laude* with distinction in psychology. President's award for outstanding graduate.

Professional: Ohio State University College of Medicine (pre-clinical), dual enrollment, 1966-68; Guy's Hospital Medical School, London, MB (British MD), 1969; Junior House Officer, Associated Medical Schools, British Virgin Islands 1969-1970, MD qualified to practice as a Public Health Physician (psychiatric epidemiologist), British Health Service, 1970

Graduate: Ohio State University, Mathematics, MS, 1969; Mathematics (Statistics and Biostatistics); PhD, 1971

Honorary: MA in Arts and Letters, honoris causa, University of Pennsylvania, 1981

# **Previous Appointments:**

Scholar in Residence, Department of Psychiatry, Johns Hopkins School of Medicine, 2016-2017

Professor of Statistics, Biostatistics, and Economics, Arizona State University, 1995-

(Affiliate) Professor, Mayo Clinic/ASU Program in Biomedical Informatics, 2008-2017

Professor of Psychiatry and Public Health (Part-time), School of Medicine and Bloomberg School of Public Health, Johns Hopkins University, 1989-2016

Detective (Fully Sworn), District (County) Attorney's Office, Maricopa County, Arizona 1998-2016 (retired) and State Resource Officer (Fully Sworn), State of Arizona, 1983-1998

Professor of Epidemiology, College of Public Health, University of Arizona, 2000-2016

Research Staff Member, Mayo Clinic, 2014-2016

Consultant in Psychiatric Epidemiology, Banner Alzheimer's Institute, Phoenix, 2003-2016

Chief, Epidemiology and Biostatistics Section, Integrated Fellowship in Cardiology, Phoenix, 1998-2016

Faculty Member, Medical Education, Banner Good Samaritan Medical Center, Phoenix, 1993-2016

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Visiting Professor, Division of Neuropsychiatry, Department of Psychiatry, Johns Hopkins Medicine, 2003-2004

Visiting Professor, Department of Biostatistics, Johns Hopkins School of Public Health, 1996-1997, 1989-1990

Director of Research, Maricopa Integrated Health System, 2003-2006

System Director, Research and Director and Medical Director of the Banner Health Research Institute, Banner Health System, Phoenix, 2001-2003

Director, Wharton Analysis Center, Wharton School; Associate Professor of Statistics, Public and Urban Policy, and Epidemiology, University of Pennsylvania, 1979-1983

Visiting Professor, Department of Statistics, Stanford University, 1982-1983

Research Statistician and Lecturer with Rank of Associate Professor, Department of Statistics; Member, Center for Energy and Environmental Studies; Associate Master and Fellow, Princeton Inn College; Instructor, Woodrow Wilson School of Public Affairs; Princeton University, 1974-1979

Assistant Professor of Statistics (with secondary appointments in Political Science, Sociology, and Education) Virginia Polytechnic Institute and State University, 1971-1974

Assistant Professor, Department of Political Science, The Ohio State University, 1971

Teaching Assistant, Department of Mathematics, The Ohio State University, 1967-1968

Visiting Scholar, Department of Statistics, Stanford University, Summer Semesters, 1984-1988

Instructor, Summer Programs, Inter-University Consortium for Political and Social Research, Institute for Social Research, University of Michigan, 1971-1980

#### **Other Major Appointments:**

Clinical Professor, College of Medicine, University of Arizona, 1997-2006

Chair, Division of Research, Medical Professionals of Arizona, Phoenix, 2003-2006

Director, Good Samaritan Research Institute, Phoenix, 1999-2001

Consultant in Biostatistics and Clinical Epidemiology, Good Samaritan Medical

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Center, Phoenix, 1993-2000

Thesis Advisor, Masters in Public Health, School of Public Health, University of Arizona, 1996-1998

Member, Committee on Statistics, Graduate College, Arizona State University, 1989-2004

Member, Program on Law and the Social Sciences, Arizona State University, 1983-2004

Member, Committee on Malpractice Reform, Arizona Supreme Court, 1989-1993

Erskine Fellow, Occupational Medicine, University of Canterbury, Christchurch, New Zealand, 1989-90

### Scholarly Publications:

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Hoyer, R.W. and Mayer, L.S. (1974). "Comparing Strategies in a Spatial Model of Electoral Competition," <u>American Journal of Political Science</u>, 18, 501-523

Bush, W. and Mayer, L.S. (1974). "Some Implications of Anarchy for the Distribution of Property," <u>Journal of Economic Theory</u>, 4, 401-411

Mayer, L.S., Singh, J. and Willke, T.A. (1974). "Utilizing Initial Estimates in Estimating the Coefficients in a Linear Model," <u>Journal of the American Statistical Association</u>, 69, 219-222

Mayer, L.S. and Younger, M.S. (1974). "Procedures for Estimating Standardized Regression Coefficients from Sample Data," <u>Sociological Methods and Research</u>, 1, 431-453

Mayer, L.S. and Good, I.J. (1974). "On Ordinal Prediction Problems," <u>Social Forces</u>, 52 (4), 543-549

Mayer, L.S. (1974). "On the Use of Non-Random Exogenous Variables in Path Analysis," <u>American Sociological Review</u>, 39, 891-893

Klemmack, D.L., Leggette, T.A. and Mayer, L.S. (1973). "Non-Random Exogenous Variables in Path Analysis," <u>American Sociological Review</u>, 38 (December), 778-784

Mayer, L.S. and Hendrickson, A. (1973). "A Method for Constructing an Optimal Regression Design After an Initial Set of Input Values Has Been Selected," <u>Communications in Statistics</u>, 2(5), 465-477

Mayer, L.S. and Willke, T.A. (1973). "On Biased Estimation in Linear Models," <u>Technometrics</u>, 15, 497-508

Mayer, L.S. (1973). "Estimating a Correlation Coefficient When One Variable is Not Directly Observed," Journal of the American Statistical Association, 68, 420-421

Burgess, P.M. and Mayer, L.S. (1973). "Simulation and Society, A Review Essay," Journal of Regional Science, 12, 303-311

Good, I.J. and Mayer, L.S. (1973). "On Surfaces of Constant Societal Loss in a Model of Social Choice," <u>Journal of Mathematical Sociology</u>, 2, 209-219

Mayer, L.S. (1972). "Using Monotone Regression to Estimate a Correlation Coefficient," <u>Sociological Methodology</u>, (Herbert Costner, ed.), Jossey-Bass: San Francisco, 200-212

Mayer, L.S. (1972). "An Analysis of Measures of Crosscutting and Fragmentation," <u>Comparative Politics</u>, 4, 405-415

Mayer, L.S. (1971). "Comment on 'The Assignment of Numbers to Rank Order Categories'," <u>American Sociological Review</u>, 35, 916-917

Mayer, L.S. (1971). "A Note on Treating Ordinal Data as Interval Data," <u>American</u> <u>Sociological Review</u>, 36, 519-520

Mayer, L.S. (1971). "A Note on An Axiomatic Model of Voting Bodies," <u>American Political</u> <u>Science Review</u>, 65, 764-65

Mayer. L.S. (1971). "A Method of Cluster Analysis When There Exists Multiple Indicators of a Theoretic Concept," <u>Biometrics</u>, 27, 143-155

Mayer, L.S. (1971). "A Comment on 'A Theorem on Voting'," <u>American Political Science</u> <u>Review</u>, 65, 779-780

# **Research Monographs:**

<u>Energy Consumption Measurement: Data Needs for Public Policy</u>, (1977) Committee on Measurement of Energy Consumption, Washington: National Academy of Science

Mayer, L.S. (1976). <u>An Analysis of Alternative Voter Registration Systems</u>, <u>Modules in</u> <u>Applied Mathematics</u>, Washington: Mathematical Association of America

#### **Chapters in Research Monographs:**

Mayer, L. S. (1994) "On Cross-Lagged Panel Studies with Serially Correlated Errors," <u>Frontiers in Econometrics</u>, G. Maddala (ed), 154-165

Mayer, L.S. (1980). "The Effects of Price on Energy Demand: Econometrics Versus Exploratory Data Analysis," in <u>Evaluation of Econometric Models</u> (J. Kmenta and J. Ramsey, eds.), Academic Press, 15-45

Mayer, L.S. and Benjamin, Y. (1980). "Modelling Residential Demand for Natural Gas as a Function of the Coldness of the Month," in <u>Saving Energy in the Home</u>, (R. Socolow, ed.) New York: Ballinger

Bush, W. and Mayer, L.S. (1976). "On the Economics of Human Fertility," in <u>Essays on</u> <u>Unorthodox Economic Strategies: Anarchy, Politics and Population</u>, (A.T. Denzau and R.J. Mackay, eds.), University Publications, 163-181

Mayer, L.S. (1974). "Optimal Voting Behavior in a Two-Party Primary", in <u>Applications</u> of <u>Mathematics in Political Science</u>, Vol. VIII, (J. Herndon and J. Bernd, eds.), Charlottesville: University of Virginia Press, 4-14

### Published Book Reviews

On the Verge: The Legal Fight of Travellers in England for their Rights (many authors), <u>Romani Studies</u>, 2001, 144-146

Firms and Markets (C. Tucker and R. Fuller, eds.), Perspective, Winter, 1988, 41

Social Science and Social Policy (R. Shotland and M. Mark, eds.), Perspective, April, 1986, 60

<u>Principles of Epidemiology</u> (Kleinbaum, Kupper and Morgenstern) <u>Journal of the</u> <u>American Statistical Association</u>, July/August 1984, 108

U.S. Interests and Global Natural Resources (Castle and Price, eds.), <u>Perspective</u>, September, 1984, 725-726

Proximity and Preference: Problems in the Multidimensional Analysis of Large Data

#### Case: 3:17-cv-00264-wmc Document #: 90-2 Filed: 06/06/18 Page 13 of 37

Sets (R. Golledge and J. Raynor, eds.), <u>Journal of the American Statistical Association</u>, September, 1983, 78, 734

Statistical Applications in the Spatial Sciences (N. Wrigley, ed.), <u>Journal of the</u> <u>American Statistical Association</u>, June, 1983, 78, 509-510

Power, Voting, and Voting Power (Manfred J. Holler, ed.), Perspective, February, 1983

Exploratory Data Analysis (J. Tukey), <u>Evaluation and Program Planning</u>, 1981, 4, 195-196

On the Social Use of Information (A. Wissel), Perspective, June, 1977, Vol. 6, No. 5

Simulation Model Building: A Statistical Approach to Modeling in the Social Sciences With The Simulation Method (U. Norlen), <u>Perspective</u>, March 1977, Vol. 6, No. 2

Research Methods in the Social Sciences (D. Nachimas and C. Nachimas), <u>Perspective</u>, November 1976, Vol. 5, No. 9

Registering Voters by Mail: The Maryland and New Jersey Experience (R. Smolka), <u>Perspective</u>, October 1975, Vol. 4, No. 8

# **Other Professional Activities:**

Guest Lecture, Statistics and Epidemiology in Court, University of Maryland Law School, March, 2012

Editorial Board Member, Journal of Cardiology Research, 2003-

Member, Development Board, Copper Ridge Institute, Sykesville, MD, 1998-2000

Member, Expert Panel, Sexually Transmitted Disease and Teens, W. T. Grant Foundation, 2000-2001

Advisor, Sexually Transmitted Diseases & the Internet, American Social Health Association, 2000-2001

Invited Member, Panel on Mental Health Problems of Asylum Seekers, University of Greenwich, July 2000

Invited participant, Expert Panel on Mortality Associated with Alternative Fuels, Department of Energy, Carmel, May, 2000

Chief, Epidemiology and Biostatistics Branch, Phoenix Integrated Residency in Cardiology, 1999-

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Clinical Professor, Prevention Center, College of Medicine, University of Arizona, 1999-

Member, Faculty of the Psychiatry Residency Program, Good Samaritan, 1998 -

Member of the Board of Directors, Palms Clinic, Phoenix, 1998-

Invited Participant, US Environmental Protection Agency Expert Panel on Cryptosporidium, October, 1998

Member, Evaluation Panel, Graduate Programs, University of Greenwich, London, August, 1998

Expert Witness, Appropriations Hearing on NIH Budget, US Senate, October, 1997-

Member, Expert Review Committee on Grant Applications and Awards, Health Care and Promotion Fund, Hong Kong, 1996-1998

Member, Clinical Committee, Health Services Advisory Group, Arizona, [the arm of the Medicare system that advises Medicare on reimbursements], 1994-1996

Alternate Member, Institutional Review Board, Samaritan Health Systems 1994-2001

Invited Attendee, Workshop on Psychosocial Research, American Psychiatric Association, Massachusetts General Hospital, Boston, October, 1996

Invited Attendee, Risk Estimation Conference, Environmental Protection Agency, Durham, North Carolina, September, 1996

Invited Attendee, Society for Prevention Research, Annual Conference, Puerto Rico, May, 1996

Proposal Evaluation Site Visit, Raptor Research Center, Boise State University, March 1996

Workshop Attendee, The Epidemiology of Avian Mortality, California Energy Commission, Sacramento, California, January, 1996

Invited Attendee, Prevention Science and Methodology Conference, Baltimore, MD, October, 1995

Invited Attendee, Avian Windpower Planning Meeting, Palm Springs, September, 1995

Invited Attendee, US Department of Energy Course on Risk Assessment, Boulder, July 1995

Invited Attendee, Mini-conference on Measuring Health Outcomes, Phoenix, March

1995

Invited Attendee, Private Conference on Wind Energy Research, California Energy Commission, Grand Island, California, December, 1994

Invited Participant, Workshop on Prevention Methodology, University of South Florida, Baltimore, December, 1994

Invited Participant, National Conference on Prevention Research, Washington, DC, December, 1994

Invited Consultant, California Energy Commission, Flagstaff, Arizona, November, 1994

Invited Participant, Workshop on the Science of Prevention, NIMH, Baltimore, December, 1994

Invited Participant, Meeting on Renewable Energy, California Energy Commission, Flagstaff, Arizona, November, 1994

Invited Participant, Workshop on Prevention Methodology, Oregon Social Learning Center, Eugene Oregon, August, 1994

Invited Technical Advisor, National Planning Meeting on Wind Power and Avian Mortality, Lakewood, CO, July, 1994

Invited Participant, Workshop on Biostatistical Methods in Preventive Mental Health Research, College of Public Health, University of South Florida, Tampa, March, 1994

Invited Participant, Biomedical Effects of Renewable Energy, Invited Conference, US Department of Energy, Washington, DC February, 1994

Member, Special Study Section, National Institute of Health, 1993-

Invited Participant, Avian Mortality Taskforce Meeting, October, Pleasonton, CA, December, 1993

Invited Participant, Conference on Avian Mortality and Wind Energy, Pacific Gas and Electric, Livermore, CA, October, 1993

Invited Participant, Prevention Center Directors Meeting, National Institute of Mental Health, Tysons Corner, September, 1993

Invited Participant, National Conference on Prevention Research, McLean, Virginia, April, 1993.

Invited Participant, Prevention Center Directors Meeting, National Institute of Mental

Health, Rockville, September, 1992

Invited Participant, Prevention Center Directors Meeting, National Institute of Mental Health, Rockville, September, 1991

Invited Participant, Conference on the Future of Prevention Research, National Institute of Mental Health, Washington, DC, July, 1991

Invited Participant, Workshop on Development of Delinquency, National Academy of Science, Woods Hole Study Center, July, 1991

Invited Participant, Workshop on Preventive Research, National Institute of Mental Health, October, 1990

Invited Lecturer, Exploratory Data Analysis, The Bootstrap and Panel Models in Occupational Medicine, lecture series, College of Business Administration, University of Canterbury, Christchurch, New Zealand, September - October, 1989

Invited Host, Mini-conference on The Epidemiology of Bladder Cancer, August, 1988, Lenox, Massachusetts

Expert Witness, Department of Public Health, Commonwealth of Massachusetts, July, 1988

Expert Witness, Department of Labor and Industry, Commonwealth of Massachusetts, July, 1988

Invited Participant, Workshop in Multidimensional Analysis, Information Theory and Asymptotic Methods, Stanford University, July 1983

Assisted in Preparation and Coordination, Conference on Science and Technology in the Soviet Union, Stanford University, July, 1983

Session Organizer, International Conference on Energy Use Management, Berlin, October, 1981

Member, Committee on Industrial Use of Solar Energy, Solar Energy Research Institute, Golden, Colorado, 1979-1981

Press Conference on Wharton's Support to Litigation Project Award, April, 1981, Philadelphia

Invited Participant, Workshop on Model Validation, Department of Economics, New York University, April, 1980.

Expert Witness, Hearings on Energy Tax Exemptions, Energy Committee, Pennsylvania State Assembly, April, 1980

Lecturer, Workshop in Environmental Policy, Florida Atlantic University, March, 1980

Interviewed on Feasibility of Philadelphia's Refinery Tax Proposal, WUSL Radio, Philadelphia, November, 1980

Member, Committee on Health Manpower Training, Department of Health, New Jersey, 1976-79.

Interviewed on Model Validation, WPEN Radio, Philadelphia, November, 1979.

Interviewed on Value of Energy Forecasts, Philadelphia Inquirer, October, 1979.

Invited Panelist, Panel on Energy Models in Energy Policy-making, Program in Science Technology and Public Policy, George Washington University, Washington, D.C., October, 1979

Organizer, Workshop on Resource Estimation, Department of Energy Statistical Symposium, Gatlinburg, Tennessee, October, 1979

Session Chairperson, Special Topics Meetings on Regression, Institute of Mathematical Statistics, October, 1979

Invited Participant, Workshop on the Measurement and Interpretation of Model Confidence, National Bureau of Standards, U.S. Department of Commerce, Washington, D.C., October, 1979

Invited Participant, Workshop on Measuring Model Confidence, National Bureau of Standards, Gaithersburg, MD, October 1979

Expert Witness, Hearings on State Health Benefits, Ohio State Assembly, February, 1979

Member, Committee on Model Evaluation, General Accounting Office, United States Congress, 1977-1978.

Participant, Workshop on Assessment of Energy Models, Massachusetts Institute of Technology, October, 1978.

Organizer, Session on Multivariate Statistics, Annual Meeting, Institute of Mathematical Statistics, August, 1978

Lecturer, Program on Environmental Management, Florida Atlantic University, April, 1978

Expert Witness, Hearings on Local Energy Policies, Subcommittee on Energy and Power, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, May, 1978

Invited Panelist, Policy Workshop on Energy Policy, Swarthmore College, March, 1978

Chairperson, Committee on Membership, Institute of Mathematical Statistics, 1974-78

Invited Participant, Workshop on Energy Information, Stanford University, December 1977

Invited Participant, Conference on Criteria for Evaluation of Econometric Models, University of Michigan, June 1977

Expert Witness, Hearings on Health Impacts of Energy Conservation, Commerce Committee, US House Representatives, April, 1977

Conference Chair, Conference on the Analysis of Large Data Sets, Institute of Mathematical Statistics and American Statistical Association, Dallas, February 1977

Panelist, Seminars on Models and Energy Policy, Program in Public Policy, George Washington University, February, 1977

Invited Participant, Workshop on Stochastic Models of Social Structure Carnegie-Mellon University, MSSB Workshop, Pittsburgh, December, 1977

Interviewed on Energy Policy, West Virginia Public Television Network, October, 1976

Member, Committee on Measurement of Energy Consumption, National Academy of Sciences, 1975-76

Interviewed on Energy Policy, West Virginia Public Television Network, October, 1976

Participant, Workshop on Model Building, Mathematical Association of America, Cornell University, August, 1976

Organizer and Chair, Session on Voting Models, Annual Meeting of the Public Choice Society, Roanoke, VA, April, 1976

Instructor, Short Course on Advances in Data Analysis, Princeton University, April, 1976

Member, Organizing Committee, Annual Convention, Institute of Mathematical Statistics, 1975-76

Member, Site Review Committee, University of Texas, San Antonio, National Science Foundation, 1975

Participant, Workshop on Validation of Econometric Models, National Science Foundation, Vail, Colorado, June, 1975

Participant, Workshop on Decentralization Theory, National Science Foundation, Princeton University, March, 1975

Member of the Council, Polymetrics Section, International Studies Association, 1973-75

Member, Committee on Education of Gifted Children, Department of Education, Virginia, 1973-74

Member, Committee on Health Training, State Council of Higher Education, Virginia, 1973-74

Instructor, Workshop on Survey Research, University of Cologne, Cologne, West Germany, 1973

Lecturer, Institute on Model Building, National Science Foundation, Blacksburg, Virginia, August, 1973

Clinical Assistant [Clinical Rotations], Associated Medical Schools, British Virgin Islands, 1969-1970

Summer Fellow, College of Medicine, University of Michigan, Summer, 1970

# Major Consulting Appointments (Other than Public and Non-profit):

Play an active advisory role to several CEO's, corporate medical directors, courts, boards, and non-profits on specific health issues, which are confidential, private, proprietary or privileged. I would be glad to discuss these activities in an executive session. They are not appropriate for open documentation.

# Major Consulting Appointments (Public and Non-profit):

Consultant in Research Compliance, Maricopa Integrated Medical System, 2002-2003

Consultant, California Energy Commission, 1994-2002

Consultant, National Renewable Energy Laboratory, 1992-1996

Consultant, Department of Mental Hygiene, Johns Hopkins Medical Institutions, June-August, 1990 -1993

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Consultant, Program on Delinquency, Child and Maternal Health, Harvard School of Public Health, 1991.

Consultant, Committee on the Courts, Arizona Supreme Court, 1988-1989.

Consultant, Bonneville Power Authority, 1986-1988.

Consultant, Special Counsel, Department of Energy, 1979-82.

Consultant, National Governors Association, 1979-81

Consultant, Environmental Monitoring Project, Environmental Protection Agency, 1979

Consultant, Energy Office, State of New York, 1976-78

Consultant, Department of Health, City of New York, 1976-78

Consultant, Center for the Study of Emergency Health Services, University of Pennsylvania, 1977

Consultant, Chancellor, The University of Missouri, 1976

Consultant, National Commission on Water Quality, 1974-76

Consultant, Trout Unlimited, 1976

Consultant, Policy Analysis Division, Department of Housing and Urban Development, 1974

Consultant, Department of Political Science, Ohio State University, 1974

Consultant, Committee on State Employee Benefits, Assembly of the State of Ohio, 1973

Consultant, Department of Preventive Medicine, Ohio State University, 1972-73

### **Editorial Service:**

Abstract Review Board, Annual Meeting, Society for General Internal Medicine, 1995

Member, Editorial Board, <u>Sociological Methodology</u>, Publication of the American Sociological Association, 1979-1983

Associate Editor, Series on Social Methodology, Sage Publications, 1974-81

Member, Editorial Board, Journal of Politics, 1974-81

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Associate Editor, Journal of the American Statistical Association, 1977-79

Abstracter, Executive Sciences Incorporated, 1974-79

Abstracter, Mathematical Reviews, 1974-76

Proposal reviewer for a variety of public agencies. In 1991-93 reviewed proposals for NIH, NIMH, NSF, DOE, EPA and others

Manuscript reviewer for several publishers including John Wiley and Sons and Wadsworth

### Honors and Awards:

Listed in the International Who's Who in Medicine, 1997-

Listed in Who's Who in Medicine, 1994-

Honorary Member, Phi Beta Phi, Honorary Society, inducted 1991

Distinguished Research Professor, Arizona State University, 1987-88

Fellow, Royal Statistical Society, elected November, 1984.

Listed in Who's Who in the West, 1983-

Listed in Who's Who in Medical Research, 1982-

Listed in Personalities in America, 1981-

Listed in Distinguished Educators, 1982-

Member, Phi Beta Kappa, inducted 1967

Member, Alpha Iota Delta (Decision Science Honorary Society), elected 1986

Distinguished Alumni Award, Ohio State University, 1971

Awardee, Graduate Scholarship, National Science Foundation, 1967

Recipient, President's Scholarship Award, Ohio State University, 1968

Recipient, President's Scholarship Award, Ohio State University, 1967

### **Research Grants and Contracts:**

Co-Principal Investigator, Alzheimer's Disease and Anti-Inflammatory Prevention: Is Elevated Serum Cholesterol Predictive of Developing AD?, D. Larry Sparks, PI, Institute for the Study of Aging, funded, March 2001, 360,000

Biostatistical Problems in Research Methodology, Samaritan Health Services, Principal Investigator: L.S. Mayer, 1996-2003, approximate award 450,000

Statistical Problems in Developing Intermediate Outcome Models of the Role of Apolipoprotein E in Alzheimer's Disease, Office of Research, Arizona State University, 1994-95, approximate award 20,000.

Biostatistical Problems in Research Methodology, Samaritan Health Services, Principal Investigator: L.S. Mayer, 1995-96, approximate award 26,000

Co-Principal Investigator, Prevention Research Training Grant, awarded by the Prevention Branch, National Institute of Mental Health, to the Prevention Center, Department of Mental Hygiene, Johns Hopkins School of Hygiene and Public Health. Principal Investigator: S. G. Kellam, 1994-1999, approximate award 500,000

Co-Principal Investigator, Epidemiological Prevention Center for Early Risk Behavior, awarded by the Prevention Branch, National Institute of Mental Health, to the Prevention Center, Department of Mental Hygiene, Johns Hopkins School of Hygiene and Public Health. Principal Investigator: S. G. Kellam, 1990-1995, approximate award, 5,000,000

Biostatistical Problems in Research Methodology, Samaritan Health Services, Principal Investigator: L.S. Mayer, 1994-95, approximate award 26,000

Biostatistical Problems in Research Methodology, Samaritan Health Services, Principal Investigator: L.S. Mayer, 1993-94, approximate award 25,000

Wharton Support to Litigation Project, awarded by the Office of the Special Counsel, Department of Energy to the Wharton Analysis Center, Wharton School, University of Pennsylvania. Principal Investigator: L.S. Mayer, 1981-83, approximate award: 2,200,000

Wharton Energy Allocation Project, awarded by the Department of Energy to the Wharton Analysis Center, Wharton School, University of Pennsylvania, Principal Investigator: L.S. Mayer, 1981-83, approximate award: 100,000

Wharton Energy Data Analysis Project, awarded by Oak Ridge National Laboratory to the Wharton Analysis Center, Wharton School, University of Pennsylvania, Principal Investigator: L.S. Mayer, 1980-81, approximate award: 450,000

Wharton Petroleum Data Analysis Project, awarded by CEXEC, Inc. to the Wharton Analysis Center, Wharton School, University of Pennsylvania, Principal Investigator:

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L.S. Mayer, 1980-81, approximate award: 100,000

Wharton Model Evaluation Project, awarded by the Energy Information Administration, Department of Energy to the Wharton Analysis Center, Wharton School, University of Pennsylvania, Principal Investigator: L.S. Mayer, 1979-81, approximate award: 900,000

Wharton Energy Assessment Project, awarded by Oak Ridge National Laboratory to the Wharton Analysis Center, Wharton School, University of Pennsylvania, Principal Investigator: L.S. Mayer, 1980-81, approximate award: 100,000

Princeton Resource Estimation and Validation Project, awarded by the Energy Information Administration, Department of Energy, to the Departments of Statistics and Geology, Princeton University, Principal Investigators: K. Deffeyes, G. Watson, and L. Mayer, 1978-79, approximate award: 450,000

Analysis of Residential Energy Demand, awarded by the Office of Conservation, Department of Energy to the Center for Energy and Environmental Studies, Princeton University, Principal Investigators: R. Socolow, D. Harrje, L. Mayer and F. Sinden, 1977-78, approximate award: 300,000

Analysis of Statistical Issues Arising from Energy Studies, awarded by the National Science Foundation to the Center for Energy and Environmental Studies, Princeton University, Principal Investigator: L.S. Mayer, 1977-78, approximate award: 50,000

Analysis of Residential Energy Demand, awarded by the Energy Research and Development Administration to the Center for Energy and Environmental Studies, Princeton University, Principal Investigators: R. Socolow, D. Harrje and L. Mayer, 1976-77, approximate award: 300,000

Assessing the Value of Econometric Energy Models, awarded by the Department of Commerce to the Center for Energy and Environmental Studies, Princeton University, Principal Investigator: L.S. Mayer, 1976-77, approximate award: 25,000

Energy Husbandry in Residential Housing, awarded by the National Science Foundation to the Center for Environmental Studies, Princeton University, Principal Investigators: R. Socolow, D. Harrje and L. Mayer, 1975-76, approximate award: 300,000

On Comparing Factor Matrices, awarded by the National Institute of Mental Health to the Department of Statistics, Princeton University, Principal Investigator: L.S. Mayer, 1974 - 1975, approximate award: 15,000

Measuring the Relationship Between Abstract Variables, awarded by the National Institute of Mental Health to the Department of Statistics, Virginia Polytechnic Institute and State University, Principal Investigator: L.S. Mayer, 1972-74, approximate award: 15,000

Component Analysis of Variance, awarded by the National Institute of Mental Health to the Behavioral Sciences Laboratory, Ohio State University and the Department of Statistics, Virginia Polytechnic Institute and State University, Principal Investigator: L.S. Mayer, 1971-72, approximate award: 15,000

### Papers Presented at Professional Meetings:

Depression in Assisted Living is Common and Related To Physical Burden, Gerontology Society Annual Meeting, Washington DC, November 2004

"Methodological Issues In Modeling The Incidence Of Alzheimer's Disease As A Function Of Age", World Congress of Epidemiology, Toronto, June, 2001

"Biostatistical Problems in Forecasting the Prevalence of Alzheimer's Disease" World Psychiatric Congress, Baltimore, March, 2001

"Using Latent Growth Models and Exploratory Methods to Assess the Relationship Between Responses in a Bivariate Prevention Model (with M. Reiser) Society for Prevention Research, Annual Meeting, Washington DC, May 1997

"Standard Metrics and Methods for Conducting Avian Wind Energy Interaction Studies (with R. Anderson) American Wind Energy Association Conference, Austin Texas, June, 1997

"A Randomized Clinical Trial of a Group Empowerment Program for Somatizing Patients: Six Months Follow-up Results", (with J. C. Peirce, A. Miller and J. Westley), invited lecture, Society for General Internal Medicine, Washington, DC, May 1997

"Measuring Effectiveness: Lessons from Heparinizing Patients with Deep Vein Thrombosis and Pulmonary Embolism" (with J. C. Peirce and R. A. Raschke), invited lecture, Society for General Internal Medicine, Washington, DC, May 1997

"Latent Growth Models of the Impact of Intervention on a Bivariate Longitudinal Response", invited lecture, Society for Research on Child Development, Washington, DC, March, 1997

"Developmental Epidemiology and its Implications for Prevention Research" invited lecture (with Sheppard Kellam), Life History Society Annual Meeting, London, December, 1996

"Standard Methods for Conducting Avian Mortality Studies", with R. L. Anderson, European Wind Energy Conference, Rome, October, 1996

"Using Multilevel Models to Tease Out Variability in Individual Behavior", invited lecture,

Association for Clinical Psychosocial Research, American Psychiatric Association, Boston, October, 1996

"Statistical Issues Arising from Application of the Proximal-Distal Model in Prevention Research, Society for Prevention Research, San Juan, Puerto Rico, June, 1996.

"Recent Advances in Prevention Methodology: Multilevel Models", invited lecture, Prevention Methodology Conference, Tempe, Arizona, May 1996

"Advances in the Methods of Prevention Research", invited lecture, National Forum on Prevention, McLean, VA, May, 1996

"Multilevel Models in Prevention Science", invited presentation, Prevention Science Methodology Group meeting, College of Public Health, University of South Florida, Tampa, March, 1996

"Prevented Fractions and Attributable Risk in Proximal Distal Prevention Models", invited lecture, College of Public Health, University of South Florida, Tampa, February, 1996

"Prevented Fractions and Attributable Risks in Preventive Trials", invited paper, Prevention Science and Methodology Conference, Baltimore, MD, October, 1995

"The Use of Epidemiological Measures to Estimate the Effects of Adverse Factors and Preventive Interventions", Workshop on Avian Mortality, Palm Springs, September, 1995

"The Use of Epidemiological Measures to Estimate the Effects of Adverse Factors and Preventive Interventions", invited presentation, Workshop on Avian Mortality and Avian Windpower Planning Meeting, Department of Energy, Palm Springs, September, 1995

"Methodological Advances in Prevention Research", with S. Kellam and J. Anthony, invited symposium, Prevention Research Society, Scottsdale Arizona, June 1995

"Multilevel Modeling and the Development of Aggressive Behavior", invited paper, World Psychiatric Association, New York, May, 1995

"Attributable Risk and Preventive Fractions in Prevention Research", invited lecture, Workshop on the Science of Prevention, NIMH, Baltimore, December, 1994

"Reduction of Aggressive Behavior Among First Graders and Its Consequences for Later Antisocial Behavior and Drug Use", with S. Kellam, H. Chilcoat, J. Anthony, G. Rebok, and N. Ialongo, invited lecture, Society for Prevention Research, Washington, June, 1994 "The Impact of Failure on Boys and Girls: Preventive Intervention Studies on Achievement and Depression" with S. Kellam, G. Rebok, and N. Ialongo, Society for Life History, Durham, November, 1993

"The Course and Malleability of Aggressive Behavior", with S. Kellam, G. Rebok, and N. Ialongo, invited lecture, American Society of Criminology, Annual Meeting, Phoenix, October, 1993

"Mediated Effects in Structural Equation Models", invited paper, American Statistical Association Annual Meeting, August, 1992

"The Course and Malleability of Aggressive Behavior in Young Children", invited presentation, with S. Kellam, et. al., National Academy of Science Institute of Medicine, Committee on Prevention of Mental Disorders, June, 1992

"Developmental Epidemiology and the course of Aggressive Behavior", Life Course Development Society, Philadelphia, April, 1992

"Modeling the Cotemporal Effects in a Cross-Lagged Panel Model", ASA Annual Meeting, New Orleans, August, 1988

"Estimating Multivariate Continuous Variable Panel Models", ASA Annual Meeting, San Francisco, August, 1987

"Inferences in Cross-Lagged Panel Models," invited paper, AIDS Convention, Phoenix, March, 1986

"Recent Advances in Cross-Lagged Panel Analysis," invited lecture, Southwest Social Science Convention, San Antonio, March, 1986

Hypothesis Testing with Continuous Variable Panel Data," Annual Meeting, Biometrics Society (WNAR), San Luis Obispo, June, 1985

"Multivariate Cross-Lagged Panel Models: Does IQ Cause Achievement?" invited lecture, Regional Meeting, Institute of Mathematical Statistics, Humboldt State University, Arcata, CA, June, 1983

"Analysis of the U.S. Short-Term Integrated (Energy) Forecasting System," invited lecture, International Energy Conference, Berlin, October 1981

"Assessing Energy Models: A Policy Process Approach," invited lecture, Workshop on Energy Model Validation, National Bureau of Standards, January 1979

"Energy Use and Potential for Conservation," (with David Harrje et al.), invited lecture, International Conference on Energy Use Management, Tucson, October 1977 "Large Data Sets and the Meta-Theorems of Exploratory Data Analysis," invited lecture, American Statistical Association, Special Topic Meeting, Dallas, 1977

"The Internalization of Cosmopolitan-Local Orientations Among College Students," (with W. Snizek), invited lecture, Southern Sociological Association, Washington, D.C., April 1975

"Equivalent Estimation and a Special Group Structure," (with T. Woteki), invited lecture, Regional Meeting, Institute of Mathematical Statistics, Minneapolis, March 1975

"The Use and Abuses of Probability in Voting Theory Models," invited lecture, Annual Meeting, Public Choice Society, New Haven, April 1974

"Some Problems with the Theory of Coalitions as Applied to the Judiciary," invited paper, Annual Meeting, American Political Science Association Convention, Chicago, August 1974

"On Principal Components and Clusters," invited lecture, Annual Meeting, International Classification Society, Atlanta, Georgia, April, 1973

"On Biased Estimation in Linear Models," invited lecture, Annual Meeting, American Statistical Association, New York, December, 1973

"Invariant Estimation with Applications to Linear Models," (with M.S. Younger), Institute of Mathematical Statistics, Blacksburg, Virginia, Academy of Science, May, 1972

"On Biased Estimation in Linear Models," invited lecture, Virginia Academy of Science, Lexington, Virginia, May, 1972

"Methods of Cluster Analysis Which Utilize Principle Components," invited lecture, International Classification Society Convention, Chicago, Illinois, April 1972

"A Method of Cluster Analysis," invited lecture, Annual Meeting, Biometrics Society, Fort Collins, Colorado, August, 1971

"Measures of Association," invited lecture, International Studies Association, San Juan, Puerto Rico, March, 1971

"Utilizing Initial Estimates in Estimating the Coefficients in a General Linear Model," Annual Meeting, Institute of Mathematical Statistics, Laramie, Wyoming, August 1970

## Speeches, Presentations, Lectures and Colloquia:

"Validating Biomarkers in Psychiatry", Department of Psychiatry, University of Athens,

Athens, Greece, October, 2006

"Fitting Failure Models to the Incidence of Alzheimer's Disease: Methodological Problems", invited lecture, Johns Hopkins School of Public Health, Noon conference series on Mental Heath, January, 2001

"Psychiatric Epidemiology", Residency Program in Psychiatry, Samaritan Health System, September, 2000

"Critical Appraisal in Internal Medicine", invited speaker, Good Samaritan Internal Medicine Program. April, 2000

"Psychiatric Epidemiology", Residency Program in Psychiatry, Samaritan Health System, September, 1999

"Tradeoffs Between Latent Growth Models and Epidemiological Models of Preventive Interventions, invited colloquium, Department of Mental Hygiene, Johns Hopkins School of Hygiene and Public Health, October, 1998

"Psychiatric Epidemiology", Residency Program in Psychiatry, Samaritan Health System, September, 1998

"Advances in Psychiatric Epidemiology", Clinical Epidemiology Section, Royal Medical Society (Edinburgh), August, 1998

"Latent Growth Models and Attributable Risks", luncheon speaker, Fellowship in Drug Epidemiology, Johns Hopkins University, April 1998

"Attributable Risk Measure in Mediational Impact Models: Somatizing Behavior", invited colloquium, Department of Mental Hygiene, Johns Hopkins School of Hygiene and Public Health, March, 1998

"Statistical Issues in Using Attributable Risk Measures in Intermediate Outcome Models", Department of Statistics, The University of Lancaster, Lancaster, England, June, 1997

"Statistical Problems that Arise in Applying Intermediate outcome Models in Prevention Research", invited lecture, Department of Statistics, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, May, 1997

"The Epidemiology of Thyroid Disease", invited lecture, Grand Rounds in Endocrinology, Samaritan Health Services, April, 1997

"Attributable Risk and Preventive Fractions in Prevention Research", invited lecture, Workshop on the Science of Prevention, NIMH, Baltimore, December, 1994 "Advances in Prevention Methodology", invited lecture, Prevention Research Center, Johns Hopkins University, September, 1994

"Multi-level Modeling in Prevention Research", invited colloquium, Prevention Research Center, Arizona State University, April, 1994

"Multi-level Modeling of Health Data; The Effects of Intervention on Aggressive Behavior", invited lecture, Program in Developmental Biology, University of North Carolina, April, 1994

"Mediation in Intermediate Variable Models", Department of Epidemiology and Biostatistics, College of Public Health, University of South Florida, March, 1994

"Assessing the Impact of Interventions on Proximal and Distal Outcomes" NIMH Prevention Research Center Directors Meeting, October 1993 with Reiser, M. and Warsi, G

"Epidemiology and Social Methodology: Complementarity in Prevention Research", invited presentation, with S. Kellam, et. al., NIMH Prevention Research Conference, Tysons Corners, VA, April, 1993

"Statistical Issues in Prevention Research", invited lecture, Directors' Meeting, Prevention Research Center Directors Meeting, National Institute of Mental Health, Rockville, Maryland, October, 1992

"The Course and Malleability of Aggressive Behavior in Young Children", invited presentation, with S. Kellam, et. al., National Academy of Science Institute of Medicine, Committee on Prevention of Mental Disorders, June, 1992

"Causal Models in Prevention Research: Mediation Moderation and Confounding", invited seminar, Carl A. Taube Memorial Colloquium Series in Psychiatry and Mental Health, Johns Hopkins University, May, 1992

"Breast Implants, Risk Surveillance and Health Statistics", invited lecture, MBA Special Colloquium Series, Arizona State University, March, 1992

"Proximal/Distal Effects on Two Developmental Epidemiologically-Based Preventive Interventions", invited seminar, Colloquium Series in Mental Health, Johns Hopkins School of Hygiene and Public Health, February, 1992

"Analyzing Subgroups and Contextual Effects" [with Sheppard Kellam], invited presentation, Directors' Meeting, Prevention Research Center Directors Meeting, National Institute of Mental Health, Rockville, Maryland, September, 1991

"Proximal/Distal Effects on Two Developmental Epidemiologically-Based Preventive Interventions" [with Sheppard Kellam, et. al.], invited seminar, Carl A. Taube Memorial

Colloquium Series in Mental Health, Johns Hopkins School of Hygiene and Public Health, September 1991

"The Epidemiology of Preventive Care in the Workplace", invited lecture, Phoenix Chapter, Association of Corporate Fitness Directors, Phoenix, May 1991.

"Statistics, Medicine and the Law", Invited Lecture, East Mesa Doctors Club, November 1990

"Statistical Models in the Analysis of Panel Data", invited lecture, Department of Biostatistics, Johns Hopkins School of Hygiene and Public Health, April, 1990

"Applications of Statistics to Occupational Health Problems", invited lecture, Department of Statistics, MacQuarie University, Australia, October, 1989

"Panel Models and Policy Analysis", invited lecture, Lincoln College, Christchurch, New Zealand, September 1989

"Panel Analysis and Occupational Health Analysis", invited lecture, University of Otago, New Zealand", September 1989

"Current Trends in Data Analysis, invited lecture, MBA colloquium, University of Canterbury, Christchurch, New Zealand, September 1989

"Managing the Health of Workers and the Health of the Firm", invited banquet speech, Conference on Analysis of Occupational Health Risks, Phoenix, August 1987

"Panel Models, Covariance Structures and the Exclusion of Liberals from 'Death-Sentence' Juries", invited colloquium, Department of Statistics, Stanford University, August, 1986

"A Statistician Looks at Panel Analysis or a Perfidious Peek at Pundits and Pookas," invited lecture, Arizona Chapter, American Statistical Association, March, 1984.

"A Statistician Looks at Panel Analysis", invited lecture, College of Business, University of Tennessee, June, 1983

"The Use of Panel Models in Non-experimental Research", invited lecture, College of Medicine, University of California, San Francisco, June, 1983

"Competing Approaches to Analysis of Panel Data", invited lecture, Econometrics Seminar, Stanford University, May 1983

"Science Analysis in Politics and the Politics of Science Analysis", invited lecture, Butler University, Indianapolis, March, 1983 "Statistical Problems in Panel Models", invited lecture, College of Education, Stanford University, March, 1983

"A Statistician Looks at Panel Analysis or a Perfidious Peek at Pundits and Pookas", invited lecture, Department of Computer and Information Sciences, University of California, Santa Cruz, February, 1983

"A Statistician Looks at Panel Analysis or a Perfidious Peek at Pundits and Pookas", invited lecture, Department of Computer and Information Sciences, University of Santa Clara, February, 1983

"Statistical Problems in Panel Analysis", invited lecture, Department of Mathematics, University of California, Santa Barbara, February, 1983

"A Statistician Looks at Panel Analysis", invited lecture, Department of Statistics, University of Arizona, February, 1983

"A Crossed Lagged Penal Analysis of Cross-Lagged Panel Analysis", invited colloquium, Department of Statistics, Stanford University, January, 1983

"Some Exciting Problems in Energy Modeling", invited lecture, Department of Mathematics, Arizona State University, August, 1982

"Statistical Problems in Short-term Energy Forecasting", invited lecture, Energy Information Administration, Washington, D.C., February, 1982

"Problems in Forecasting Energy Supplies", Decision Sciences Seminar, Wharton School, September, 1981

"Energy Policy: Myth and Reality", invited lecture, Philadelphia Business Seminar, April, 1981

"Energy Management: Building Image and Minimizing Liabilities", invited lecture, Wharton Executive Development Seminar, April, 1981

"Evaluating Energy Models", invited lecture, Delaware Chapter, American Statistical Association, University of Delaware, May, 1980

"Evaluating Models of Resource Depletion", invited lecture, Department of Economics, New York University, April, 1980.

"Exploratory Methods and the Art of Data Analysis", Dinner speech, Philadelphia Chapter, American Statistical Association, October, 1979

"Models of Domestic Oil Resources: Science Products and Political Agents", invited lecture, Thayer School of Engineering, Dartmouth College, March, 1979

"Models of Sequential Voting", invited lecture, Department of Political Science, Dartmouth College, March, 1979

"Estimating Oil Reserves: The Methods, Models and Policy Issues", invited lecture, School of Public and Urban Policy, University of Pennsylvania, December, 1978

"Estimating the Domestic Crude Oil Resource Base: Examining the King's Approach", invited lecture, Department of Statistics, University of Pennsylvania, November, 1978

"Picking a Multivariate Test Function, The Eenie-Meany Principle", invited lecture, Montreal Joint Statistics Colloquium, Montreal, November, 1977

"Econometric Energy Models: The Emperor's Quantitative Suit", invited lecture, Department of Commerce, October, 1977

"Exploratory Data Analysis as an Alternative to the Econometric Analysis of Social Problems," invited lecture, Department of Psychology, College of William and Mary, April, 1977

"Analyzing Energy Policy: The Competing Roles of the Economist, Engineer and Mathematician", invited lecture, Department of Mathematics, University of South Carolina, April, 1977

"Analyzing Political Data: What Can Statistics Tell Us?," invited lecture, School of International Studies, University of Denver, May, 1976

"Schur-Convexity and the Equivalence of Multivariate Tests", invited seminar, Department of Statistics, Rutgers University, October, 1975

"On Communal Indifference Curves," (with I.J. Good), invited seminar, Mathematical Economics Seminar, Virginia Polytechnic Institute and State University, October, 1975

"The Statistical Analysis of Energy Problems: Who Should We Believe?", invited lecture, Office of Energy Analysis, Department of Commerce, October, 1975

"Energy Research and Residential Housing", invited lecture, The Federal Energy Administration, September, 1975

"Consumer Reaction to the Energy Crisis: The Long Underwear Effect", invited address, West Virginia University, February, 1975

"Mathematical Models and other Forms of Hocus-Pocus", invited lecture, Department of Political Science, West Virginia University, February, 1975

"Factor Analysis: The Short Bed Problem", invited lecture, Department of Statistics

and Operations Research, University of Pennsylvania, March, 1975

"LSD and Political Science: Distinguishing Uppers and Downers", invited address, Western New England College, November, 1974

"Probability, Statistics and the Theory of Democracy", invited lecture, Department of Statistics, University of Connecticut, October, 1974

"Statistical Policy Analysis: Assessing the Unobservable", invited lecture, Department of Statistics, Princeton University, January, 1974

"On Procedures for Comparing Factor Matrices", invited lecture, Department of Statistics, University of Connecticut, January, 1974.

"A Mathematician's Doubts About Econometric Solutions to Political Problems", invited lecture, Department of Political Science, Ohio State University, May, 1973

"Estimating the Relationship Between Unobserved Variables, or Can We Sell the Second Canonical Correlation to the Social Scientists?", invited lecture, Department of Statistics, Ohio State University, May, 1973

"Generalized Spatial Models of Voting Theory", invited lecture, Center for Public Choice, Virginia Polytechnic Institute and State University, February, 1973

"Estimating the Relationship Between Ordinal Variables", invited lecture, Department of Statistics, Harvard University, 1973.

"Some Statistical Problems in Spatial Models", invited colloquium, Department of Statistics, Carnegie-Mellon University, Pittsburgh, October, 1972.

"Sex, the Generation Gap, and Fermat's Last Theorem", invited speech, Tidewater Council of Teachers of Mathematics, Norfolk, Virginia, September, 1972

"Mathematics: Is it Irrelevant by Necessity or Design?", invited lecture, Department of Mathematics, Emory and Henry College, Emory, Virginia, April, 1972

"Is There Reason for a Mathematician to help a Social Scientist?", invited to deliver annual Phi Mu Epsilon Lecture, Blacksburg, Virginia, 1972

"Probability Without Calculus and Statistics Without Mathematics", invited lecture, Virginia Mathematics Teachers Annual Convention, Roanoke, Virginia, November, 1972

"If Educators Educate Educators, Who Educates the Educated?", banquet address, State Mathematics Teachers Convention, Norfolk, Virginia, 1971 "Two-Stage Estimation in linear Models", invited lecture, Department of Statistics, Pennsylvania State University, January, 1971

"Problems in Cluster Analysis", invited lecture, Department of Applied Statistics, University of Minnesota, January 1971

### Papers in Proceedings:

Mayer, L. S. and Reiser M.(1992) "Mediation and Confounding in Panel Models of Prevention Research" <u>Proceedings of the Social Statistics Section, American Statistical</u> <u>Association</u>

Mayer, L. S. and Carroll, S. S.(1988) "Modeling the Cotemporal Effect in a Cross-Lagged Panel Model," <u>Proceedings of the Business and Economics Section, American Statistical</u> <u>Association</u>

Carroll, S. S. and Mayer, L. S. (1987) "Testing for Serial Correlation in Cross-Lagged Panel Studies," <u>Proceedings of the Business and Economics Section, American</u> <u>Statistical Association</u>

Carroll, S. S. and Mayer, L. S. (1986) "Evaluation of the Cross Effects Parameters in a Cross-Lagged Panel Model," <u>Proceedings of the Business and Economic Section</u>, <u>American Statistical Association</u>

Mayer, L. S. (1985) "Hypothesis Testing in Cross-Lagged Panel Models," <u>Proceedings</u> of the Social Statistics Section, American Statistical Association

Mayer, L. S. and Carroll, S. S. (1985) "Testing for Serial Correlation in Cross-Lagged Panel Studies," <u>Proceedings of the Business and Economics Section, American</u> <u>Statistical Association</u>

Mayer, L.S. et. al. (1982). "Analysis of the U.S. Short-Term Integrated (Energy) Forecasting System," <u>Proceedings of the International Conference on Energy Use</u> <u>Management</u>, New York: Pergamon Press, 971-982

Harrje, D. and Mayer, L.S. (1978). "Energy Use and the Potential for Conservation," <u>Proceedings of the International Conference on Energy Use Management</u>, Volume II, R. Fazzolare and C. Smith (eds.), New York: Pergamon Press, 749-771

Mayer, L.S. (1978). "The Use of Semi-Controlled Experiments in the Analysis of Residential Energy Demand," <u>Proceedings of the 1978 Department of Energy</u> <u>Symposium</u>, Washington: Government Printing Office

Mayer, L.S. (1978). "The Value of the Econometric Approach to Forecasting Our Energy Future," <u>Proceedings of the International Conference on Energy Use Management</u>,, Volume III, R. Fazzolare and C. Smith (eds.), New York: Pergamon Press, 1073-1082 Mayer, L.S. (1978). "Difficulty in Developing Local Energy Policy," expert testimony, <u>Hearings on Local Energy Policy</u>, Washington: U.S. Congress

Mayer, L.S. (1977). "Exploratory Data Analysis and Classical Statistics: Their Abilities to Shed Light on Energy Issues," <u>Proceedings of the 1977 Department of Energy</u> <u>Symposium</u>, 27-32, Washington: Government Printing Office

## **Published Abstracts:**

"Equivariant Estimation and A Special Group Structure", (with T. Woteki), <u>Bulletin of the Institute of Mathematical Statistics</u>, 1975

"A Fortran Program for Linear Log Odds Analysis", (with P.J. Pichotta), <u>Behavior</u> <u>Research Methods and Instrumentation</u>, 1974, 6, p. 521

"Invariant Estimation in the Social Sciences", (with M. S. Younger), <u>Bulletin of the</u> <u>Institute of Mathematical Statistics</u>, 1973

"On Principal Components and Clusters", <u>Bulletin of the International Classification</u> <u>Society</u>, 1973

"Methods of Cluster Analysis Which Utilize Principal Components", <u>Bulletin of the</u> <u>International Classification Society</u>, 1972

"Utilizing Initial Estimates in Estimating the Coefficients in General Linear Model", <u>Annals of Mathematical Statistics</u>, October 1970

### Society Membership:

Society for Epidemiological Research, Society for Environmental Epidemiology, Royal Statistical Society, Society for Medical Decision Making, American Statistical Association, Biometrics Society, Institute for Mathematical Statistics, Psychometric Society, Econometric Society, American Association for the Advancement of Science, American Political Science Association, American Sociological Association, and Council for Applied for Social Research.

## Courses Taught at Arizona State University and Banner Good Samaritan Medical Center

Epidemiology, Epidemiology Methodology, Clinical Epidemiology, Panel Analysis, Biostatistics, Multiple Regression, Time Series Modeling, Applied Forecasting Methods, Stochastic Processes, Exploratory Data Analysis, Seminar in Multivariate Analysis, Advanced Topics in Statistical Inference, Advanced Topics in Linear Models, Advanced Research Methods.

### **Courses taught at other Universities:**

### <u>Undergraduate:</u>

Biostatistics, Data Analysis, Nonparametric Methods, Regression Analysis, Mathematical Statistics, Mathematical Modeling, Design of Experiments, Statistics for the Social Sciences, Educational Statistics, Statistics and Public Policy, Computers and Society, Forecasting.

### <u>Graduate:</u>

Biostatistics, Clinical Epidemiology, Statistical Forecasting, Exploratory Data Analysis, Epidemiological Methods, Econometrics, Applied Multivariate Statistics, Advanced Multivariate Statistics, Stochastic Processes, Advanced Probability, Linear Models, Advanced Inference, Time Series, Sampling Theory, Quantitative Methods of Policy Analysis, Philosophy of Science, Advances in Social Methodology.

### Professional:

Statistics and Public Policy (Woodrow Wilson School, Princeton University); Advanced Study in Energy Analysis (Wharton MBA Program, University of Pennsylvania); Advanced Study in Statistics and Law (Law School, University of Pennsylvania): Medical Statistics (College of Medicine, Ohio State University)

### Notable University Committees:

Member, Graduate Committee on Ph.D. program in Health Services Administration and Policy, Arizona State University (ASU) 1991-1992

Member, Executive Board, Program on Law and the Social Sciences, ASU, 1983-1989

Faculty Senate (elected), ASU, 1987-89

University Services Committee, ASU, 1988-89

Council on Research and Creative Activities, ASU, 1986-1988

Sunset Review Committee, Meteorite Center, ASU, 1987

Sunset Review Committee, Energy Research Center, ASU, 1987

Chair, Sunset Review Committee, Center for Advanced Research in Transportation, ASU, 1987

Women Studies Research Awards Committee, ASU, 1984-1989

Board, Ph.D. Program in Justice Studies, ASU, 1987-1989

Biomedical Research Committee, ASU< 1986-1988

## Notable Previous University Committee Assignments:

Member, Health Professions Advisory Board, University of Pennsylvania, 1980-83

Member, Environmental Task Force Committee, Office of the Provost, University of Pennsylvania, 1979-82

Member, Committee on Undergraduate Student Life, Princeton University, 1976

Member, Council of Masters, Princeton University, 1976-79

Fellow, Princeton Inn College, Princeton University, 1975-76

Member, Chair Search Committee, Department of Statistics, Virginia Polytechnic Institute and State University, 1972-74 Case: 3:17-cv-00264-wmc Document #: 90-3 Filed: 06/06/18 Page 1 of 1

## Appendix C: Compensation

\$400.00 per hour.

# **APPENDIX D**

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# Preface

A JOURNAL OF TECHNOLOGY & SOCIET

This report was written for the general public and for mental health professionals in order to draw attention to—and offer some scientific insight about—the mental health issues faced by LGBT populations.

It arose from a request from Paul R. McHugh, M.D., the former chief of psychiatry at Johns Hopkins Hospital and one of the leading psychiatrists in the world. Dr. McHugh requested that I review a monograph he and colleagues had drafted on subjects related to sexual orientation and identity; my original assignment was to guarantee the accuracy of statistical inferences and to review additional sources. In the months that followed, I closely read over five hundred scientific articles on these topics and perused hundreds more. I was alarmed to learn that the LGBT community bears a disproportionate rate of mental health problems compared to the population as a whole.

As my interest grew, I explored research across a variety of scientific fields, including epidemiology, genetics, endocrinology, psychiatry, neuroscience, embryology, and pediatrics. I also reviewed many of the academic empirical studies done in the social sciences including psychology, sociology, political science, economics, and gender studies.

I agreed to take over as lead author, rewriting, reorganizing, and expanding the text. I support every sentence in this report, without reservation and without prejudice regarding any political or philosophical debates. This report is about science and medicine, nothing more and nothing less.

Readers wondering about this report's synthesis of research from so many different fields may wish to know a little about its lead author. I am a full-time academic involved in all aspects of teaching, research, and professional service. I am a biostatistician and epidemiologist who focuses on the design, analysis, and interpretation of experimental and observational data in public health and medicine, particularly when the data are complex in terms of underlying scientific issues. I am a research physician, having trained in medicine and psychiatry in the U.K. and received the British equivalent (M.B.) to the American M.D. I have never practiced medicine (including psychiatry) in the United States or abroad. I have testified in dozens of federal and state legal proceedings and regulatory hearings, in

 $<sup>4 \</sup>sim \text{The New Atlantis}$ 

### Preface

most cases reviewing scientific literature to clarify the issues under examination. I strongly support equality and oppose discrimination for the LGBT community, and I have testified on their behalf as a statistical expert.

I have been a full-time tenured professor for over four decades. I have held professorial appointments at eight universities, including Princeton, the University of Pennsylvania, Stanford, Arizona State University, Johns Hopkins University Bloomberg School of Public Health and School of Medicine, Ohio State, Virginia Tech, and the University of Michigan. I have also held research faculty appointments at several other institutions, including the Mayo Clinic.

My full-time and part-time appointments have been in twenty-three disciplines, including statistics, biostatistics, epidemiology, public health, social methodology, psychiatry, mathematics, sociology, political science, economics, and biomedical informatics. But my research interests have varied far less than my academic appointments: the focus of my career has been to learn how statistics and models are employed across disciplines, with the goal of improving the use of models and data analytics in assessing issues of interest in the policy, regulatory, or legal realms.

I have been published in many top-tier peer-reviewed journals (including *The Annals of Statistics, Biometrics,* and *American Journal of Political Science*) and have reviewed hundreds of manuscripts submitted for publication to many of the major medical, statistical, and epidemiological journals (including *The New England Journal of Medicine, Journal of the American Statistical Association,* and *American Journal of Public Health*).

I am currently a scholar in residence in the Department of Psychiatry at Johns Hopkins School of Medicine and a professor of statistics and biostatistics at Arizona State University. Up until July 1, 2016, I also held part-time faculty appointments at the Johns Hopkins Bloomberg School of Public Health and School of Medicine, and at the Mayo Clinic.

An undertaking as ambitious as this report would not be possible without the counsel and advice of many gifted scholars and editors. I am grateful for the generous help of Laura E. Harrington, M.D., M.S., a psychiatrist with extensive training in internal medicine and neuroimmunology, whose clinical practice focuses on women in life transition, including affirmative treatment and therapy for the LGBT community. She contributed to the entire report, particularly lending her expertise to the sections on endocrinology and brain research. I am indebted also to Bentley J. Hanish, B.S., a young geneticist who expects to graduate medical school in 2021 with an M.D./Ph.D. in psychiatric epidemiology.

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He contributed to the entire report, particularly to those sections that concern genetics.

I gratefully acknowledge the support of Johns Hopkins University Bloomberg School of Public Health and School of Medicine, Arizona State University, and the Mayo Clinic.

In the course of writing this report, I consulted a number of individuals who asked that I not thank them by name. Some feared an angry response from the more militant elements of the LGBT community; others feared an angry response from the more strident elements of religiously conservative communities. Most bothersome, however, is that some feared reprisals from their own universities for engaging such controversial topics, regardless of the report's content—a sad statement about academic freedom.

I dedicate my work on this report, first, to the LGBT community, which bears a disproportionate rate of mental health problems compared to the population as a whole. We must find ways to relieve their suffering.

I dedicate it also to scholars doing impartial research on topics of public controversy. May they never lose their way in political hurricanes.

And above all, I dedicate it to children struggling with their sexuality and gender. Children are a special case when addressing gender issues. In the course of their development, many children explore the idea of being of the opposite sex. Some children may have improved psychological well-being if they are encouraged and supported in their cross-gender identification, particularly if the identification is strong and persistent over time. But nearly all children ultimately identify with their biological sex. The notion that a two-year-old, having expressed thoughts or behaviors identified with the opposite sex, can be labeled for life as transgender has absolutely no support in science. Indeed, it is iniquitous to believe that all children who have gender-atypical thoughts or behavior at some point in their development, particularly before puberty, should be encouraged to become transgender.

As citizens, scholars, and clinicians concerned with the problems facing LGBT people, we should not be dogmatically committed to any particular views about the nature of sexuality or gender identity; rather, we should be guided first and foremost by the needs of struggling patients, and we should seek with open minds for ways to help them lead meaningful, dignified lives.

LAWRENCE S. MAYER, M.B., M.S., Ph.D.

 $<sup>6 \</sup>sim$  The New Atlantis

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# **Executive Summary**

T his report presents a careful summary and an up-to-date explanation of research—from the biological, psychological, and social sciences—related to sexual orientation and gender identity. It is offered in the hope that such an exposition can contribute to our capacity as physicians, scientists, and citizens to address health issues faced by LGBT populations within our society.

Some key findings:

### Part One: Sexual Orientation

• The understanding of sexual orientation as an innate, biologically fixed property of human beings—the idea that people are "born that way"—is not supported by scientific evidence.

• While there is evidence that biological factors such as genes and hormones are associated with sexual behaviors and attractions, there are no compelling causal biological explanations for human sexual orientation. While minor differences in the brain structures and brain activity between homosexual and heterosexual individuals have been identified by researchers, such neurobiological findings do not demonstrate whether these differences are innate or are the result of environmental and psychological factors.

• Longitudinal studies of adolescents suggest that sexual orientation may be quite fluid over the life course for some people, with one study estimating that as many as 80% of male adolescents who report same-sex attractions no longer do so as adults (although the extent to which this figure reflects actual changes in same-sex attractions and not just artifacts of the survey process has been contested by some researchers).

• Compared to heterosexuals, non-heterosexuals are about two to three times as likely to have experienced childhood sexual abuse.

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EXECUTIVE SUMMARY

### Part Two: Sexuality, Mental Health Outcomes, and Social Stress

• Compared to the general population, non-heterosexual subpopulations are at an elevated risk for a variety of adverse health and mental health outcomes.

• Members of the non-heterosexual population are estimated to have about 1.5 times higher risk of experiencing anxiety disorders than members of the heterosexual population, as well as roughly double the risk of depression, 1.5 times the risk of substance abuse, and nearly 2.5 times the risk of suicide.

• Members of the transgender population are also at higher risk of a variety of mental health problems compared to members of the non-transgender population. Especially alarmingly, the rate of lifetime suicide attempts across all ages of transgender individuals is estimated at 41%, compared to under 5% in the overall U.S. population.

• There is evidence, albeit limited, that social stressors such as discrimination and stigma contribute to the elevated risk of poor mental health outcomes for non-heterosexual and transgender populations. More high-quality longitudinal studies are necessary for the "social stress model" to be a useful tool for understanding public health concerns.

### Part Three: Gender Identity

• The hypothesis that gender identity is an innate, fixed property of human beings that is independent of biological sex—that a person might be "a man trapped in a woman's body" or "a woman trapped in a man's body"—is not supported by scientific evidence.

• According to a recent estimate, about 0.6% of U.S. adults identify as a gender that does not correspond to their biological sex.

• Studies comparing the brain structures of transgender and non-transgender individuals have demonstrated weak correlations between brain structure and cross-gender identification. These correlations do not provide any evidence for a neurobiological basis for cross-gender identification.

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### EXECUTIVE SUMMARY

• Compared to the general population, adults who have undergone sex-reassignment surgery continue to have a higher risk of experiencing poor mental health outcomes. One study found that, compared to controls, sex-reassigned individuals were about 5 times more likely to attempt suicide and about 19 times more likely to die by suicide.

• Children are a special case when addressing transgender issues. Only a minority of children who experience cross-gender identification will continue to do so into adolescence or adulthood.

• There is little scientific evidence for the therapeutic value of interventions that delay puberty or modify the secondary sex characteristics of adolescents, although some children may have improved psychological well-being if they are encouraged and supported in their cross-gender identification. There is no evidence that all children who express gender-atypical thoughts or behavior should be encouraged to become transgender.

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# **Sexuality and Gender**

Findings from the Biological, Psychological, and Social Sciences

Lawrence S. Mayer, M.B., M.S., Ph.D. and Paul R. McHugh, M.D.

# Introduction

**F** ew topics are as complex and controversial as human sexual orientation and gender identity. These matters touch upon our most intimate thoughts and feelings, and help to define us as both individuals and social beings. Discussions of the ethical questions raised by sexual orientation and gender identity can become heated and personal, and the associated policy issues sometimes provoke intense controversies. The disputants, journalists, and lawmakers in these debates often invoke the authority of science, and in our news and social media and our broader popular culture we hear claims about what "science says" on these matters.

This report offers a careful summary and an up-to-date explanation of many of the most rigorous findings produced by the biological, psychological, and social sciences related to sexual orientation and gender identity. We examine a vast body of scientific literature from several disciplines. We try to acknowledge the limitations of the research and to avoid premature conclusions that would result in over-interpretation of scientific findings. Since the relevant literature is rife with inconsistent and ambiguous definitions, we not only examine the empirical evidence but also delve into underlying conceptual problems. This report does not, however, discuss matters of morality or policy; our focus is on the scientific evidence—what it shows and what it does not show.

We begin in Part One by critically examining whether concepts such as heterosexuality, homosexuality, and bisexuality represent distinct, fixed, and biologically determined properties of human beings. As part of this discussion, we look at the popular "born that way" hypothesis, which

<sup>10</sup>  $\sim$  The New Atlantis

#### INTRODUCTION

posits that human sexual orientation is biologically innate; we examine the evidence for this claim across several subspecialties of the biological sciences. We explore the developmental origins of sexual attractions, the degree to which such attractions may change over time, and the complexities inherent in the incorporation of these attractions into one's sexual identity. Drawing on evidence from twin studies and other types of research, we explore genetic, environmental, and hormonal factors. We also explore some of the scientific evidence relating brain science to sexual orientation.

In Part Two we examine research on health outcomes as they relate to sexual orientation and gender identity. There is a consistently observed higher risk of poor physical and mental health outcomes for lesbian, gay, bisexual, and transgender subpopulations compared to the general population. These outcomes include depression, anxiety, substance abuse, and most alarmingly, suicide. For example, among the transgender subpopulation in the United States, the rate of attempted suicide is estimated to be as high as 41%, ten times higher than in the general population. As physicians, academics, and scientists, we believe all of the subsequent discussions in this report must be cast in the light of this public health issue.

We also examine some ideas proposed to explain these differential health outcomes, including the "social stress model." This hypothesis which holds that stressors like stigma and prejudice account for much of the additional suffering observed in these subpopulations—does not seem to offer a complete explanation for the disparities in the outcomes.

Much as Part One investigates the conjecture that sexual orientation is fixed with a causal biological basis, a portion of Part Three examines similar issues with respect to gender identity. Biological sex (the binary categories of male and female) is a fixed aspect of human nature, even though some individuals affected by disorders of sex development may exhibit ambiguous sex characteristics. By contrast, gender identity is a social and psychological concept that is not well defined, and there is little scientific evidence that it is an innate, fixed biological property.

Part Three also examines sex-reassignment procedures and the evidence for their effectiveness at alleviating the poor mental health outcomes experienced by many people who identify as transgender. Compared to the general population, postoperative transgender individuals continue to be at high risk of poor mental health outcomes.

An area of particular concern involves medical interventions for gender-nonconforming youth. They are increasingly receiving therapies that affirm their felt genders, and even hormone treatments or surgical

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modifications at young ages. But the majority of children who identify as a gender that does not conform to their biological sex will no longer do so by the time they reach adulthood. We are disturbed and alarmed by the severity and irreversibility of some interventions being publicly discussed and employed for children.

Sexual orientation and gender identity resist explanation by simple theories. There is a large gap between the certainty with which beliefs are held about these matters and what a sober assessment of the science reveals. In the face of this complexity and uncertainty, we need to be humble about what we know and do not know. We readily acknowledge that this report is neither an exhaustive analysis of the subjects it addresses nor the last word on them. Science is by no means the only avenue for understanding these astoundingly complex, multifaceted topics; there are other sources of wisdom and knowledge—including art, religion, philosophy, and lived human experience. And much of our scientific knowledge in this area remains unsettled. However, we offer this overview of the scientific literature in the hope that it can provide a shared framework for intelligent, enlightened discourse in political, professional, and scientific exchanges—and may add to our capacity as concerned citizens to alleviate suffering and promote human health and flourishing.

 $<sup>12 \</sup>sim \mathrm{The} \ \mathrm{New} \ \mathrm{Atlantis}$ 

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Part One

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# **Sexual Orientation**

While some people are under the impression that sexual orientation is an innate, fixed, and biological trait of human beings—that, whether heterosexual, homosexual, or bisexual, we are "born that way"—there is insufficient scientific evidence to support that claim. In fact, the concept of sexual orientation itself is highly ambiguous; it can refer to a set of behaviors, to feelings of attraction, or to a sense of identity. Epidemiological studies show a rather modest association between genetic factors and sexual attractions or behaviors, but do not provide significant evidence pointing to particular genes. There is also evidence for other hypothesized biological causes of homosexual behaviors, attractions, or identity—such as the influence of hormones on prenatal development—but that evidence, too, is limited. Studies of the brains of homosexuals and heterosexuals have found some differences, but have not demonstrated that these differences are inborn rather than the result of environmental factors that influenced both psychological and neurobiological traits. One environmental factor that appears to be correlated with non-heterosexuality is childhood sexual abuse victimization, which may also contribute to the higher rates of poor mental health outcomes among non-heterosexual subpopulations, compared to the general population. Overall, the evidence suggests some measure of fluidity in patterns of sexual attraction and behavior—contrary to the "born that way" notion that oversimplifies the vast complexity of human sexuality.

The popular discussion of sexual orientation is characterized by two conflicting ideas about why some individuals are lesbian, gay, or bisexual. While some claim that sexual orientation is a choice, others say that sexual orientation is a fixed feature of one's nature, that one is "born that way." We hope to show here that, though sexual orientation is not a choice, neither is there scientific evidence for the view that sexual orientation is a fixed and innate biological property.

A prominent recent example of a person describing sexual orientation as a choice is Cynthia Nixon, a star of the popular television series *Sex and the City*, who in a January 2012 *New York Times* interview explained, "For me it's a choice, and you don't get to define my gayness for me," and commented that she was "very annoyed" about the issue of whether or not gay people are born that way. "Why can't it be a choice? Why is that any less legitimate?"<sup>1</sup> Similarly, Brandon Ambrosino wrote in *The New Republic* in

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2014 that "It's time for the LGBT community to stop fearing the word 'choice,' and to reclaim the dignity of sexual autonomy."<sup>2</sup>

By contrast, proponents of the "born that way" hypothesis—expressed for instance in Lady Gaga's 2011 song "Born This Way"—posit that there is a causal biological basis for sexual orientation and often try to bolster their claims with scientific findings. Citing three scientific studies<sup>3</sup> and an article from *Science* magazine,<sup>4</sup> Mark Joseph Stern, writing for *Slate* in 2014, claims that "homosexuality, at least in men, is clearly, undoubtedly, inarguably an inborn trait."<sup>5</sup> However, as neuroscientist Simon LeVay, whose work in 1991 showed brain differences in homosexual men compared to heterosexual men, explained some years after his study, "It's important to stress what I didn't find. I did not prove that homosexuality is genetic, or find a genetic cause for being gay. I didn't show that gay men are 'born that way,' the most common mistake people make in interpreting my work. Nor did I locate a gay center in the brain."<sup>6</sup>

Many recent books contain popular treatments of science that make claims about the innateness of sexual orientation. These books often exaggerate—or at least oversimplify—complex scientific findings. For example, in a 2005 book, psychologist and science writer Leonard Sax responds to a worried mother's question as to whether her teenage son will outgrow his homosexual attractions: "Biologically, the difference between a gay man and a straight man is something like the difference between a left-handed person and a right-handed person. Being left-handed isn't just a phase. A left-handed person won't someday magically turn into a righthanded person.... Some children are destined at birth to be left-handed, and some boys are destined at birth to grow up to be gay."<sup>7</sup>

As we argue in this part of the report, however, there is little scientific evidence to support the claim that sexual attraction is simply fixed by innate and deterministic factors such as genes. Popular understandings of scientific findings often presume deterministic causality when the findings do not warrant that presumption.

Another important limitation for research and for interpretation of scientific studies on this topic is that some central concepts—including "sexual orientation" itself—are often ambiguous, making reliable measurements difficult both within individual studies and when comparing results across studies. So before turning to the scientific evidence concerning the development of sexual orientation and sexual desire, we will examine at some length several of the most troublesome conceptual ambiguities in the study of human sexuality in order to arrive at a fuller picture of the relevant concepts.

 $<sup>14 \</sup>sim \text{The New Atlantis}$ 

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### **Problems with Defining Key Concepts**

A 2014 New York Times Magazine piece titled "The Scientific Quest to Prove Bisexuality Exists"<sup>8</sup> provides an illustration of the themes explored in this Part—sexual desire, attraction, orientation, and identity—and of the difficulties with defining and studying these concepts. Specifically, the article shows how a scientific approach to studying human sexuality can conflict with culturally prevalent views of sexual orientation, or with the self-understanding that many people have of their own sexual desires and identities. Such conflicts raise important questions about whether sexual orientation and related concepts are as coherent and well-defined as is often assumed by researchers and the public alike.

The author of the article, Benoit Denizet-Lewis, an openly gay man, describes the work of scientists and others trying to demonstrate the existence of a stable bisexual orientation. He visited researchers at Cornell University and participated in tests used to measure sexual arousal, tests that include observing the way pupils dilate in response to sexually explicit imagery. To his surprise, he found that, according to this scientific measure, he was aroused when watching pornographic films of women masturbating:

Might I actually be bisexual? Have I been so wedded to my gay identity—one I adopted in college and announced with great fanfare to family and friends—that I haven't allowed myself to experience another part of myself? In some ways, even asking those questions is anathema to many gays and lesbians. That kind of publicly shared uncertainty is catnip to the Christian Right and to the scientifically dubious, psychologically damaging ex-gay movement it helped spawn. As out gay men and lesbians, after all, we're supposed to be sure—we're supposed to be "born this way."<sup>9</sup>

Despite the apparently scientific (though admittedly limited) evidence of his bisexual-typical patterns of arousal, Denizet-Lewis rejected the idea that he was actually bisexual, because "It doesn't feel true as a sexual orientation, nor does it feel right as my identity."<sup>10</sup>

Denizet-Lewis's concerns here illustrate a number of the quandaries raised by the scientific study of human sexuality. The objective measures the researchers used seemed to be at odds with the more intuitive, subjective understanding of what it is to be sexually aroused; our own understanding of what we are sexually aroused by is tied up with the entirety of our lived experience of sexuality. Furthermore, Denizet-Lewis's insistence

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that he is gay, not bisexual, and his concern that uncertainty about his identity could have social and political implications, points to the fact that sexual orientation and identity are understood not only in scientific and personal terms, but in social, moral, and political terms as well.

But how do categories of sexual orientation—with labels such as "bisexual" or "gay" or "straight"—help scientists study the complex phenomenon of human sexuality? When we examine the concept of sexual orientation, it becomes apparent, as this part will show, that it is too vague and poorly defined to be very useful in science, and that in its place we need more clearly defined concepts. We strive in this report to use clear terms; when discussing scientific studies that rely on the concept of "sexual orientation," we try as much as possible to specify how the scientists defined the term, or related terms.

One of the central difficulties in examining and researching sexual orientation is that the underlying concepts of "sexual desire," "sexual attraction," and "sexual arousal" can be ambiguous, and it is even less clear what it means that a person identifies as having a sexual orientation grounded in some pattern of desires, attractions, or states of arousal.

The word "desire" all by itself might be used to cover an aspect of volition more naturally expressed by "want": I want to go out for dinner, or to take a road trip with my friends next summer, or to finish this project. When "desire" is used in this sense, the objects of desire are fairly determinate *goals*—some may be perfectly achievable, such as moving to a new city or finding a new job; others may be more ambitious and out of reach, like the dream of becoming a world-famous movie star. Often, however, the language of desire is meant to include things that are less clear: indefinite *longings* for a life that is, in some unspecified sense, different or better; an inchoate sense of something being missing or lacking in one-self or one's world; or, in psychoanalytic literature, unconscious dynamic forces that shape one's cognitive, emotional, and social behaviors, but that are separate from one's ordinary, conscious sense of self.

This more full-blooded notion of desire is, itself, ambiguous. It might refer to a hoped-for state of affairs like finding a sense of meaning, fulfillment, and satisfaction with one's life, a desire that, while not completely clear in its implications, is presumably not entirely out of reach, although such longings may also be forms of fantasizing about a radically altered or perhaps even unattainable state of affairs. If I want to take a road trip with my friends, the steps are clear: call up my friends, pick a date, map out a route, and so on. However, if I have an inchoate longing for change, a hope for sustainable intimacy, love, and belonging, or an unconscious conflict

 $<sup>16 \</sup>sim \text{The New Atlantis}$ 

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that is disrupting my ability to move forward in the life I have tried to build for myself, I face a different sort of challenge. There is not necessarily a set of well-defined or conscious goals, much less established ways of achieving them. This is not to say that the satisfaction of these longings is impossible, but doing so often involves not only choosing concrete actions to achieve particular goals but the more complex shaping of one's own life through acting in and making sense of the world and one's place in it.

So the first thing to note when considering both popular discussions and scientific studies of sexuality is that the use of the term "desire" could refer to distinct aspects of human life and experience.

Just as the meanings that might be intended by the term "desire" are many, so also is each of these meanings varied, making clear delineations a challenge. For example, a commonsense understanding might suggest that the term "sexual desire" means wanting to engage in specific sexual acts with particular individuals (or categories of individuals). Psychiatrist Steven Levine articulated this common view in his definition of sexual desire as "the sum of the forces that incline us toward and away from sexual behavior."<sup>11</sup> But it is not obvious how one might study this "sum" in a rigorous way. Nor is it obvious why all the diverse factors that can potentially influence sexual behavior, such as material poverty—in the case of prostitution, for instance—alcohol consumption, and intimate affection, should all be grouped together as aspects of sexual desire. As Levine himself points out, "In anyone's hands, sexual desire can be a slippery concept."<sup>12</sup>

Consider a few of the ways that the term "sexual desire" has been employed in scientific contexts—designating one or more of the following distinct phenomena:

1. States of physical arousal that may or may not be linked to a specific physical activity and may or may not be objects of conscious awareness.

2. Conscious erotic interest in response to finding others attractive (in perception, memory, or fantasy), which may or may not involve any of the bodily processes associated with measurable states of physical arousal.

3. Strong interest in finding a companion or establishing a durable relationship.

4. The romantic aspirations and feelings associated with infatuation or falling in love with a specific individual.

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5. Inclination towards attachment to specific individuals.

6. The general motivation to seek intimacy with a member of some specific group.

7. An aesthetic measure that latches onto perceived beauty in others.  $^{13}$ 

In a given social science study, the concepts mentioned above will often each have its own particular operational definition for the purposes of research. But they cannot all mean the *same* thing. Strong interest in finding a companion, for example, is clearly distinguishable from physical arousal. Looking at this list of experiential and psychological phenomena, one can easily envision what confusions might arise from using the term "sexual desire" without sufficient care.

The philosopher Alexander Pruss provides a helpful summary of some of the difficulties involved in characterizing the related concept of sexual attraction:

What does it mean to be "sexually attracted" to someone? Does it mean to have a tendency to be aroused in their presence? But surely it is possible to find someone sexually attractive without being aroused. Does it mean to form the belief that someone is sexually attractive to one? Surely not, since a belief about who is sexually attractive to one might be wrong—for instance, one might confuse admiration of form with sexual attraction. Does it mean to have a noninstrumental desire for a sexual or romantic relationship with the person? Probably not: we can imagine a person who has no sexual attraction to anybody, but who has a noninstrumental desire for a romantic relationship because of a belief, based on the testimony of others, that romantic relationships have noninstrumental value. These and similar questions suggest that there is a cluster of related concepts under the head of "sexual attraction," and any precise definition is likely to be an undesirable shoehorning. But if the concept of sexual attraction is a cluster of concepts, neither are there simply univocal concepts of heterosexuality, homosexuality, and bisexuality.14

The ambiguity of the term "sexual desire" (and similar terms) should give us pause to consider the diverse aspects of human experience that are often associated with it. The problem is neither irresolvable nor unique to this subject matter. Other social science concepts—aggression and addiction, for example—may likewise be difficult to define and to

<sup>18</sup>  $\sim$  The New Atlantis

operationalize and for this reason admit of various usages.\* Nevertheless, the ambiguity presents a significant challenge for both research design and interpretation, requiring that we take care in attending to the meanings, contexts, and findings specific to each study. It is also important to bracket any subjective associations with or uses of these terms that do not conform to well-defined scientific classifications and techniques.

It would be a mistake, at any rate, to ignore the varied uses of this and related terms or to try to reduce the many and distinct experiences to which they might refer to a single concept or experience. As we shall see, doing so could in some cases adversely affect the evaluation and treatment of patients.

### The Context of Sexual Desire

We can further clarify the complex phenomenon of sexual desire if we examine what relationship it has to other aspects of our lives. To do so, we borrow some conceptual tools from a philosophical tradition known as phenomenology, which conceives of human experience as deriving its meaning from the whole context in which it appears.

The testimony of experience suggests that one's experience of sexual desire and sexual attraction is not voluntary, at least not in any immediate way. The whole set of inclinations that we generally associate with the experience of sexual desire—whether the impulse to engage in particular acts or to enjoy certain relationships—does not appear to be the sole product of any deliberate choice. Our sexual appetites (like other natural appetites) are experienced as given, even if their expression is shaped in subtle ways by many factors, which might very well include volition. Indeed, far from appearing as a product of our will, sexual desire—however we define it—is often experienced as a powerful force, akin to hunger, that many struggle (especially in adolescence) to bring under direction and control. Furthermore, sexual desire can impact one's attention involuntarily or color one's day-to-day perceptions, experiences, and encounters. What seems to be to some extent in our control is how we choose to live with this appetite, how we integrate it into the rest of our lives.

But the question remains: What *is* sexual desire? What is this part of our lives that we consider to be given, prior even to our capacity to

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<sup>\* &</sup>quot;Operationalizing" refers to the way social scientists make a variable measurable. Homosexuality may be operationalized as the answers that survey respondents give to questions about their sexual orientation. Or it could be operationalized as answers to questions about their desires, attractions, and behavior. Operationalizing variables in ways that will reliably measure the trait or behavior being studied is a difficult but important part of any social science research.

deliberate and make rational choices about it? We know that some sort of sexual appetite is present in non-human animals, as is evident in the mammalian estrous cycle; in most mammalian species sexual arousal and receptivity are linked to the phase of the ovulation cycle during which the female is reproductively receptive.<sup>15</sup> One of the relatively unique features of Homo sapiens, shared with only a few other primates, is that sexual desire is not exclusively linked to the woman's ovulatory cycle.<sup>16</sup> Some biologists have argued that this means that sexual desire in humans has evolved to facilitate the formation of sustaining relationships between parents, in addition to the more basic biological purpose of reproduction. Whatever the explanation for the origins and biological functions of human sexuality, the lived experience of sexual desires is laden with significance that goes beyond the biological purposes that sexual desires and behaviors serve. This significance is not just a subjective add-on to the more basic physiological and functional realities, but something that pervades our lived experience of sexuality.

As philosophers who study the structure of conscious experience have observed, our way of experiencing the world is shaped by our "embodiment, bodily skills, cultural context, language and other social practices."<sup>17</sup> Long before most of us experience anything like what we typically associate with sexual desire, we are already enmeshed in a cultural and social context involving other persons, feelings, emotions, opportunities, deprivations, and so on. Perhaps sexuality, like other human phenomena that gradually become part of our psychological constitution, has roots in these early meaning-making experiences. If meaning-making is integral to human experience in general, it is likely to play a key role in sexual experience in particular. And given that volition is operative in these other aspects of our lives, it stands to reason that volition will be operative in our experience of sexuality too, if only as one of many other factors.

This is not to suggest that sexuality—including sexual desire, attraction, and identity—is the result of any deliberate, rational decision calculus. Even if volition plays an important role in sexuality, volition itself is quite complex: many, perhaps most, of our volitional choices do not seem to come in the form of discrete, conscious, or deliberate decisions; "volitional" does not necessarily mean "deliberate." The life of a desiring, volitional agent involves many tacit patterns of behavior owing to habits, past experiences, memories, and subtle ways of adopting and abandoning different stances on one's life.

If something like this way of understanding the life of a desiring, volitional agent is true, then we do not deliberately "choose" the objects of our

<sup>20</sup>  $\sim$  The New Atlantis

sexual desires any more than we choose the objects of our other desires. It might be more accurate to say that we gradually guide and give ourselves over to them over the course of our growth and development. This process of forming and reforming ourselves as human beings is similar to what Abraham Maslow calls self-actualization.<sup>18</sup> Why should sexuality be an exception to this process? In the picture we are offering, internal factors, such as our genetic make-up, and external environmental factors, such as past experiences, are only ingredients, however important, in the complex human experience of sexual desire.

## **Sexual Orientation**

Just as the concept of "sexual desire" is complex and difficult to define, there are currently no agreed-upon definitions of "sexual orientation," "homosexuality," or "heterosexuality" for purposes of empirical research. Should homosexuality, for example, be characterized by reference to desires to engage in particular acts with individuals of the same sex, or to a patterned history of having engaged in such acts, or to particular features of one's private wishes or fantasies, or to a consistent impulse to seek intimacy with members of the same sex, or to a social identity imposed by oneself or others, or to something else entirely?

As early as 1896, in a book on homosexuality, the French thinker Marc-André Raffalovich argued that there were more than ten different types of affective inclination or behavior captured by the term "homosexuality" (or what he called "unisexuality").<sup>19</sup> Raffalovich knew his subject matter up close: he chronicled the trial, imprisonment, and resulting social disgrace of the writer Oscar Wilde, who had been prosecuted for "gross indecency" with other men. Raffalovich himself maintained a prolonged and intimate relationship with John Gray, a man of letters thought to be the inspiration for Wilde's classic The Picture of Dorian Gray.<sup>20</sup> We might also consider the vast psychoanalytic literature from the early twentieth century on the topic of sexual desire, in which the experiences of individual subjects and their clinical cases are catalogued in great detail. These historical examples bring into relief the complexity that researchers still face today when attempting to arrive at clean categorizations of the richly varied affective and behavioral phenomena associated with sexual desire, in both same-sex and opposite-sex attractions.

We may contrast such inherent complexity with a different phenomenon that can be delineated unambiguously, such as pregnancy. With very few exceptions, a woman is or is not pregnant, which makes classification

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of research subjects for the purposes of study relatively easy: compare pregnant women with other, non-pregnant women. But how can researchers compare, say, "gay" men to "straight" men in a single study, or across a range of studies, without mutually exclusive and exhaustive definitions of the terms "gay" and "straight"?

To increase precision, some researchers categorize concepts associated with human sexuality along a continuum or scale according to variations in pervasiveness, prominence, or intensity. Some scales focus on both intensity and the objects of sexual desire. Among the most familiar and widely used is the Kinsey scale, developed in the 1940s to classify sexual desires and orientations using purportedly measurable criteria. People are asked to choose one of the following options:

- 0 Exclusively heterosexual
- 1 Predominantly heterosexual, only incidentally homosexual
- 2 Predominantly heterosexual, but more than incidentally homosexual
- 3 Equally heterosexual and homosexual
- 4 Predominantly homosexual, but more than incidentally heterosexual
- 5 Predominantly homosexual, only incidentally heterosexual
- 6 Exclusively homosexual<sup>21</sup>

But there are considerable limitations to this approach. In principle, measurements of this sort are valuable for social science research. They can be used, for example, in empirical tests such as the classic "t-test," which helps researchers measure statistically meaningful differences between data sets. Many measurements in social science, however, are "ordinal," meaning that variables are rank-ordered along a single, one-dimensional continuum but are not intrinsically significant beyond that. In the case of the Kinsey scale, this situation is even worse, because it measures the self-identification of individuals, while leaving unclear whether the values they report all refer to the same aspect of sexuality-different people may understand the terms "heterosexual" and "homosexual" to refer to feelings of attraction, or to arousal, or to fantasies, or to behavior, or to any combination of these. The ambiguity of the terms severely limits the use of the Kinsey scale as an ordinal measurement that gives a rank order to variables along a single, onedimensional continuum. So it is not clear that this scale helps researchers to make even rudimentary classifications among the relevant groups using qualitative criteria, much less to rank-order variables or conduct controlled experiments.

 $<sup>22 \</sup>sim \mathrm{The} \ \mathrm{New} \ \mathrm{Atlantis}$ 

Perhaps, given the inherent complexity of the subject matter, attempts to devise "objective" scales of this sort are misguided. In a critique of such approaches to social science, philosopher and neuropsychologist Daniel N. Robinson points out that "statements that lend themselves to different interpretation do not become 'objective' merely by putting a numeral in front of them."<sup>22</sup> It may be that self-reported identifications with culturally fraught and inherently complex labels simply cannot provide an objective basis for quantitative measurements in individuals or across groups.

Another obstacle for research in this area may be the popular, but not well-supported, belief that romantic desires are sublimations of sexual desires. This idea, traceable to Freud's theory of unconscious drives, has been challenged by research on "attachment theory," developed by John Bowlby in the 1950s.<sup>23</sup> Very roughly, attachment theory holds that later affective experiences that are often grouped under the general rubric "romantic" are explained in part by early childhood attachment behaviors (associated with maternal figures or caregivers)—not by unconscious, sexual drives. Romantic desires, following this line of thought, might not be as strongly correlated with sexual desires as is commonly thought. All of this is to suggest that simple delineations of the concepts relating to human sexuality cannot be taken at face value and that ongoing empirical research sometimes changes or complicates the meanings of the concepts.

If we look at recent research, we find that scientists often use at least one of three categories when attempting to classify people as "homosexual" or "heterosexual": sexual *behavior*; sexual *fantasies* (or related emotional or affective experiences); and *self-identification* (as "gay," "lesbian," "bisexual," "asexual," and so forth).<sup>24</sup> Some add a fourth: inclusion in a community defined by sexual orientation. Consider, for example, the American Psychological Association's definition of sexual orientation in a 2008 document designed to educate the public:

Sexual orientation refers to an enduring pattern of emotional, romantic and/or sexual *attractions* to men, women or both sexes. Sexual orientation also refers to a person's sense of *identity* based on those attractions, related *behaviors*, and membership in a *community* of others who share those attractions. Research over several decades has demonstrated that sexual orientation ranges along a *continuum*, from exclusive attraction to the other sex to exclusive attraction to the same sex.<sup>25</sup> [Emphases added.]

One difficulty with grouping these categories together under the same general rubric of "sexual orientation" is that research suggests they often

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do not coincide in real life. Sociologist Edward O. Laumann and colleagues summarize this point clearly in a 1994 book:

While there is a core group (about 2.4 percent of the total men and about 1.3 percent of the total women) in our survey who *define themselves* as homosexual or bisexual, have same-gender *partners*, and express homosexual *desires*, there are also sizable groups who do not consider themselves to be either homosexual or bisexual but have had adult homosexual experiences or express some degree of desire....[T]his preliminary analysis provides unambiguous evidence that no single number can be used to provide an accurate and valid characterization of the incidence and prevalence of homosexuality in the population at large. In sum, homosexuality is fundamentally a multidimensional phenomenon that has manifold meanings and interpretations, depending on context and purpose.<sup>26</sup> [Emphases added.]

More recently, in a 2002 study, psychologists Lisa M. Diamond and Ritch C. Savin-Williams make a similar point:

The more carefully researchers map these constellations—differentiating, for example, between *gender identity* and *sexual identity, desire* and *behavior, sexual* versus *affectionate* feelings, early-appearing versus late-appearing *attractions* and *fantasies*, or social *identifications* and sexual *profiles*—the more complicated the picture becomes because few individuals report uniform inter-correlations among these domains.<sup>27</sup> [Emphases added.]

Some researchers acknowledge the difficulties with grouping these various components under a single rubric. For example, researchers John C. Gonsiorek and James D. Weinrich write in a 1991 book: "It can be safely assumed that there is no necessary relationship between a person's sexual behavior and self-identity unless both are individually assessed."<sup>28</sup> Likewise, in a 1999 review of research on the development of sexual orientation in women, social psychologist Letitia Anne Peplau argues: "There is ample documentation that same-sex attractions and behaviors are not inevitably or inherently linked to one's identity."<sup>29</sup>

In sum, the complexities surrounding the concept of "sexual orientation" present considerable challenges for empirical research on the subject. While the general public may be under the impression that there are widely accepted scientific definitions of terms such as "sexual orientation," in fact, there are not. Diamond's assessment of the situation in 2003 is still true today, that "there is currently no scientific or popular consensus on

<sup>24</sup>  $\sim$  The New Atlantis

the exact constellation of experiences that definitively 'qualify' an individual as lesbian, gay, or bisexual."  $^{30}$ 

It is owing to such complexities that some researchers, for instance Laumann, proceed by characterizing sexual orientation as a "multidimensional phenomenon." But one might just as well wonder whether, in trying to shoehorn this "multidimensional phenomenon" into a single category, we are not reifying a concept that corresponds to something far too plastic and diffuse in reality to be of much value in scientific research. While labels such as "heterosexual" and "homosexual" are often taken to designate stable psychological or even biological traits, perhaps they do not. It may be that individuals' affective, sexual, and behavioral experiences do not conform well to such categorical labels because these labels do not, in fact, refer to natural (psychological or biological) kinds. At the very least, we should recognize that we do not yet possess a clear and well-established framework for research on these topics. Rather than attempting to research sexual desire, attraction, identity, and behavior under the general rubric of "sexual orientation," we might do better to examine empirically each domain separately and in its own specificity.

To that end, this part of our report considers research on sexual desire and sexual attraction, focusing on the empirical findings related to etiology and development, and highlighting the underlying complexities. We will continue to employ ambiguous terms like "sexual orientation" where they are used by the authors we discuss, but we will try to be attentive to the context of their use and the ambiguities attaching to them.

# Challenging the "Born that Way" Hypothesis

Keeping in mind these reflections on the problems of definitions, we turn to the question of how sexual desires originate and develop. Consider the different patterns of attraction between individuals who report experiencing predominant sexual or romantic attraction toward members of the same sex and those who report experiencing predominant sexual or romantic attraction toward members of the opposite sex. What are the causes of these two patterns of attraction? Are such attractions or preferences innate traits, perhaps determined by our genes or prenatal hormones; are they acquired by experiential, environmental, or volitional factors; or do they develop out of some combination of both kinds of causes? What role, if any, does human agency play in the genesis of patterns of attraction? What role, if any, do cultural or social influences play?

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Research suggests that while genetic or innate factors may influence the emergence of same-sex attractions, these biological factors cannot provide a complete explanation, and environmental and experiential factors may also play an important role.

The most commonly accepted view in popular discourse we mentioned above—the "born that way" notion that homosexuality and heterosexuality are biologically innate or the product of very early developmental factors—has led many non-specialists to think that homosexuality or heterosexuality is in any given person unchangeable and determined entirely apart from choices, behaviors, life experiences, and social contexts. However, as the following discussion of the relevant scientific literature shows, this is not a view that is well-supported by research.

## **Studies of Twins**

One powerful research design for assessing whether biological or psychological traits have a genetic basis is the study of identical twins. If the probability is high that both members in a pair of identical twins, who share the same genome, exhibit a trait when one of them does—this is known as the concordance rate—then one can infer that genetic factors are likely to be involved in the trait. If, however, the concordance rate for identical twins is no higher than the concordance rate of the same trait in fraternal twins, who share (on average) only half their genes, this indicates that the shared environment may be a more important factor than shared genes.

One of the pioneers of behavioral genetics and one of the first researchers to use twins to study the effect of genes on traits, including sexual orientation, was psychiatrist Franz Josef Kallmann. In a landmark paper published in 1952, he reported that for all the pairs of identical twins he studied, if one of the twins was gay then both were gay, yielding an astonishing 100% concordance rate for homosexuality in identical twins.<sup>31</sup> Were this result replicated and the study designed better, it would have given early support to the "born that way" hypothesis. But the study was heavily criticized. For example, philosopher and law professor Edward Stein notes that Kallmann did not present any evidence that the twins in his study were in fact genetically identical, and his sample was drawn from psychiatric patients, prisoners, and others through what Kallmann described as "direct contacts with the clandestine homosexual world," leading Stein to argue that Kallmann's sample "in no way constituted a reasonable cross-section of the homosexual population."<sup>32</sup>

<sup>26 ~</sup> The New Atlantis

(Samples such as Kallmann's are known as convenience samples, which involve selecting subjects from populations that are conveniently accessible to the researcher.)

Nevertheless, well-designed twin studies examining the genetics of homosexuality indicate that genetic factors likely play some role in determining sexual orientation. For example, in 2000, psychologist J. Michael Bailey and colleagues conducted a major study of sexual orientation using twins in the Australian National Health and Medical Research Council Twin Registry, a large probability sample, which was therefore more likely to be representative of the general population than Kallmann's.<sup>33</sup> The study employed the Kinsey scale to operationalize sexual orientation and estimated concordance rates for being homosexual of 20% for men and 24% for women in identical (maternal, monozygotic) twins, compared to 0% for men and 10% for women in non-identical (fraternal, dizygotic) twins.34 The difference in the estimated concordance rates was statistically significant for men but not for women. On the basis of these findings, the researchers estimated that the heritability of homosexuality for men was 0.45 with a wide 95% confidence interval of 0.00-0.71; for women, it was 0.08 with a similarly wide confidence interval of 0.00-0.67. These estimates suggest that for males 45% of the differences between certain sexual orientations (homosexual versus heterosexuals as measured by the Kinsey scale) could be attributed to differences in genes.

The large confidence intervals in the study by Bailey and colleagues mean that we must be careful in assessing the substantive significance of these findings. The authors interpret their findings to suggest that "any major gene for strictly defined homosexuality has either low penetrance or low frequency,"<sup>35</sup> but their data did show (marginal) statistical significance. While the concordance estimates seem somewhat high in the models used, the confidence intervals are so wide that it is difficult to judge the reliability, including the replicability, of these estimates.

It is worth clarifying here what "heritability" means in these studies, since the technical meaning in population genetics is narrower and more precise than the everyday meaning of the word. Heritability is a measure of how much variation in a particular trait within a population can be attributed to variation in genes in that population. It is not, however, a measure of how much a trait is genetically determined.

Traits that are almost entirely genetically determined can have very low heritability values, while traits that have almost no genetic basis can be found to be highly heritable. For instance, the number of fingers human beings have is almost completely genetically determined. But there is little

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*variation* in the number of fingers humans have, and most of the variation we do see is due to non-genetic factors such as accidents, which would lead to low heritability estimates for the trait. Conversely, cultural traits can sometimes be found to be highly heritable. For instance, whether a given individual in mid-twentieth century America wore earrings would have been found to be highly heritable, because it was highly associated with being male or female, which is in turn associated with possessing XX or XY sex chromosomes, making variability in earring-wearing behavior highly associated with genetic differences, despite the fact that wearing earrings is a cultural rather than biological phenomenon. Today, heritability estimates for earring-wearing behavior would be lower than they were in mid-twentieth century America, not because of any changes in the American gene pool, but because of the increased acceptance of men wearing earrings.<sup>36</sup>

So, a heritability estimate of 0.45 does not mean that 45% of sexuality is determined by genes. Rather, it means that 45% of the variation between individuals in the population studied can be attributed in some way to genetic factors, as opposed to environmental factors.

In 2010, psychiatric epidemiologist Niklas Långström and colleagues conducted a large, sophisticated twin study of sexual orientation, analyzing data from 3,826 identical and fraternal same-sex twin pairs (2,320 identical and 1,506 fraternal pairs).<sup>37</sup> The researchers operationalized homosexuality in terms of lifetime same-sex sexual partners. The sample's concordance rates were somewhat lower than those found in the study by Bailey and colleagues. For having had at least one same-sex partner, the concordance for men was 18% in identical twins and 11% in fraternal twins; for women, 22% and 17%, respectively. For total number of sexual partners, concordance rates for men were 5% in identical twins and 0% in fraternal twins; for women, 11% and 7%, respectively.

For men, these rates suggest an estimated heritability rate of 0.39 for having had at least one lifetime same-sex partner (with a 95% confidence interval of 0.00–0.59), and 0.34 for total number of same-sex partners (with a 95% confidence interval of 0.00–0.53). Environmental factors experienced by one twin but not the other explained 61% and 66% of the variance, respectively, while environmental factors shared by the twins failed to explain any of the variance. For women, the heritability rate for having had at least one lifetime same-sex partner was 0.19 (95% confidence interval of 0.00–0.49); for total number of same-sex partners, it was 0.18 (95% confidence interval of 0.11–0.45). Unique environmental factors accounted for 64% and 66% of the variance, respectively, while

<sup>28</sup>  $\sim$  The New Atlantis

shared environmental factors accounted for 17% and 16%, respectively. These values indicate that, while the genetic component of homosexual behavior is far from negligible, non-shared environmental factors play a critical, perhaps preponderant, role. The authors conclude that sexual orientation arises from both heritable and environmental influences unique to the individual, stating that "the present results support the notion that the individual-specific environment does indeed influence sexual preference."<sup>38</sup>

Another large and nationally representative study of twins published by sociologists Peter S. Bearman and Hannah Brückner in 2002 used data from the National Longitudinal Study of Adolescent to Adult Health (commonly abbreviated as "Add Health") of adolescents in grades 7-12.39 They attempted to estimate the relative influence of social factors, genetic factors, and prenatal hormonal factors on the development of same-sex attractions. Overall, 8.7% of the 18,841 adolescents in their study reported same-sex attractions, 3.1% reported a same-sex romantic relationship, and 1.5% reported same-sex sexual behavior. The authors first analyzed the "social influence hypothesis," according to which opposite-sex twins receive less gendered socialization from their families than same-sex twins or opposite-sex siblings, and found that this hypothesis was well-supported in the case of males. While female opposite-sex twins in the study were the least likely of all the groups to report same-sex attractions (5.3%), male opposite-sex twins were the likeliest to report same-sex attractions (16.8%)—more than twice as likely as males with a full, non-twin sister (16.8% vs. 7.3%). The authors concluded there was "substantial indirect evidence in support of a socialization model at the individual level."40

The authors also examined the "intrauterine hormone transfer hypothesis," according to which prenatal hormone transfers between oppositesex twin fetuses influences the sexual orientation of the twins. (Note that this is different from the more general hypothesis that prenatal hormones influence the development of sexual orientation.) In the study, the proportion of male opposite-sex twins reporting same-sex attraction was about twice as high for those without older brothers (18.7%) as for those with older brothers (8.8%). The authors argued that this finding was strong evidence against the hormone-transfer hypothesis, since the presence of older brothers should not decrease the likelihood of same-sex attraction if that attraction has a basis in prenatal hormonal transfers. However, that conclusion seems premature: the observations are consistent with the possibility of *both* hormonal factors *and* the presence of an older brother having an effect (especially if the latter influences the former). This study

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also found no correlation between experiencing same-sex attraction and having multiple older brothers, which had been reported in some earlier studies.  $^{41}$ 

Finally, Bearman and Brückner did not find evidence of significant genetic influence on sexual attraction. Significant influence would require that identical twins have significantly higher concordance rates for samesex attraction than fraternal twins or non-twin siblings. But in the study, the rates were statistically similar: identical twins were 6.7% concordant, dizygotic pairs 7.2% concordant, and full siblings 5.5% concordant. The authors concluded that "it is more likely that any genetic influence, if present, can only be expressed in specific and circumscribed social structures."42 Based on their data, they suggested the one observed social structure that might enable this genetic expression is the more limited "gender socialization associated with firstborn OS [opposite-sex] twin pairs."43 Thus, they inferred that their results "support the hypothesis that less gendered socialization in early childhood and preadolescence shapes subsequent same-sex romantic preferences."44 While the findings here are suggestive, further research is needed to confirm this hypothesis. The authors also argued that the higher concordance rates for same-sex attraction reported in previous studies may be unreliable due to methodological problems such as non-representative samples and small sample sizes. (It should be noted, however, that these remarks were published prior to the study by Långström and colleagues discussed above, which uses a study design that does not appear to have these limitations.)

To reconcile the somewhat mixed data on heritability, we could hypothesize that attraction to the same sex may have a stronger heritable component as people age—that is, when researchers attempt to measure sexual orientation later in life (as in the 2010 study by Långström and colleagues) than when measured earlier in life. Heritability estimates can change depending on the age at which a trait is measured because changes in the environmental factors that might influence variation in the trait may vary for individuals at different ages, and because genetically influenced traits may become more fixed at a later stage in an individual's development (height, for instance, becomes fixed in early adulthood). This hypothesis is also suggested by findings, discussed below, that same-sex attraction may be more fluid in adolescence than in later stages of adulthood.

In contrast to the studies just summarized, psychiatrist Kenneth S. Kendler and colleagues conducted a large twin study using a probability sample of 794 twin pairs and 1,380 non-twin siblings.<sup>45</sup> Based on concordance rates for sexual orientation (defined in this study as self-iden-

<sup>30</sup>  $\sim$  The New Atlantis

tification based on attraction), the authors state that their results "suggest that genetic factors may provide an important influence on sexual orientation."<sup>46</sup> The study does not, however, appear to be sufficiently powerful to draw strong conclusions about the degree of genetic influence on sexuality: only 19 of 324 identical twin pairs had any non-heterosexual member, with 6 of the 19 pairs concordant; 15 of 240 same-sex fraternal twin pairs had any non-heterosexual member, with 2 of the 15 pairs concordant. Because only 8 twin pairs were concordant for non-heterosexuality, the study's ability to draw substantively significant comparisons between identical and fraternal twins (or between twins and non-twin siblings) is limited.

Overall, these studies suggest that (depending on how homosexuality is defined) in anywhere from 6% to 32% of cases, both members of an identical twin pair would be homosexual if at least one member is. Since some twin studies found higher concordance rates in identical twins than in fraternal twins or non-twin siblings, there may be genetic influences on sexual desire and behavioral preferences. One needs to bear in mind that identical twins typically have even more similar environments—early attachment experiences, peer relationships, and the like—than fraternal twins or non-twin siblings. Because of their similar appearances and temperaments, for example, identical twins may be more likely than fraternal twins or other siblings to be treated similarly. So some of the higher concordance rates may be attributable to environmental factors rather than genetic factors. In any case, if genes do play a role in predisposing people toward certain sexual desires or behaviors, these studies make clear that genetic influences cannot be the whole story.

Summarizing the studies of twins, we can say that there is no reliable scientific evidence that sexual orientation is determined by a person's genes. But there is evidence that genes play a role in influencing sexual orientation. So the question "Are gay people born that way?" requires clarification. There is virtually no evidence that anyone, gay or straight, is "born that way" if that means their sexual orientation was genetically determined. But there is some evidence from the twin studies that certain genetic profiles probably increase the likelihood the person later identifies as gay or engages in same-sex sexual behavior.

Future twin studies on the heritability of sexual orientation should include analyses of larger samples or meta-analyses or other systematic reviews to overcome the limited sample size and statistical power of some of the existing studies, and analyses of heritability rates across different dimensions of sexuality (such as attraction, behavior, and identity) to

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overcome the imprecisions of the ambiguous concept of sexual orientation and the limits of studies that look at only one of these dimensions of sexuality.

## **Molecular Genetics**

In examining the question whether, and perhaps to what extent, there may be genetic contributions to homosexuality, we have so far looked at studies that employ methods of classical genetics to estimate the heritability of a trait like sexual orientation but that do not identify particular genes that may be associated with the trait.<sup>47</sup> But genetics can also be studied using what are often called molecular methods that provide estimates of which particular genetic variations are associated with traits, whether physical or behavioral.

One early attempt to identify a more specific genetic basis for homosexuality was a 1993 study by geneticist Dean Hamer and colleagues of 40 pairs of homosexual brothers.<sup>48</sup> By examining the family history of homosexuality for these individuals, they identified a possible linkage between homosexuality in males and genetic markers on the Xq28 region of the X chromosome. Attempts to replicate this influential study's results have had mixed results: George Rice and colleagues attempted and failed to replicate Hamer's findings,<sup>49</sup> though in 2015 Alan R. Sanders and colleagues were able to replicate Hamer's original findings using a larger population size of 409 male twin pairs of homosexual brothers, and to find additional genetic linkage sites.<sup>50</sup> (Since the effect was small, however, the genetic marker would not be a good predictor of sexual orientation.)

Genetic linkage studies like the ones discussed above are able to identify particular regions of chromosomes that may be associated with a trait by looking at patterns of inheritance. Today, one of the chief methods for inferring which genetic variants are associated with a trait is the genome-wide association study, which uses DNA sequencing technologies to identify particular differences in DNA that may be associated with a trait. Scientists examine millions of genetic variants in large numbers of individuals who have a particular trait, as well as individuals who do not have the trait, and compare the frequency of genetic variants that occur more frequently among those who have than those who do not have the trait are inferred to have some association with that trait. Genome-wide association studies have become popular in recent years, yet few such scientific studies have found significant associations of genetic variants with sexual

 $<sup>32 \</sup>sim$  The New Atlantis

orientation. The largest attempt to identify genetic variants associated with homosexuality, a study of over 23,000 individuals from the 23andMe database presented at the American Society of Human Genetics annual meeting in 2012, found no linkages reaching genome-wide significance for same-sex sexual identity for males or females.<sup>51</sup>

So, again, the evidence for a genetic basis for homosexuality is inconsistent and inconclusive, which suggests that, though genetic factors explain some of the variation in sexual orientation, the genetic contribution to this trait is not likely to be strong and even less likely to be decisive.

As is often true of human behavioral tendencies, there may be genetic contributions to the tendency toward homosexual inclinations or behaviors. Phenotypic expression of genes is usually influenced by environmental factors—different environments may lead to different phenotypes even for the same genes. So even if there are genetic factors that contribute to homosexuality, an individual's sexual attractions or preferences may also be influenced by a number of environmental factors, such as social stressors, including emotional, physical, or sexual abuse. Looking to developmental, environmental, experiential, social, or volitional factors will be necessary to arrive at a fuller picture of how sexual interests, attractions, and desires develop.

## The Limited Role of Genetics

Lay readers might note at this point that even at the purely biological level of genetics, the shopworn "nature vs. nurture" debates regarding human psychology have been abandoned by scientists, who recognize that no credible hypothesis can be offered for any particular traits that would be determined either purely by genetics or the environment. The growing field of epigenetics, for example, demonstrates that even for relatively simple traits, gene expression itself can be influenced by innumerable other external factors that can shape the functioning of genes.<sup>52</sup> This is even more relevant when it comes to the relationship between genes and complex traits like sexual attraction, drives, and behaviors.

These gene-environment relationships are complex and multidimensional. Non-genetic developmental factors and environmental experiences may be sculpted, in part, by genetic factors working in subtle ways. For example, social geneticists have documented the indirect role of genes in peer-aligned behaviors, such that an individual's physical appearance could influence whether a particular social group will include or exclude that individual.<sup>53</sup>

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Contemporary geneticists know that genes can influence a person's range of interests and motivations, therefore indirectly affecting behavior. While genes may in this way incline a person to certain behaviors, compelling behavior directly, independently of a wide range of other factors, seems less plausible. They may influence behavior in more subtle ways, depending on external environmental stimuli (for instance, peer pressure, suggestion, and behavioral rewards) in conjunction with psychological factors and physical makeup. Dean Hamer, whose work on the possible role of genetics in homosexuality was examined above, explained some of the limitations of behavioral genetics in a 2002 article in Science: "The real culprit [of lack of progress in behavioral genetics] is the assumption that the rich complexity of human thought and emotion can be reduced to a simple, linear relation between individual genes and behaviors....This oversimplified model, which underlies most current research in behavior genetics, ignores the critical importance of the brain, the environment, and gene expression networks."54

The genetic influences affecting any complex human behavior whether sexual behaviors, or interpersonal interactions—depend in part on individuals' life experiences as they mature. Genes constitute only one of the many key influences on behavior in addition to environmental influences, personal choices, and interpersonal experiences. The weight of evidence to date strongly suggests that the contribution of genetic factors is modest. We can say with confidence that genes are not the sole, essential cause of sexual orientation; there is evidence that genes play a modest role in contributing to the development of sexual attractions and behaviors but little evidence to support a simplistic "born that way" narrative concerning the nature of sexual orientation.

## The Influence of Hormones

Another area of research relevant to the hypothesis that people are born with dispositions toward different sexual orientations involves prenatal hormonal influences on physical development and subsequent male- or female-typical behaviors in early childhood. For ethical and practical reasons, the experimental work in this field is carried out in non-human mammals, which limits how this research can be generalized to human cases. However, children who are born with disorders of sexual development (DSD) serve as a population in which to examine the influence of genetic and hormonal abnormalities on the subsequent development of non-typical sexual identity and sexual orientation.

<sup>34</sup>  $\sim$  The New Atlantis

Hormones responsible for sexual differentiation are generally thought to exert on the developing fetus either *organizational* effects—which produce permanent changes in the wiring and sensitivity of the brain, and thus are considered largely irreversible—or *activating* effects, which occur later in an individual's life (at puberty, and into adulthood).<sup>55</sup> Organizational hormones may prime the fetal systems (including the brain) structurally, and set the stage for sensitivity to hormones presenting at puberty and beyond, when the hormone will then "activate" systems which were "organized" prenatally.

Periods of peak response to the hormonal environment are thought to occur during gestation. For example, testosterone is thought to influence the male fetus maximally between weeks 8 and 24, and then again at birth, until about three months of age.<sup>56</sup> Estrogens are provided throughout gestation by the placenta and the mother's blood system.<sup>57</sup> Studies in animals reveal there may even be multiple periods of sensitivity for a variety of hormones, that the presence of one hormone may influence the action of another hormone, and the sensitivity of the receptors for these hormones can influence their actions.<sup>58</sup> Sexual differentiation, alone, is a highly complex system.

Specific hormones of interest in this area of research are testosterone, dihydrotestosterone (a metabolite of testosterone, and more potent than testosterone), estradiol, progesterone, and cortisol. The generally accepted pathways of normal hormonal influence of development in utero are as follows. The typical pattern of sex differentiation in human fetuses begins with the differentiation of the sex organs into testes or ovaries, a process that is largely genetically controlled. Once these organs have differentiated, they produce specific hormones that determine development of external genitalia. This window of time in gestation is when hormones exert their phenotypic and neurological effects. Testosterone secreted by the testes contributes to the development of male external genitalia and affects neurological development in males;<sup>59</sup> it is the absence of testosterone in females which allows for the female pattern of external genitalia to develop.<sup>60</sup> Imbalances of testosterone or estrogen, as well as their presence or absence at specific critical periods of gestation, may cause disorders of sexual development. (Genetic or environmental effects can also lead to disorders of sexual development.)

Stress may also play some role in influencing the way hormones shape gonadal development, neurodevelopment, and subsequent sex-typical behaviors in early childhood.<sup>61</sup> Cortisol is the main hormone associated

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with stress responses. It may originate from the mother, if she experiences severe stressors during her pregnancy, or from the fetus under stress.<sup>62</sup> Elevated levels of cortisol may also occur from genetic defects.<sup>63</sup> One of the most extensively studied disorders of sexual development is congenital adrenal hyperplasia (CAH), which in females can result in genital virilization.<sup>64</sup> Over 90% of cases of CAH result from a mutation in a gene that codes for an enzyme that helps synthesize cortisol.<sup>65</sup> This results in an overproduction of cortisol precursors, some of which are converted into androgens (hormones associated with male sex development).<sup>66</sup> As a result, girls are born with some degree of virilization of their genitalia, depending on the severity of the genetic defect.<sup>67</sup> For severe cases of genital virilization, surgical intervention is sometimes performed to normalize the genitalia. Hormone therapies are also often administered to mitigate the effects of excess androgen production.<sup>68</sup> Females with CAH, who as fetuses were exposed to above-average levels of androgens, are less likely to be exclusively heterosexual than females without CAH, and females with more severe forms of CAH are more likely to be non-heterosexual than females with milder forms of the condition.<sup>69</sup>

Likewise, there are disorders of sexual development in genetic males affected by androgen insensitivity. In males with androgen insensitivity syndrome, the testes produce testosterone normally, but the receptors to testosterone are not functional.<sup>70</sup> The genitalia, at birth, appear to be female, and the child is usually raised as a female. The individual's endogenous testosterone is broken down into estrogen, such that the individual begins to develop female secondary sex characteristics.<sup>71</sup> It does not become apparent that there is a problem until puberty, when the individual does not start menses appropriately.<sup>72</sup> These patients generally prefer to continue life as females, and their sexual orientation does not differ from females having an XX genotype.<sup>73</sup> Studies have suggested that they are just as likely if not more likely to be exclusively interested in male partners than XX females.<sup>74</sup>

There are other disorders of sexual development affecting some genetic males (i.e., with an XY genotype) in whom androgen deficiencies are a direct result of the lack of enzymes either to synthesize dihydrotestosterone from testosterone or to produce testosterone from its precursor hormone.<sup>75</sup> Individuals with these deficiencies are born with varied degrees of ambiguous genitalia, and are sometimes raised as girls. During puberty, however, these individuals often experience physical virilization, and must then decide whether to live as men or women. Peggy T. Cohen-Kettenis, a professor of gender development and psychopathology, found that 39 to

<sup>36</sup>  $\sim$  The New Atlantis

64% of individuals with these deficiencies who are raised as girls change to live as men in adolescence and early adulthood, and she also reported that "the degree of external genital masculinization at birth does not seem to be related to gender role changes in a systematic way."<sup>76</sup>

The twin studies reviewed earlier may shed light on the role of maternal hormonal influences, since both identical and fraternal twins are exposed to similar maternal hormonal influences in utero. The relatively weak concordance rates in the twin studies suggest that prenatal hormones, like genetic factors, do not play a strongly determinative role in sexual orientation. Other attempts at finding significant hormonal influences on sexual development have likewise been mixed, and the salience of the findings is not yet clear. Since direct studies of prenatal hormonal influences on sexual development are methodologically difficult, some studies have tried to develop models whereby differences in prenatal hormonal exposure can be inferred indirectly—by measuring subtle morphological changes or by examining hormonal disorders that are present later during development.

For example, one rough proxy of prenatal testosterone levels used by researchers is the ratio between the length of the second finger (index finger) and the fourth finger (ring finger), which is commonly called the "2D:4D ratio." Some evidence suggests that the ratio may be influenced by prenatal exposure to testosterone, such that in males higher levels of exposure to testosterone cause shorter index fingers relative to the ring finger (or having a low 2D:4D ratio), and vice versa.<sup>77</sup> According to one hypothesis, homosexual men may have a higher 2D:4D ratio (closer to the ratio found in females than in heterosexual males), while another hypothesis suggests the opposite, that homosexual men may be hypermasculinized by prenatal testosterone, resulting in a lower ratio than in heterosexual men. For women, the hypothesis for homosexuality that they have been hypermasculinized (lower ratio, higher testosterone) has also been proposed. Several studies comparing this trait in homosexually versus heterosexually identified men and women have shown mixed results.

A study published in *Nature* in 2000 found that in a sample of 720 California adults, the right-hand 2D:4D ratio of homosexual women was significantly more masculine (that is, the ratio was smaller) than that of heterosexual women and did not differ significantly from that of heterosexual men.<sup>78</sup> This study also found no significant difference in mean 2D:4D ratio between heterosexual and homosexual men. Another study that year, which used a relatively small sample of homosexual and heterosexual men from the United Kingdom, reported a lower 2D:4D (that

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is, more masculine) ratio in homosexual men.<sup>79</sup> A 2003 study using a London-based sample also found that homosexual men had a lower 2D:4D ratio than heterosexuals,<sup>80</sup> while two other studies with samples from California and Texas showed *higher* 2D:4D ratios for homosexual men.<sup>81</sup>

A 2003 twin study compared seven female monozygotic twin pairs discordant for homosexuality (one twin was lesbian) and five female monozygotic twin pairs concordant for homosexuality (both twins were lesbian).<sup>82</sup> In the twin pairs discordant for sexual orientation, the individuals identifying as homosexual had significantly lower 2D:4D ratios than their twins, whereas the concordant twins showed no difference. The authors interpreted this result as suggesting that "low 2D:4D ratio is a result of differences in prenatal environment."<sup>83</sup> Finally, a 2005 study of 2D:4D ratios in an Austrian sample of 95 homosexual and 79 heterosexual men found that the 2D:4D ratios of heterosexual men were not significantly different from those of homosexual men.<sup>84</sup> After reviewing the several studies on this trait, the authors conclude that "more data are essential before we can be sure whether there is a 2D:4D effect for sexual orientation in men when ethnic variation is controlled for."<sup>85</sup>

Much research has examined the effects of prenatal hormones on behavior and brain structure. Again, these results come primarily from studies of non-human primates, but the study of disorders of sexual development has provided helpful insights into the effects of hormones on sexual development in humans. Since hormonal influences typically occur during time-sensitive periods of development, when their effects manifest physically, it is reasonable to assume that organizational effects of these early, time-linked hormonal patterns are likely to direct aspects of neural development. Neuroanatomical connectivity and neurochemical sensitivities may be among such influences.

In 1983, Günter Dörner and colleagues performed a study investigating whether there is any relationship between maternal stress during pregnancy and later sexual identity of their children, interviewing two hundred men about stressful events that may have occurred to their mothers during their prenatal lives.<sup>86</sup> Many of these events occurred as a consequence of World War II. Of men who reported that their mothers had experienced moderately to severely stressful events during pregnancy, 65% were homosexual, 25% were bisexual, and 10% were heterosexual. (Sexual orientation was assessed using the Kinsey scale.) However, more recent studies have shown much smaller or no significant correlations.<sup>87</sup> In a 2002 prospective study on the relationship between sexual orientation and prenatal stress during the second and third trimesters, Hines

<sup>38</sup>  $\sim$  The New Atlantis

and colleagues found that stress reported by mothers during pregnancy showed "only a small relationship" to male-typical behaviors in their daughters at the age of 42 months, "and no relationship at all" to female-typical behaviors in their sons.<sup>88</sup>

In summary, some forms of prenatal hormone exposure, particularly CAH in females, are associated with differences in sexual orientation, while other factors are often important in determining the physical and psychological effects of those exposures. Hormonal conditions that contribute to disorders of sex development may contribute to the development of non-heterosexual orientations in some individuals, but this does not demonstrate that such factors explain the development of sexual attractions, desires, and behaviors in the majority of cases.

## Sexual Orientation and the Brain

There have been several studies examining neurobiological differences between individuals who identify as heterosexual and those who identify as homosexual. This work began with neuroscientist Simon LeVay's 1991 study that reported biological differences in the brains of gay men as compared to straight men-specifically, a difference in volume in a particular cell group of the interstitial nuclei of the anterior hypothalamus (INAH3).<sup>89</sup> Later work by psychiatrist William Byne and colleagues showed more nuanced findings: "In agreement with two prior studies... we found INAH3 to be sexually dimorphic, occupying a significantly greater volume in males than females. In addition, we determined that the sex difference in volume was attributable to a sex difference in neuronal number and not in neuronal size or density."90 The authors noted that, "Although there was a trend for INAH3 to occupy a smaller volume in homosexual men than in heterosexual men, there was no difference in the number of neurons within the nucleus based on sexual orientation." They speculated that "postnatal experience" may account for the differences in volume in this region between homosexual and heterosexual men, though this would require further research to confirm.<sup>91</sup> They also noted that the functional significance of sexual dimorphism in INAH3 is unknown. The authors conclude: "Based on the results of the present study as well as those of LeVay (1991), sexual orientation cannot be reliably predicted on the basis of INAH3 volume alone."92 In 2002, psychologist Mitchell S. Lasco and colleagues published a study examining a different part of the brain-the anterior commissure-and found that there were no significant differences in that area based either on sex or sexual orientation.93

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Other studies have since been conducted to ascertain structural or functional differences between the brains of heterosexual and homosexual individuals (using a variety of criteria to define these categories). Findings from several of these studies are summarized in a 2008 commentary published in the Proceedings of the National Academy of Sciences.94 Research of this kind, however, does not seem to reveal much of relevance regarding the etiology or biological origins of sexual orientation. Due to inherent limitations, this research literature is fairly unremarkable. For example, in one study functional MRI was used to measure activity changes in the brain when pictures of men and women were shown to subjects, finding that viewing a female face produced stronger activity in the thalamus and orbitofrontal cortex of heterosexual men and homosexual women, whereas in homosexual men and heterosexual women these structures reacted more strongly to the face of a man.<sup>95</sup> That the brains of heterosexual women and homosexual men reacted distinctively to the faces of men, whereas the brains of heterosexual men and homosexual women reacted distinctively to the faces of women, is a finding that seems rather trivial with respect to understanding the etiology of homosexual attractions. In a similar vein, one study reported different responses to pheromones between homosexual and heterosexual men,<sup>96</sup> and a follow-up study showed a similar finding in homosexual compared to heterosexual women.97 Another study showed differences in cerebral asymmetry and functional connectivity between homosexual and heterosexual subjects.98

While findings of this kind may suggest avenues for future investigation, they do not move us much closer to an understanding of the biological or environmental determinants of sexual attractions, interests, preferences, or behaviors. We will say more about this below. For now, we will briefly illustrate a few of the inherent limitations in this area of research with the following hypothetical example. Suppose we were to study the brains of yoga teachers and compare them to the brains of bodybuilders. If we search long enough, we will eventually find statistically significant differences in some area of brain morphology or brain function between these two groups. But this would not imply that such differences determined the different life trajectories of the yoga teacher and the bodybuilder. The brain differences could have been the result, rather than the cause, of distinctive patterns of behavior or interests.<sup>99</sup> Consider another example. Suppose that gay men tend to have less body fat than straight men (as indicated by lower average scores on body mass indices). Even though body mass is, in part, determined by genetics, we could not claim based on this finding that there is some innate, genetic cause of both body

<sup>40</sup>  $\sim$  The New Atlantis

mass and homosexuality at work. It could be the case, for instance, that being gay is associated with a diet that lowers body mass. These examples illustrate one of the common problems encountered in the popular interpretation of such research: the suggestion that the neurobiological pattern determines a particular behavioral expression.

With this overview of studies on biological factors that might influence sexual attraction, preferences, or desires, we can understand the rather strong conclusion by social psychologist Letitia Anne Peplau and colleagues in a 1999 review article: "To recap, more than 50 years of research has failed to demonstrate that biological factors are a major influence in the development of women's sexual orientation.... Contrary to popular belief, scientists have not convincingly demonstrated that biology determines women's sexual orientation."<sup>100</sup> In light of the studies we have summarized here, this statement could also be made for research on male sexual orientation, however this concept is defined.

# Misreading the Research

There are some significant built-in limitations to what the kind of empirical research summarized in the preceding sections can show. Ignoring these limitations is one of the main reasons the research is routinely misinterpreted in the public sphere. It may be tempting to assume, as we just saw with the example of brain structure, that if a particular biological profile is associated with some behavioral or psychological trait, then that biological profile *causes* that trait. This reasoning relies on a fallacy, and in this section we explain why, using concepts from the field of epidemiology. While some of these issues are rather technical in detail, we will try to explain them in a general way that is accessible to the non-specialist reader.

Suppose for the sake of illustration that one or more differences in a biological trait are found between homosexual and heterosexual men. That difference could be a discrete measure (call this D) such as presence of a genetic marker, or it could be a continuous measure (call this C) such as the average volume of a particular part of the brain.

Showing that a risk factor significantly increases the chances of a particular health outcome or a behavior might give us a clue to development of that health outcome or that behavior, but it does not provide evidence of causation. Indeed, it may not provide evidence of anything but the weakest of correlations. The inference is sometimes made that if it can be shown that gay men and straight men differ significantly in the

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probability that D is present (whether a gene, a hormonal factor, or something else), no matter how low that probability, then this finding suggests that being gay has a biological basis. But this inference is unwarranted. Doubling (or even tripling or quadrupling) the probability of a relatively rare trait can have little value in terms of predicting who will or will not identify as gay.

The same would be true for any continuous variable (C). Showing a significant difference at the mean or average for a given trait (such as the volume of a particular brain region) between men who identify as heterosexual and men who identify as homosexual does not suffice to show that this average difference contributes to the probability of identifying as heterosexual or homosexual. In addition to the reasons explained above, a significant difference at the means of two distributions can be consistent with a great deal of overlap between the distributions. That is, there may be virtually no separation in terms of distinguishing between some individual members of each group, and thus the measure would not provide much predictability for sexual orientation or preference.

Some of these issues could, in part, be addressed by additional methodological approaches, such as the use of a training sample or crossvalidation procedures. A training sample is a small sample used to develop a model (or hypothesis); this model is then tested on a larger independent sample. This method avoids testing a hypothesis on the same data used to develop the hypothesis. Cross-validation includes procedures used to examine whether a statistically significant effect is really there or just due to chance. If one wants to show the result did not occur by chance (and if the sample is large), one can run the same tests on a random split of the relevant sample. After finding a difference in the prevalence of trait D or C between a gay sample and a straight sample, researchers could randomly split the gay sample into two groups and then show that these two groups do not differ regarding D or C. Suppose one finds five differences out of 100 comparing gay to straight men in the overall samples, then finds five differences out of 100 when comparing the split gay samples. This would cast additional doubt on the initial finding of a difference between the means of gay and straight individuals.

## **Sexual Abuse Victimization**

Whereas the preceding discussion considered the part that biological factors might play in the development of sexual orientation, this section will summarize evidence that a particular environmental factor—childhood

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sexual abuse—is reported significantly more often among those who later identify as homosexual. The results presented below raise the question whether there is an association between sexual abuse, particularly in childhood, and later expressions of sexual attraction, behavior, or identity. If so, might child abuse increase the probability of having a non-heterosexual orientation?

Correlations, at least, have been found, as we will summarize below. But we should note first that they might be accounted for by one or more of the following conjectures:

1. Abuse might contribute to the development of non-heterosexual orientation.

2. Children with (signs of future) non-heterosexual tendencies might attract abusers, placing them at elevated risk.

3. Certain factors might contribute to *both* childhood sexual abuse and non-heterosexual tendencies (for instance, a dysfunctional family or an alcoholic parent).

It should be kept in mind that these three hypotheses are not mutually exclusive; all three, and perhaps others, might be operative. As we summarize the studies on this issue, we will try to evaluate each of these hypotheses in light of current scientific research.

Behavioral and community health professor Mark S. Friedman and colleagues conducted a 2011 meta-analysis of 37 studies from the United States and Canada examining sexual abuse, physical abuse, and peer victimization in heterosexuals as compared to non-heterosexuals.<sup>101</sup> Their results showed that non-heterosexuals were on average 2.9 times more likely to report having been abused as children (under 18 years of age). In particular, non-heterosexual males were 4.9 times likelier—and non-heterosexual females, 1.5 times likelier—than their heterosexual counterparts to report sexual abuse. Non-heterosexual adolescents as a whole were 1.3 times likelier to indicate physical abuse by parents than their heterosexual peers, but gay and lesbian adolescents were only 0.9 times as likely (bisexuals were 1.7 times likelier to report being injured or threatened with a weapon or being attacked.

The authors note that although they hypothesized that the rates of abuse would decrease as social acceptance of homosexuality rose, "disparities in prevalence rates of sexual abuse, parental physical abuse, and peer

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victimization between sexual minority and sexual nonminority youths did not change from the 1990s to the first decade of the 2000s."<sup>102</sup> While these authors cite authorities who claim that sexual abuse does not "cause individuals to become gay, lesbian, or bisexual,"<sup>103</sup> their data do not give evidence against the hypothesis that childhood sexual abuse might affect sexual orientation. On the other hand, the causal path could be in the opposite direction or bi-directional. The evidence does not refute or support this conjecture; the study's design is not capable of shedding much light on the question of directionality.

The authors invoke a widely-cited hypothesis to explain the higher rates of sexual abuse among non-heterosexuals, the hypothesis that "sexual minority individuals are...more likely to be targeted for sexual abuse, as youths who are perceived to be gay, lesbian, or bisexual are more likely to be bullied by their peers."<sup>104</sup> The two conjectures—that abuse is a cause and that it is a result of non-heterosexual tendencies—are not mutually exclusive: abuse may be a causal factor in the development of non-heterosexual attractions and desires, and at the same time nonheterosexual attractions, desires, and behaviors may increase the risk of being targeted for abuse.

Community health sciences professor Emily Faith Rothman and colleagues conducted a 2011 systematic review of the research investigating the prevalence of sexual assault against people who identify as gay, lesbian, or bisexual in the United States.<sup>105</sup> They examined 75 studies (25 of which used probability sampling) involving a total of 139,635 gay or bisexual (GB) men and lesbian or bisexual (LB) women, which measured the prevalence of victimization due to lifetime sexual assault (LSA), childhood sexual assault (CSA), adult sexual assault (ASA), intimate partner sexual assault (IPSA), and hate-crime-related sexual assault (HC). Although the study was limited by not having a heterosexual control group, it showed alarmingly high rates of sexual assault, including childhood sexual assault, for this population, as summarized in Table 1.

Using a multi-state probability-based sample in a 2013 study, psychologist Judith Anderson and colleagues compared differences in adverse childhood experiences—including dysfunctional households; physical, sexual, or emotional abuse; and parental discord—among self-identified homosexual, heterosexual, and bisexual adults.<sup>106</sup> They found that bisexuals had significantly higher proportions than heterosexuals of all adverse childhood experience factors, and that gays and lesbians had significantly higher proportions than heterosexuals of all these measures except parental separation or divorce. Overall, gays and lesbians had nearly 1.7 times,

<sup>44</sup>  $\sim$  The New Atlantis

GB Men (%)	LB Women (%)
CSA: 4.1–59.2 (median 22.7)	CSA: 14.9–76.0 (median 34.5)
ASA: 10.8-44.7 (median 14.7)	ASA: 11.3–53.2 (median 23.2)
LSA: 11.8-54.0 (median 30.4)	LSA: 15.6–85.0 (median 43.4)
IPSA: 9.5–57.0 (median 12.1)	IPSA: 3.0-45.0 (median 13.3)
HC: 3.0-19.8 (median 14.0)	HC: 1.0-12.3 (median 5.0)

# Table 1. Sexual Assault among Gay/Bisexual Men and Lesbian/Bisexual Women

and bisexuals 1.6 times, the heterosexual rate of adverse childhood experiences. The data for abuse are summarized in Table 2.

While this study, like some others we have discussed, may be limited by recall bias—that is, inaccuracies introduced by errors of memory—it has the merit of having a control group of self-identified heterosexuals to compare with self-identified gay/lesbian and bisexual cohorts. In their discussion of findings, the authors critique the hypothesis that childhood trauma has a causal relationship to homosexual preferences. Among their reasons for skepticism, they note that the vast majority of individuals who suffer childhood trauma do not become gay or bisexual, and that gendernonconforming behavior may help explain the elevated rates of abuse. However, it is plausible from these and related results to hypothesize

# Table 2. Adverse Childhood Experiences among Gays/Lesbians, Bisexuals, and Heterosexuals

Sexual Abuse (%)		
GLs	Bisexuals	Heterosexuals
29.7	34.9	14.8

#### **Emotional Abuse (%)**

GLs	Bisexuals	Heterosexuals
47.9	48.4	29.6

## Physical Abuse (%)

GLs	Bisexuals	Heterosexuals
29.3	30.3	16.7

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that adverse childhood experiences may be a significant—but not a determinative—factor in developing homosexual preferences. Further studies are needed to see whether either or both hypotheses have merit.

A 2010 study by professor of social and behavioral sciences Andrea Roberts and colleagues examined sexual orientation and risk of posttraumatic stress disorder (PTSD) using data from a national epidemiological face-to-face survey of nearly 35,000 adults.<sup>107</sup> Individuals were placed into several categories: heterosexual with no same-sex attraction or partners (reference group); heterosexual with same-sex attraction but no same-sex partners; heterosexual with same-sex partners; self-identified gay/lesbian; and self-identified bisexual. Among those reporting exposure to traumatic events, gay and lesbian individuals as well as bisexuals had about twice the lifetime risk of PTSD compared to the heterosexual reference group. Differences were found in rates of childhood maltreatment and interpersonal violence: gays, lesbians, bisexuals, and heterosexuals with same-sex partners reported experiencing worse traumas during childhood and adolescence than the reference group. The findings are summarized in Table 3.

Similar patterns emerged in a 2012 study by psychologist Brendan Zietsch and colleagues that primarily focused on the distinct question of whether common causal factors could explain the association between sexual orientation—in this study defined as sexual preference—and depression.<sup>108</sup> In a community sample of 9,884 adult twins, the authors found that non-heterosexuals had significantly elevated prevalence of lifetime depression (odds ratio for males 2.8; odds ratio for females 2.7). As the authors point out, the data raised questions about whether higher rates of depression for non-heterosexuals could be explained, in their entirety, by the social stress hypothesis (the idea, discussed in depth in Part Two of this report, that social stress

Women	Men
49.2% of lesbians	31.5% of gays
51.2% of bisexuals	Approximately 32% of bisexuals <sup>109</sup>
40.9% of heterosexuals with same-sex partners	27.9% of heterosexuals with same-sex partners
21.2% of heterosexuals	19.8% of heterosexuals

## Table 3. Childhood Exposure to Maltreatment or Interpersonal Violence (before Age 18)

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experienced by sexual minorities accounts for their elevated risks of poor mental health outcomes). Heterosexuals with a non-heterosexual twin had higher rates of depression (39%) than heterosexual twin pairs (31%), suggesting that genetic, familial, or other factors may play a role.

The authors note that "in both males and females, significantly higher rates of non-heterosexuality were found in participants who experienced childhood sexual abuse and in those with a risky childhood family environment."<sup>110</sup> Indeed, 41% of non-heterosexual males and 42% of non-heterosexual females reported childhood family dysfunction, compared to 24% and 30% of heterosexual males and females, respectively. And 12% of non-heterosexual males and 24% of non-heterosexual females reported sexual abuse before the age of 14, compared with 4% and 11% of heterosexual males and females, respectively. The authors are careful to emphasize that their findings should not be interpreted as disproving the social stress hypothesis, but suggest that there may be other factors at work. Their findings do, however, suggest there could be common etiological factors for depression and nonheterosexual preferences, as they found that genetic factors account for 60% of the correlation between sexual orientation and depression.<sup>111</sup>

In a 2001 study, psychologist Marie E. Tomeo and colleagues noted that the previous literature had consistently found increased rates of reported childhood molestation in the homosexual population, with somewhere between 10% and 46% reporting that they had experienced childhood sexual abuse.<sup>112</sup> The authors found that 46% of homosexual men and 22% of homosexual women reported that they had been molested by a person of the same gender, as compared with 7% of heterosexual men and 1% of heterosexual women. Moreover, 38% of homosexual women interviewed did not identify as homosexual until after the abuse, while the authors report conflicting figures—68% in one part of the paper and (by inference) 32% in another for the number of homosexual men who did not identify as homosexual until after the abuse. The sample for this study was relatively small, only 267 individuals; also, the "sexual contact" measure of abuse in the survey was somewhat vague, and the subjects were recruited from participants in gay pride events in California. But the authors state that "it is most unlikely that all the present findings apply only to homosexual persons who go to homosexual fairs and volunteer to participate in questionnaire research."113

In 2010, psychologists Helen Wilson and Cathy S. Widom published a prospective 30-year follow-up study—one that looked at children who had experienced abuse or neglect between 1961 and 1971, and then followed up with those children after 30 years—to ascertain whether physical abuse, sexual abuse, or neglect in childhood increased the likelihood of same-sex

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sexual relationships later in life.<sup>114</sup> An original sample of 908 abused and/ or neglected children was matched with a non-maltreated control group of 667 individuals (matched for age, sex, race or ethnicity, and approximate socioeconomic status). Homosexuality was operationalized as anyone who had cohabited with a same-sex romantic partner or had a same-sex sexual partner, which made up 8% of the sample. Among these 8%, most individuals also reported having had opposite-sex partners, suggesting high rates of bisexuality or fluidity in sexual attractions or behaviors. The study found that those who reported histories of childhood sexual abuse were 2.8 times more likely to report having had same-sex sexual relationships, though the "relationship between childhood sexual abuse and samesex sexual orientation was significant only for men."<sup>115</sup> This finding suggested that boys who are sexually abused may be more likely to establish both heterosexual and homosexual relationships.

The authors advised caution in interpreting this result, because the sample size of sexually abused men was small, but the association remained statistically significant when they controlled for total lifetime number of sexual partners and for engaging in prostitution. The study was also limited by a definition of sexual orientation that was not sensitive to how participants identified themselves. It may have failed to capture people with same-sex attractions but no same-sex romantic relationship history. The study had two notable methodological strengths. The prospective design is better suited for evaluating causal relationships than the typical retrospective design. Also, the childhood abuse recorded was documented when it occurred, thus mitigating recall bias.

Having examined the statistical association between childhood sexual abuse and later homosexuality, we turn to the question of whether the association suggests causation.

A 2013 analysis by health researcher Andrea Roberts and colleagues attempted to provide an answer to this question.<sup>116</sup> The authors noted that while studies show 1.6 to 4 times more reported childhood sexual and physical abuse among gay and lesbian individuals than among heterosexuals, conventional statistical methods cannot demonstrate a strong enough statistical relationship to support the argument of causation. They argued that a sophisticated statistical method called "instrumental variables," imported from econometrics and economic analysis, could increase the level of association.<sup>117</sup> (The method is somewhat similar to the method of "propensity scores," which is more sophisticated and more familiar to public health researchers.) The authors applied the method of instrumental variables to data collected from a nationally representative sample.

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They used three dichotomous measures of sexual orientation: any vs. no same-sex attraction; any vs. no lifetime same-sex sexual partners; and lesbian, gay, or bisexual vs. heterosexual self-identification. As in other studies, the data showed associations between childhood sexual abuse or maltreatment and all three dimensions of non-heterosexuality (attraction, partners, identity), with associations between sexual abuse and sexual identity being the strongest.

The authors' instrumental variable models suggested that early sexual abuse increased the predicted rate of same-sex attraction by 2.0 percentage points, same-sex partnering by 1.4 percentage points, and same-sex identity by 0.7 percentage points. The authors estimated the rate of homosexuality that might be attributable to sexual abuse "using effect estimates from conventional models" and found that on conventional effect estimates, "9% of same-sex attraction, 21% of any lifetime same-sex sexual partnering, and 23% of homosexual or bisexual identity was due to childhood sexual abuse."118 We should note that these correlations are crosssectional: they compare groups of people to groups of people, rather than model the course of individuals over time. (A study design with a timeseries analysis would give the strongest statistical support to the claim of causality.) Additionally, these results have been strongly criticized on methodological grounds for having made unjustified assumptions in the instrumental variables regression; a commentary by Drew H. Bailey and J. Michael Bailey claims, "Not only do Roberts et al.'s results fail to provide support for the idea that childhood maltreatment causes adult homosexuality, the pattern of differences between males and females is opposite what should be expected based on better evidence."119

Roberts and colleagues conclude their study with several conjectures to explain the epidemiological associations. They echo suggestions made elsewhere that sexual abuse perpetrated by men might cause boys to think they are gay or make girls averse to sexual contact with men. They also conjecture that sexual abuse might leave victims feeling stigmatized, which in turn might make them more likely to act in ways that are socially stigmatized (as by engaging in same-sex sexual relationships). The authors also point to the biological effects of maltreatment, citing studies that show that "quality of parenting" can affect chemical and hormonal receptors in children, and hypothesizing that this might influence sexuality "through epigenetic changes, particularly in the stria terminalis and the medial amygdala, brain regions that regulate social behavior."<sup>120</sup> They also mention the possibilities that emotional numbing caused by maltreatment may drive victims to seek out risky behaviors associated

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with same-sex sexuality, or that same-sex attractions and partnering may result from "the drive for intimacy and sex to repair depressed, stressed, or angry moods," or from borderline personality disorder, which is a risk factor in individuals who have been maltreated.<sup>121</sup>

In short, while this study suggests that sexual abuse may sometimes be a causal contributor to having a non-heterosexual orientation, more research is needed to elucidate the biological or psychological mechanisms. Without such research, the idea that sexual abuse may be a causal factor in sexual orientation remains speculative.

## **Distribution of Sexual Desires and Changes Over Time**

However sexual desires and interests develop, there is a related issue that scientists debate: whether sexual desires and attractions tend to remain fixed and unalterable across the lifespan of a person—or are fluid and subject to change over time but tend to become fixed after a certain age or developmental period. Advocates of the "born that way" hypothesis, as mentioned earlier, sometimes argue that a person is not only born with a sexual orientation but that that orientation is immutable; it is fixed for life.

There is now considerable scientific evidence that sexual desires, attractions, behaviors, and even identities can, and sometimes do, change over time. For findings in this area we can turn to the most comprehensive study of sexuality to date, the 1992 National Health and Social Life Survey conducted by the National Opinion Research Center at the University of Chicago (NORC).<sup>122</sup> Two important publications have appeared using data from NORC's comprehensive survey: *The Social Organization of Sexuality: Sexual Practices in the United States*, a large tome of data intended for the research community, and *Sex in America: A Definitive Survey*, a smaller and more accessible book summarizing the findings for the general public.<sup>123</sup> These books present data from a reliable probability sample of the American population between ages 18 and 59.

According to data from the NORC survey, the estimated prevalence of non-heterosexuality, depending on how it was operationalized, and on whether the subjects were male or female, ranged between roughly 1% and 9%.<sup>124</sup> The NORC studies added scientific respectability to sexual surveys, and these findings have been largely replicated in the United States and abroad. For example, the British National Survey of Sexual Attitudes and Lifestyles (Natsal) is probably the most reliable source of information on sexual behavior in that country—a study conducted every ten years since 1990.<sup>125</sup>

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The NORC study also suggested ways in which sexual behaviors and identities can vary significantly under different social and environmental circumstances. The findings revealed, for example, a sizable difference in rates of male homosexual behavior among individuals who spent their adolescence in rural as compared to large metropolitan cities in America, suggesting the influence of social and cultural environments. Whereas only 1.2% of males who had spent their adolescence in a rural environment responded that they had had a male sexual partner in the year of the survey, those who had spent adolescence living in metropolitan areas were close to four times (4.4%) more likely to report that they had had such an encounter.<sup>126</sup> From these data one cannot infer differences between these environments in the prevalence of sexual interests or attractions, but the data do suggest differences in sexual behaviors. Also of note is that women who attended college were nine times more likely to identify as lesbians than women who did not.<sup>127</sup>

Moreover, other population-based surveys suggest that sexual desire may be fluid for a considerable number of individuals, especially among adolescents as they mature through the early stages of adult development. In this regard, opposite-sex attraction and identity seem to be more stable than same-sex or bisexual attraction and identity. This is suggested by data from the National Longitudinal Study of Adolescent to Adult Health (the "Add Health" study discussed earlier). This prospective longitudinal study of a nationally representative sample of U.S. adolescents starting in grades 7–12 began during the 1994–1995 school year, and followed the cohort into young adulthood, with four follow-up interviews (referred to as Waves I, II, III, IV in the literature).<sup>128</sup> The most recent was in 2007–2008, when the sample was aged 24–32.

Same-sex or both-sex romantic attractions were quite prevalent in the study's first wave, with rates of approximately 7% for the males and 5% for the females.<sup>129</sup> However, 80% of the adolescent males who had reported same-sex attractions at Wave I later identified themselves as exclusively heterosexual as young adults at Wave IV.<sup>130</sup> Similarly, for adolescent males who, at Wave I, reported romantic attraction to both sexes, over 80% of them reported no same-sex romantic attraction at Wave III.<sup>131</sup> The data for the females surveyed were similar but less striking: for adolescent females who had both-sex attractions at Wave I, more than half reported exclusive attraction to males at Wave III.<sup>132</sup>

J. Richard Udry, the director of Add Health for Waves I, II, and III,<sup>133</sup> was among the first to point out the fluidity and instability of romantic attraction between the first two waves. He reported that among boys who

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reported romantic attraction *only* to boys and *never* to girls at Wave I, 48% did so during Wave II; 35% reported no attraction to either sex; 11% reported exclusively same-sex attraction; and 6% reported attraction to both sexes.<sup>134</sup>

Ritch Savin-Williams and Geoffrey Ream published a 2007 analysis of the data from Waves I-III of Add Health.<sup>135</sup> Measures used included whether individuals ever had a romantic attraction for a given sex, sexual behavior, and sexual identity. (The categories for sexual identity were 100% heterosexual, mostly heterosexual but somewhat same-sex attracted, bisexual, mostly homosexual but somewhat attracted to opposite sex, and 100% homosexual.) While the authors noted the "stability of opposite-sex attraction and behavior" between Waves I and III, they found a "high proportion of participants with same- and both-sex attraction and behavior that migrated into opposite-sex categories between waves."136 A much smaller proportion of those in the heterosexual categories, and a similar proportion of those without attraction, moved to non-heterosexual categories. The authors summarize: "All attraction categories other than opposite-sex were associated with a lower likelihood of stability over time. That is, individuals reporting any same-sex attractions were more likely to report subsequent shifts in their attractions than were individuals without any same-sex attractions."137

The authors also note the difficulties these data present for trying to define sexual orientation and to classify individuals according to such categories: "the critical consideration is whether having 'any' same-sex sexuality qualifies as nonheterosexuality. How much of a dimension must be present to tip the scales from one sexual orientation to another was not resolved with the present data, only that such decisions matter in terms of prevalence rates."<sup>138</sup> The authors suggested that researchers could "forsake the general notion of sexual orientation altogether and assess only those components relevant for the research question."<sup>139</sup>

Another prospective study by biostatistician Miles Ott and colleagues of 10,515 youth (3,980 males; 6,535 females) in 2013 showed findings on sexual orientation change in adolescents consistent with the findings of the Add Health data, again suggesting fluidity and plasticity of same-sex attractions among many adolescents.<sup>140</sup>

A few years after the Add Health data were originally published, the *Archives of Sexual Behavior* published an article by Savin-Williams and Joyner that critiqued the Add Health data on sexual attraction change.<sup>141</sup> Before outlining their critique, Savin-Williams and Joyner summarize the key Add Health findings: "in the approximately 13 years between Waves

 $<sup>52 \</sup>sim$  The New Atlantis

I and IV, regardless of whether the measure was identical across waves (romantic attraction) or discrepant in words but not in theory (romantic attraction and sexual orientation identity), approximately 80% of adolescent boys and half of adolescent girls who expressed either partial or exclusive same-sex romantic attraction at Wave I 'turned' heterosexual (opposite-sex attraction or exclusively heterosexual identity) as young adults."<sup>142</sup> The authors propose three hypotheses to explain these discrepancies:

(1) gay adolescents going into the closet during their young adult years; (2) confusion regarding the use and meaning of romantic attraction as a proxy for sexual orientation; and (3) the existence of mischievous adolescents who played a 'jokester' role by reporting same-sex attraction when none was present.<sup>143</sup>

Savin-Williams and Joyner reject the first hypothesis but find support for the second and the third. With respect to the second hypothesis, they question the use of romantic attraction to operationalize sexual identity:

To help us assess whether the construct/measurement issue (romantic attraction versus sexual orientation identity) was driving results, we compared the two constructs at Wave IV.... Whereas over 99% of young adults with opposite-sex romantic attraction identified as heterosexual or mostly heterosexual and 94% of those with same-sex romantic attraction identified as homosexual or mostly homosexual, 33% of both-sex attracted men identified as heterosexual (just 6% of both-sex attracted women identified as heterosexual). These data indicated that young adult men and women generally understood the meaning of romantic attraction to the opposite- or same-sex to imply a particular (and consistent) sexual orientation identity, with one glaring exception—a substantial subset of young adult men who, despite their stated both-sex romantic attraction, identified as heterosexual.

Regarding the third hypothesis for explaining the Add Health data, Savin-Williams and Joyner note that surveys of adolescents sometimes yield unusual or distorted results due to adolescents who do not respond truthfully. The Add Health survey, they observe, had a significant number of unusual responders. For example, several hundred adolescents reported in the Wave I questionnaire that they had an artificial limb, whereas in later at-home interviews, only two of those adolescents reported having an artificial limb.<sup>144</sup> Adolescent boys who went from nonheterosexual in Wave I to heterosexual in Wave IV were significantly less likely to report

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having filled out the Wave I questionnaire honestly; these boys also displayed other significant differences, such as lower grade point averages. Additionally, like consistently heterosexual boys, boys who were inconsistent between Waves I and IV were more popular in their school with boys than girls, whereas consistently nonheterosexual boys were more popular with girls. These and other data<sup>145</sup> led the authors to conclude that "boys who emerged from a gay or bisexual adolescence to become a heterosexual young adulthood were, by-and-large, heterosexual adolescents who were either confused and did not understand the measure of romantic attraction or jokesters who decided, for reasons we were not able to detect, to dishonestly report their sexuality."<sup>146</sup> However, the authors were not able to estimate the proportion of inaccurate responders, which would have helped evaluate the explanatory power of the hypotheses.

Later in 2014, the Archives of Sexual Behavior published a critique of the Savin-Williams and Joyner explanation of Add Health data by psychologist Gu Li and colleagues.<sup>147</sup> Along with criticizing the methodology of Savin-Williams and Joyner, these authors argued that the data were consistent with a scenario in which some nonheterosexual adolescents went "back into the closet" in later years as a possible reaction to social stress. (We will examine the effects of social stress on mental health in LGBT populations in Part Two of this report.) They also claimed that "it makes little sense to use responses to Wave IV sexual identity to validate or invalidate responses to Waves I or IV romantic attractions when these aspects of sexual orientation may not align in the first place."148 Regarding the jokester hypothesis, these authors pose this difficulty: "Although some participants might be 'jokesters,' and we as researchers should be cautious of problems associated with self-report surveys whenever analyzing and interpreting data, it is unclear why the 'jokesters' would answer questions about delinquency honestly, but not questions about their sexual orientation."149

Savin-Williams and Joyner published a response to the critique in the same issue of the journal.<sup>150</sup> Responding to the criticism that their comparison of Wave IV self-reported sexual identity to Wave I self-reported romantic attractions was unsound, Savin-Williams and Joyner claimed that the results were quite similar if one used attraction as the Wave IV measure. They also deemed it highly unlikely that a large proportion of the respondents who were classified as nonheterosexuals in Wave I and heterosexuals in Wave IV went "back into the closet," because the proportion of individuals in adolescence and young adulthood who are "out of the closet" usually increases over time.<sup>151</sup>

<sup>54</sup>  $\sim$  The New Atlantis

The following year, the *Archives of Sexual Behavior* published another response to Savin-Williams and Joyner by psychologist Sabra Katz-Wise and colleagues, which argued that Savin-Williams and Joyner's "approach to identifying 'dubious' sexual minority youth is inherently flawed."<sup>152</sup> They wrote that "romantic attraction and sexual orientation identity are two distinct dimensions of sexual orientation that may not be concordant, even at a single time point."<sup>153</sup> They also claimed that "even if Add Health had assessed the same facets of sexual orientation at all waves, it would still be incorrect to infer 'dubious' sexual minorities from changes on the same dimension of sexual orientation, because these changes may reflect sexual fluidity."<sup>154</sup>

Unfortunately, the Add Health study does not appear to contain the data that would allow an assessment to determine which, if any, of these interpretations is likely to be correct. It may well be the case that a combination of factors contributed to the differences between the Wave I and Wave IV data. For example, there may have been some adolescents who responded to the Wave I sexual attraction questions inaccurately, some openly nonheterosexual adolescents who later went "back into the closet," and some adolescents who experienced nonheterosexual attractions before Wave I that largely disappeared by Wave IV. Other prospective study designs that track specific individuals across adolescent and adult development may shed further light on these issues.

While ambiguities in defining and characterizing sexual desire and orientation make changes in sexual desire difficult to study, data from these large, population-based national studies of randomly sampled individuals do suggest that all three dimensions of sexuality—affect, behavior, and identity—may change over time for some people. It is unclear, and current research does not address, whether and to what extent factors subject to volitional control—choice of sexual partners or sexual behaviors, for example—may influence such changes through conditioning and other mechanisms that are characterized in the behavioral sciences.

Several researchers have suggested that sexual orientation and attractions may be especially plastic for women.<sup>155</sup> For example, Lisa Diamond argued in her 2008 book *Sexual Fluidity* that "women's sexuality is fundamentally more fluid than men's, permitting greater variability in its development and expression over the life course," based on research by her and many others.<sup>156</sup>

Diamond's longitudinal five-year interviews of women in sexual relationships with other women also shed light on the problems with the concept of sexual orientation. In many cases, the women in her study

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reported not so much setting out to form a lesbian sexual relationship but rather experiencing a gradual growth of affective intimacy with a woman that eventually led to sexual involvement. Some of these women rejected the labels of "lesbian," "straight," or "bisexual" as being inconsistent with their lived experience.<sup>157</sup> In another study, Diamond calls into question the utility of the concept of sexual orientation, especially as it applies to females.<sup>158</sup> She points out that if the neural basis of parent-child attachment—including attachment to one's mother—forms at least part of the basis for romantic attachments in adulthood, then it would not be surprising for a woman to experience romantic feelings for another woman without necessarily wanting to be sexually intimate with her. Diamond's research indicates that these kinds of relationships form more often than we typically recognize, especially among women.

Some researchers have also suggested that men's sexuality is more fluid than it was previously thought. For example, Diamond presented a 2014 conference paper, based on initial results from a survey of 394 people, entitled "I Was Wrong! Men Are Pretty Darn Sexually Fluid, Too!"<sup>159</sup> Diamond based this conclusion on a survey of men and women between the ages of 18 and 35, which asked about their sexual attractions and selfdescribed identities at different stages of their lives. The survey found that 35% of self-identified gay men reported experiencing opposite-sex attractions in the past year, and 10% of self-identified gay men reported opposite-sex sexual behavior during the same period. Additionally, nearly as many men transitioned at some time in their life from gay to bisexual, queer, or unlabeled identity as did men from bisexual to gay identity.

In a 2012 review article entitled "Can We Change Sexual Orientation?" published in the *Archives of Sexual Behavior*, psychologist Lee Beckstead wrote, "Although their sexual behavior, identity, and attractions may change throughout their lives, this may not indicate a change in sexual orientation... but a change in awareness and an expansion of sexuality."<sup>160</sup> It is difficult to know how to interpret this claim—that sexual behavior, identity, and attractions may change but that this does not necessarily indicate a change in sexual orientation. We have already analyzed the inherent difficulties of defining sexual orientation, but however one chooses to define this construct, it seems that the definition would somehow be tied to sexual behavior, identity, or attraction. Perhaps we can take Beckstead's claim here as one more reason to consider dispensing with the construct of sexual orientation in the context of social science research, as it seems that whatever it might represent, it is only loosely or inconsistently tied to empirically measurable phenomena.

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#### PART ONE: SEXUAL ORIENTATION

Given the possibility of changes in sexual desire and attraction, which research suggests is not uncommon, any attempt to infer a stable, innate, and fixed identity from a complex and often shifting mélange of inner fantasies, desires, and attractions—sexual, romantic, aesthetic, or otherwise—is fraught with difficulties. We can imagine, for example, a sixteen-year-old boy who becomes infatuated with a young man in his twenties, developing fantasies centered around the other's body and build, or perhaps on some of his character traits or strengths. Perhaps one night at a party the two engage in physical intimacy, catalyzed by alcohol and by the general mood of the party. This young man then begins an anguished process of introspection and self-exploration aimed at finding the answer to the enigmatic question, "Does this mean I'm gay?"

Current research from the biological, psychological, and social sciences suggests that this question, at least as it is framed, makes little sense. As far as science can tell us, there is nothing "there" for this young man to discover—no fact of nature to uncover or to find buried within himself. What his fantasies, or his one-time liaison, "really mean" is subject to any number of interpretations: that he finds the male figure beautiful, that he was lonely and feeling rejected the night of the party and responded to his peer's attentions and affections, that he was intoxicated and influenced by the loud music and strobe lights, that he does have a deep-seated sexual or romantic attraction to other men, and so on. Indeed, psychodynamic interpretations of such behaviors citing unconscious motivational factors and inner conflicts, many of them interesting, most impossible to prove, can be spun endlessly.

What we can say with more confidence is that this young man had an experience encompassing complex feelings, or that he engaged in a sexual act conditioned by multiple complex factors, and that such fantasies, feelings, or associated behaviors may (or may not) be subject to change as he grows and develops. Such behaviors could become more habitual with repetition and thus more stable, or they may extinguish and recur rarely or never. The research on sexual behaviors, sexual desire, and sexual identity suggests that both trajectories are real possibilities.

## Conclusion

The concept of sexual orientation is unusually ambiguous compared to other psychological traits. Typically, it refers to at least one of three things: attractions, behaviors, or identity. Additionally, we have seen that sexual orientation often refers to several other things as well: belonging

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to a certain community, fantasies (as distinct in some respects from attractions), longings, strivings, felt needs for certain forms of companionship, and so on. It is important, then, that researchers are clear about which of these domains are being studied, and that we keep in mind the researchers' specified definitions when we interpret their findings.

Furthermore, not only can the term "sexual orientation" be understood in several different senses, most of the senses are themselves complex concepts. Attraction, for example, could refer to arousal patterns, or to romantic feelings, or to desires for company, or other things; and each of these things can be present either sporadically and temporarily or pervasively and long-term, either exclusively or not, either in a deep or shallow way, and so forth. For this reason, even specifying one of the basic senses of orientation (attraction, behavior, or identity) is insufficient for doing justice to the richly varied phenomenon of human sexuality.

In this part we have criticized the common assumption that sexual *desires, attractions,* or *longings* reveal some innate and fixed feature of our biological or psychological constitution, a fixed sexual *identity* or *orientation.* Furthermore, we may have some reasons to doubt the common assumption that in order to live happy and flourishing lives, we must somehow discover this innate fact about ourselves that we call *sexuality* or *sexual orientation,* and invariably express it through particular patterns of sexual behavior or a particular life trajectory. Perhaps we ought instead to consider what sorts of behaviors—whether in the sexual realm or elsewhere—tend to be conducive to health and flourishing, and what kinds of behaviors tend to undermine a healthy and flourishing life.

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105. Emily F. Rothman, Deinera Exner, and Allyson L. Baughman, "The Prevalence of Sexual Assault Against People Who Identify as Gay, Lesbian, or Bisexual in the United States: A Systematic Review," *Trauma, Violence, & Abuse* 12, no. 2 (2011): 55–66, http://dx.doi.org/10.1177/1524838010390707.

106. Judith P. Andersen and John Blosnich, "Disparities in Adverse Childhood Experiences among Sexual Minority and Heterosexual Adults: Results from a Multi-State Probability-Based Sample," *PLOS ONE* 8, no. 1 (2013): e54691, http://dx.doi. org/10.1371/journal.pone.0054691.

107. Andrea L. Roberts *et al.*, "Pervasive Trauma Exposure Among US Sexual Orientation Minority Adults and Risk of Posttraumatic Stress Disorder," *American Journal of Public Health* 100, no. 12 (2010): 2433–2441, http://dx.doi.org/10.2105/AJPH.2009.168971.

108. Brendan P. Zietsch *et al.*, "Do shared etiological factors contribute to the relationship between sexual orientation and depression?," *Psychological Medicine* 42, no. 3 (2012): 521–532, http://dx.doi.org/10.1017/S0033291711001577.

109. The exact figure is not reported in the text for reasons the authors do not specify.

110. Ibid., 526.

111. Ibid., 527.

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112. Marie E. Tomeo *et al.*, "Comparative Data of Childhood and Adolescence Molestation in Heterosexual and Homosexual Persons," *Archives of Sexual Behavior* 30, no. 5 (2001): 535–541, http://dx.doi.org/10.1023/A:1010243318426.

113. Ibid., 541.

114. Helen W. Wilson and Cathy Spatz Widom, "Does Physical Abuse, Sexual Abuse, or Neglect in Childhood Increase the Likelihood of Same-sex Sexual Relationships and Cohabitation? A Prospective 30-year Follow-up," *Archives of Sexual Behavior* 39, no. 1 (2010): 63–74, http://dx.doi.org/10.1007/s10508-008-9449-3.

115. Ibid., 70.

116. Andrea L. Roberts, M. Maria Glymour, and Karestan C. Koenen, "Does Maltreatment in Childhood Affect Sexual Orientation in Adulthood?," *Archives of Sexual Behavior* 42, no. 2 (2013): 161–171, http://dx.doi.org/10.1007/s10508-012-0021-9.

117. For those interested in the methodological details: this statistical method uses a two-step process where "instruments"—in this case, family characteristics that are known to be related to maltreatment (presence of a stepparent, parental alcohol abuse, or parental mental illness)—are used as the "instrumental variables" to predict the risk of maltreatment. In the second step, the predicted risk of maltreatment is employed as the independent variable and adult sexual orientation as the dependent variable; coefficients from this are the instrumental variable estimates. It should also be noted here that these instrumental variable estimation techniques rely on some important (and questionable) assumptions, in this case the assumption that the instruments (the stepparent, the alcohol abuse, the mental illness) do not affect the child's sexual orientation measures except through child abuse. But this assumption is not demonstrated, and therefore may constitute a foundational limitation of the method. Causation is difficult to support statistically and continues to beguile research in the social sciences in spite of efforts to design studies capable of generating stronger associations that give stronger support to claims of causation.

118. Roberts, Glymour, and Koenen, "Does Maltreatment in Childhood Affect Sexual Orientation in Adulthood?," 167.

119. Drew H. Bailey and J. Michael Bailey, "Poor Instruments Lead to Poor Inferences: Comment on Roberts, Glymour, and Koenen (2013)," *Archives of Sexual Behavior* 42, no. 8 (2013): 1649–1652, http://dx.doi.org/10.1007/s10508-013-0101-5.

120. Roberts, Glymour, and Koenen, "Does Maltreatment in Childhood Affect Sexual Orientation in Adulthood?," 169.

121. Ibid., 169.

122. For information on the study, see "National Health and Social Life Survey," Population Research Center of the University of Chicago, http://popcenter.uchicago.edu/data/nhsls.shtml.

123. Edward O. Laumann *et al.*, *The Social Organization of Sexuality: Sexual Practices in the United States* (Chicago: University of Chicago Press, 1994); Robert T. Michael *et al.*, *Sex in America: A Definitive Survey* (New York: Warner Books, 1994).

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124. Laumann et al., The Social Organization of Sexuality, 295.

125. The third iteration of Natsal from 2010 found, over an age range from 16 to 74, that 1.0% of women and 1.5% of men consider themselves gay/lesbian, and 1.4% of women and 1.0% of men think of themselves as bisexual. See Catherine H. Mercer *et al.*, "Changes in sexual attitudes and lifestyles in Britain through the life course and over time: findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal)," *The Lancet* 382, no. 9907 (2013): 1781–1794, http://dx.doi.org/10.1016/S0140-6736(13)62035-8. Full results of this survey are reported in several articles in the same issue of *The Lancet*.

126. See Table 8.1 in Laumann et al., The Social Organization of Sexuality, 304.

127. This figure is calculated from Table 8.2 in Laumann *et al.*, *The Social Organization of Sexuality*, 305.

128. For more information on the study design of Add Health, see Kathleen Mullan Harris *et al.*, "Study Design," The National Longitudinal Study of Adolescent to Adult Health, http://www.cpc.unc.edu/projects/addhealth/design. Some studies based on Add Health data use Arabic numerals rather than Roman numerals to label the waves; when describing or quoting from those studies, we stick with the Roman numerals.

129. See Table 1 in Ritch C. Savin-Williams and Kara Joyner, "The Dubious Assessment of Gay, Lesbian, and Bisexual Adolescents of Add Health," *Archives of Sexual Behavior* 43, no. 3 (2014): 413–422, http://dx.doi.org/10.1007/s10508-013-0219-5.

130. Ibid., 415.

131. Ibid.

132. Ibid.

133. "Research Collaborators," The National Longitudinal Study of Adolescent to Adult Health, http://www.cpc.unc.edu/projects/addhealth/people.

134. J. Richard Udry and Kim Chantala, "Risk Factors Differ According to Same-Sex and Opposite-Sex Interest," *Journal of Biosocial Science* 37, no. 04 (2005): 481–497, http://dx.doi.org/10.1017/S0021932004006765.

135. Ritch C. Savin-Williams and Geoffrey L. Ream, "Prevalence and Stability of Sexual Orientation Components During Adolescence and Young Adulthood," *Archives of Sexual Behavior* 36, no. 3 (2007): 385–394, http://dx.doi.org/10.1007/s10508-006-9088-5.

136. Ibid., 388.

- 137. Ibid., 389.
- 138. Ibid., 392-393.
- 139. Ibid., 393.

140. Miles Q. Ott *et al.*, "Repeated Changes in Reported Sexual Orientation Identity Linked to Substance Use Behaviors in Youth," *Journal of Adolescent Health* 52, no. 4 (2013): 465–472, http://dx.doi.org/10.1016/j.jadohealth.2012.08.004.

141. Savin-Williams and Joyner, "The Dubious Assessment of Gay, Lesbian, and Bisexual

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Adolescents of Add Health."

142. Ibid., 416.

143. Ibid., 414.

144. For more analysis of inaccurate responders in the Add Health surveys, see Xitao Fan *et al.*, "An Exploratory Study about Inaccuracy and Invalidity in Adolescent Self-Report Surveys," *Field Methods* 18, no. 3 (2006): 223–244, http://dx.doi.org/10.1177/152822X06289161.

145. Savin-Williams and Joyner were also skeptical of the Add Health survey data because the high proportion of youth reporting same-sex or both-sex attractions (7.3% of boys and 5.0% of girls) in Wave I was very unusual when compared to similar studies, and because of the dramatic reduction in reported same-sex attraction a little over a year later, in Wave II.

146. Savin-Williams and Joyner, "The Dubious Assessment of Gay, Lesbian, and Bisexual Adolescents of Add Health," 420.

147. Gu Li, Sabra L. Katz-Wise, and Jerel P. Calzo, "The Unjustified Doubt of Add Health Studies on the Health Disparities of Non-Heterosexual Adolescents: Comment on Savin-Williams and Joyner (2014)," *Archives of Sexual Behavior*, 43 no. 6 (2014): 1023–1026, http://dx.doi.org/10.1007/s10508-014-0313-3.

148. Ibid., 1024.

149. Ibid., 1025.

150. Ritch C. Savin-Williams and Kara Joyner, "The Politicization of Gay Youth Health: Response to Li, Katz-Wise, and Calzo (2014)," *Archives of Sexual Behavior* 43, no. 6 (2014): 1027–1030, http://dx.doi.org/10.1007/s10508-014-0359-2.

151. See, for example, Stephen T. Russell *et al.*, "Being Out at School: The Implications for School Victimization and Young Adult Adjustment," *American Journal of Orthopsychiatry* 84, no. 6 (2014): 635–643, http://dx.doi.org/10.1037/ort0000037.

152. Sabra L. Katz-Wise *et al.*, "Same Data, Different Perspectives: What Is at Stake? Response to Savin-Williams and Joyner (2014a)," *Archives of Sexual Behavior* 44, no. 1 (2015): 15, http://dx.doi.org/10.1007/s10508-014-0434-8.

153. Ibid., 15.

154. Ibid., 15-16.

155. For example, see Bailey, "What is Sexual Orientation and Do Women Have One?," 43–63; Peplau *et al.*, "The Development of Sexual Orientation in Women," 70–99.

156. Lisa M. Diamond, *Sexual Fluidity* (Cambridge, Mass.: Harvard University Press, 2008), 52.

157. Lisa M. Diamond, "Was It a Phase? Young Women's Relinquishment of Lesbian/ Bisexual Identities Over a 5-Year Period," *Journal of Personality and Social Psychology* 84, no. 2 (2003): 352–364, http://dx.doi.org/10.1037/0022-3514.84.2.352.

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158. Diamond, "What Does Sexual Orientation Orient?," 173-192.

159. This conference paper was summarized in Denizet-Lewis, "The Scientific Quest to Prove Bisexuality Exists."

160. A. Lee Beckstead, "Can We Change Sexual Orientation?," *Archives of Sexual Behavior* 41, no. 1 (2012): 128, http://dx.doi.org/10.1007/s10508-012-9922-x.

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Part Two

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# Sexuality, Mental Health Outcomes, and Social Stress

Compared to the general population, non-heterosexual and transgender subpopulations have higher rates of mental health problems such as anxiety, depression, and suicide, as well as behavioral and social problems such as substance abuse and intimate partner violence. The prevailing explanation in the scientific literature is the social stress model, which posits that social stressors—such as stigmatization and discrimination—faced by members of these subpopulations account for the disparity in mental health outcomes. Studies show that while social stressors do contribute to the increased risk of poor mental health outcomes for these populations, they likely do not account for the entire disparity.

Many of the issues surrounding sexual orientation and gender identity remain controversial among researchers, but there is general agreement on the observation at the heart of Part Two: lesbian, gay, bisexual, and transgender (LGBT) subpopulations are at higher risk, compared to the general population, of numerous mental health problems. Less certain are the causes of that increased risk and thus the social and clinical approaches that may help to ameliorate it. In this part we review some of the research documenting the increased risk, focusing on papers that are data-based with sound methodology, and that are widely cited in the scientific literature.

A robust and growing body of research examines the relationships between sexuality or sexual behaviors and mental health status. The first half of this part discusses the associations of sexual identities or behaviors with psychiatric disorders (such as mood disorders, anxiety disorders, and adjustment disorders), suicide, and intimate partner violence. The second half explores the reasons for the elevated risks of these outcomes among non-heterosexual and transgender populations, and considers what social science research can tell us about one of the most prevalent ways of explaining these risks, the social stress model. As we will see, social stressors such as harassment and stigma likely explain some but not all of the elevated mental health risks for these populations. More research

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is needed to understand the causes of and potential solutions for these important clinical and public health issues.

## **Some Preliminaries**

We turn first to the evidence for the statistical links between sexual identities or behaviors and mental health outcomes. Before summarizing the relevant research, we should mention the criteria used in selecting the studies reviewed. In an attempt to distill overall findings of a large body of research, each section begins by summarizing the most extensive and reliable meta-analyses—papers that compile and analyze the statistical data from the published research literature. For some areas of research, no comprehensive meta-analyses have been conducted, and in these areas we rely on review articles that summarize the research literature without going into quantitative analyses of published data. In addition to reporting these summaries, we also discuss a few select studies that are of particular value because of their methodology, sample size, controls for confounding factors, or ways in which concepts such as heterosexuality or homosexuality are operationalized; and we discuss key studies published after the meta-analyses or review articles were published.

As we showed in Part One, explaining the exact biological and psychological origins of sexual desires and behaviors is a difficult scientific task, one that has not yet been and may never be satisfactorily completed. However, researchers can study the correlations between sexual behavior, attraction, or identity and mental health outcomes, though there may be—and often are found to be—differences between how sexual behavior, attraction, and identity relate to particular mental health outcomes. Understanding the scope of the health challenges faced by individuals who engage in particular sexual behaviors or experience certain sexual attractions is a necessary step in providing these individuals with the care they need.

# Sexuality and Mental Health

In a 2008 meta-analysis of research on mental health outcomes for nonheterosexuals, University College London professor of psychiatry Michael King and colleagues concluded that gays, lesbians, and bisexuals face "higher risk of suicidal behaviour, mental disorder and substance misuse and dependence than heterosexual people."<sup>1</sup> This survey of the literature examined papers published between January 1966 and April 2005 with data from 214,344 heterosexual and 11,971 non-heterosexual individuals.

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The large sample size allowed the authors to generate estimates that are highly reliable, as indicated by the relatively small confidence intervals.<sup>2</sup>

Compiling the risk ratios found in these papers, the authors estimated that lesbian, gay, and bisexual individuals had a 2.47 times higher lifetime risk than heterosexuals for suicide attempts,<sup>3</sup> that they were about twice as likely to experience depression over a twelve-month period,<sup>4</sup> and approximately 1.5 times as likely to experience anxiety disorders.<sup>5</sup> Both non-heterosexual men and women were found to be at an elevated risk for substance abuse problems (1.51 times as likely),<sup>6</sup> with the risk for non-heterosexual women especially high—3.42 times higher than for heterosexual women.<sup>7</sup> Non-heterosexual men, on the other hand, were at a particularly high risk for suicide attempts: while non-heterosexual men and women together were at a 2.47 times greater risk of suicide attempts over their lifetimes, non-heterosexual men were found to be at a 4.28 times greater risk.<sup>8</sup>

These findings have been replicated in other studies, both in the United States and internationally, confirming a consistent and alarming pattern. However, there is considerable variation in the estimates of the increased risks of various mental health problems, depending on how researchers define terms such as "homosexual" or "non-heterosexual." The findings from a 2010 study by Northern Illinois University professor of nursing and health studies Wendy Bostwick and colleagues examined associations of sexual orientation with mood and anxiety disorders among men and women who either identified as gay, lesbian, or bisexual, or who reported engaging in same-sex sexual behavior, or who reported feeling same-sex attractions. The study employed a large, U.S.-based random population sample, using data collected from the 2004-2005 wave of the National Epidemiologic Survey on Alcohol and Related Conditions, which was based on 34,653 interviews.<sup>9</sup> In its sample, 1.4% of respondents identified as lesbian, gay, or bisexual; 3.4% reported some lifetime same-sex sexual behavior; and 5.8% reported non-heterosexual attractions.<sup>10</sup>

Women who identified as lesbian, bisexual, or "not sure" reported higher rates of lifetime mood disorders than women who identified as heterosexual: the prevalence was 44.4% in lesbians, 58.7% in bisexuals, and 36.5% in women unsure of their sexual identity, as compared to 30.5% in heterosexuals. A similar pattern was found for anxiety disorders, with bisexual women experiencing the highest prevalence, followed by lesbians and those unsure, and heterosexual women experiencing the lowest prevalence. Examining the data for women with different sexual *behavior* or sexual *attraction* (rather than identity), those reporting sexual behavior

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with or attractions to both men and women had a higher rate of lifetime disorders than women who reported exclusively heterosexual or homosexual behaviors or attractions, and women reporting exclusive same-sex sexual behavior or exclusive same-sex attraction in fact had the *lowest* rates of lifetime mood and anxiety disorders.<sup>11</sup>

Men who identified as gay had more than double the prevalence of lifetime mood disorders compared to men who identified as heterosexual (42.3% vs. 19.8%), and more than double the rate of any lifetime anxiety disorder (41.2% vs. 18.6%), while those who identified as bisexual had a slightly lower prevalence of mood disorders (36.9%) and anxiety disorders (38.7%) than gay men. When looking at sexual attraction or behavior for men, those who reported sexual attraction to "mostly males" or sexual behavior with "both females and males" had the highest prevalence of lifetime mood disorders and anxiety disorders compared to other groups, while those reporting exclusively heterosexual attraction or behavior had the lowest prevalence of any group.

Other studies have found that non-heterosexual populations are at a higher risk of physical health problems in addition to mental health problems. A 2007 study by UCLA professor of epidemiology Susan Cochran and colleagues examined data from the California Quality of Life Survey of 2,272 adults to assess links between sexual orientation and selfreported physical health status, health conditions, and disability, as well as psychological distress among lesbians, gay men, bisexuals, and those they classified as "homosexually experienced heterosexual individuals."<sup>12</sup> While the study, like most, was limited by the use of self-reporting of health conditions, it had several strengths: it studied a population-based sample; it separately measured identity and behavioral dimensions of sexual orientation; and it controlled for race (ethnicity), education, relationship status, and family income, among other factors.

While the authors of this study found a number of health conditions that appeared to have elevated prevalence among non-heterosexuals, after adjusting for demographic factors that are potential confounders the only group with significantly greater prevalence of non-HIV physical health conditions was bisexual women, who were more likely to have health problems than heterosexual women. Consistent with the 2010 study by Bostwick and colleagues, higher rates of psychological stress were reported by lesbians, bisexual women, gay men, and homosexually experienced heterosexual men, both before and after adjusting for demographic confounding. Among men, self-identified gay and homosexually experienced heterosexual respondents reported the highest rates of several health problems.

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Using the same California Quality of Life Survey, a 2009 study by UCLA professor of psychiatry and biobehavioral sciences Christine Grella and colleagues (including Cochran) examined the relationship between sexual orientation and receiving treatment for substance use or mental disorders.<sup>13</sup> They used a population-based sample, with sexual minorities oversampled to provide more statistical power to detect group differences. The usage of treatment was classified according to whether or not respondents reported receiving treatment in the preceding twelve months for "emotional, mental health, alcohol or other drug problems." Sexual orientation was operationalized by a combination of behavioral history and self-identification. For example, they grouped together as "gay/bisexual" or "lesbian/bisexual" both those who identified as gay, lesbian, or bisexual, and those who had reported same-sex sexual behaviors. They found that women who were lesbian or bisexual were most likely to have received treatment, followed by men who were gay or bisexual, then heterosexual women, with heterosexual men being the least likely group to have reported receiving treatment. Overall, more than twice as many LGB individuals, compared to heterosexuals, had reported receiving treatment in the past twelve months (48.5% compared to 22.5%). The pattern was similar for men and women; 42.5% of homosexual men, compared to 17.1% of heterosexual men, had reported receiving treatment, while 55.3% of lesbian and bisexual women and 27.1% of heterosexual women reported receiving treatment. (Bostwick and colleagues had found that women with exclusively same-sex attractions and behaviors had a lower prevalence of mood and anxiety disorders compared to heterosexual women. The difference in results could be due to the fact that Grella and colleagues grouped those who identified as lesbians together with those who identified as bisexuals or who reported same-sex sexual behavior.)

A 2006 study by Columbia University psychiatry professor Theodorus Sandfort and colleagues examined a representative, population-based sample from the second Dutch National Survey of General Practice, carried out in 2001, to assess links between self-reported sexual orientation and health status among 9,511 participants, of whom 0.9% were classified as bisexual and 1.5% as gay or lesbian.<sup>14</sup> To operationalize sexual orientation, the researchers asked respondents about their sexual preference on a 5-point scale: exclusively women, predominantly women, equally men and women, predominantly men, and exclusively men. Only those who reported an equal preference for men and women were classified as bisexual, while men reporting predominant preferences for women, or women reporting a predominant preference for men were classified as heterosexual. They

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found that gay, lesbian, and bisexual respondents reported experiencing higher numbers of acute mental health problems and reported worse general mental health than heterosexuals. The results for physical health were mixed, however: lesbian and gay respondents reported experiencing more acute physical symptoms (such as headaches, back pain, or sore throats) over the past fourteen days, though they did not report experiencing two or more such symptoms any more than heterosexuals.

Lesbian and gay respondents were more likely to report chronic health problems, though bisexual men (that is, men who reported an equal sexual preference for men and women) were less likely to report chronic health problems and bisexual women were no more likely than heterosexual women to do so. The researchers did not find a statistically significant relationship between sexual orientation and overall physical health. After controlling for the possible confounding effects of mental health problems on the reporting of physical health problems, the researchers also found that the statistical effect of reporting a gay or lesbian sexual preference on chronic and acute physical conditions disappeared, though the effect of bisexual preference remained.

The Sandfort study defined sexual orientation in terms of preference or attraction without reference to behavior or self-identification, which makes it a challenge to compare its results to the results of studies that operationalize sexual orientation differently. For example, it is difficult to compare the findings of this study regarding bisexuals (defined as men or women who report an equal sexual preference for men and women) with the findings of other studies regarding "homosexually experienced heterosexual individuals" or those who are "unsure" of their sexual identity. As in most of these types of studies, the health assessments were self-reported, which may make the results somewhat unreliable. But this study also has several strengths: it used a large and representative sample of a country's population, as opposed to the convenience samples that are sometimes used for these kinds of studies, and this sample included a sufficient number of gays and lesbians for their data to be treated in separate groups in the study's statistical analyses. Only three people in the sample reported HIV infection, so this did not appear to be a potential confounding factor, though HIV could have been underreported.

In an effort to summarize findings in this area, we can cite the 2011 report from the Institute of Medicine (IOM), *The Health of Lesbian, Gay, Bisexual, and Transgender People.*<sup>15</sup> This report is an extensive review of scientific literature citing hundreds of studies that examine the health status of LGBT populations. The authors are scientists who are well versed

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in these issues (although we wish there had been more involvement of experts in psychiatry). The report reviews findings on physical and mental health in childhood, adolescence, early and middle adulthood, and late adulthood. Consistent with the studies cited above, this report reviews evidence showing that, compared with heterosexual youth, LGB youth are at a higher risk of depression, as well as suicide attempts and suicidal ideation. They are also more likely to experience violence and harassment and to be homeless. LGB individuals in early or middle adulthood are more prone to mood and anxiety disorders, depression, suicidal ideation, and suicide attempts.

The IOM report shows that, like LGB youth, LGB adults—and women in particular—appear to be likelier than heterosexuals to smoke, use or abuse alcohol, and abuse other drugs. The report cites a study<sup>16</sup> that found that self-identified non-heterosexuals used mental health services more often than heterosexuals, and another<sup>17</sup> that found that lesbians used mental health services at higher rates than heterosexuals.

The IOM report notes that "more research has focused on gay men and lesbians than on bisexual and transgender people."<sup>18</sup> The relatively few studies focusing on transgender populations show high rates of mental disorders, but the use of nonprobability samples and the lack of non-transgender controls call into question the validity of the studies.<sup>19</sup> Although some studies have suggested that the use of hormone treatments may be associated with negative physical health outcomes among transgender populations, the report notes that the relevant research has been "limited" and that "no clinical trials on the subject have been conducted."<sup>20</sup> (Health outcomes for transgender individuals will be further discussed below in this part and also in Part Three.)

The IOM report claims that the evidence that LGBT populations have worse mental and physical health outcomes is not fully conclusive. To support this claim, the IOM report cites a 2001 study<sup>21</sup> of mental health in 184 sister pairs in which one sister was lesbian and the other heterosexual. The study found no significant differences in rates of mental health problems, and found significantly higher self-esteem in the lesbian sisters. The IOM report also cites a 2003 study<sup>22</sup> that found no significant differences between heterosexual and gay or bisexual men in general happiness, perceived health, and job satisfaction. Acknowledging these caveats and the studies that do not support the general trend, the vast majority of studies cited in the report point to a generally higher risk of poor mental health status in LGBT populations compared to heterosexual populations.

## **Sexuality and Suicide**

The association between sexual orientation and suicide has strong scientific support. This association merits particular attention, since among all the mental health risks, the increased risk of suicide is the most concerning, owing in part to the fact that the evidence is robust and consistent, and in part to the fact that suicide is so devastating and tragic for the person, family, and community. A better understanding of the risk factors for suicide could allow us, quite literally, to save lives.<sup>23</sup>

Sociologist and suicide researcher Ann Haas and colleagues published an extensive review article in 2011 based on the results of a 2007 conference sponsored by the Gay and Lesbian Medical Association, the American Foundation for Suicide Prevention, and the Suicide Prevention Resource Center.<sup>24</sup> They also examined studies reported since the 2007 conference. For the purposes of their report, the authors defined sexual orientation as "sexual self-identification, sexual behavior, and sexual attraction or fantasy."<sup>25</sup>

Haas and colleagues found the association between homosexual or bisexual orientation and suicide attempts to be well supported by data. They noted that population-based surveys of U.S. adolescents since the 1990s indicate that suicide attempts are two to seven times more likely in high school students who identify as LGB, with sexual orientation being a stronger predictor in males than females. They reviewed data from New Zealand that suggested that LGB individuals were six times more likely to have attempted suicide. They cited health-related surveys of U.S. men and Dutch men and women showing same-sex behavior linked to higher risk of suicide attempts. Studies cited in the report show that lesbian or bisexual women are likelier, on average, to experience suicidal ideation, that gay or bisexual men are more likely, on average, to attempt suicide, and that lifetime suicide attempts among non-heterosexuals are greater in men than in women.

Examining studies that looked at rates of mental disorders in relation to suicidal behavior, Haas and colleagues discussed a New Zealand study<sup>26</sup> showing that gay people reporting suicide attempts had higher rates of depression, anxiety, and conduct disorder. Large-scale health surveys suggested that rates of substance abuse are up to one third higher for the LGB subpopulation. Combined worldwide studies showed up to 50% higher rates of mental disorders and substance abuse among persons self-identifying in surveys as lesbian, gay, or bisexual. Lesbian or bisexual women showed higher levels of substance abuse, while gay or bisexual men had higher rates of depression and panic disorder.

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Haas and colleagues also examined transgender populations, noting that scant information is available about transgender suicides but that the existing studies indicate a dramatic increased risk of completed suicide. (These findings are noted here but examined in more detail in Part Three.) A 1997 clinical study<sup>27</sup> estimated elevated risks of suicide for Dutch male-to-female transsexual individuals on hormone therapy, but found no significant differences in overall mortality. A 1998 international review of 2,000 persons receiving sex-reassignment surgery identified 16 possible suicides, an "alarmingly high rate of 800 suicides for every 100,000 post-surgery transsexuals."<sup>28</sup> In a 1984 study, a clinical sample of transgender individuals requesting sex-reassignment surgery showed suicide attempt rates between 19% and 25%.<sup>29</sup> And a large sample of 40,000 mostly U.S. volunteers completing an Internet survey in 2000 found transgender persons to report higher rates of suicide attempts than any group except lesbians.<sup>30</sup>

Finally, the review by Haas and colleagues suggests that it is not clear which aspects of sexuality (identity, attraction, behavior) are most closely linked with the risk of suicidal behavior. The authors cite a 2010 study<sup>31</sup> showing that adolescents identifying as heterosexual while reporting same-sex attraction or behavior did not have significantly higher suicide rates than other self-identified heterosexuals. They also cite the large national survey of U.S. adults conducted by Wendy Bostwick and colleagues (discussed earlier),<sup>32</sup> which showed mood and anxiety disorders—key risk factors for suicidal behavior—more closely related to sexual self-identity than to behavior or attraction, especially for women.

A more recent critical review of existing studies of suicide risk and sexual orientation was presented by Austrian clinical psychologist Martin Plöderl and colleagues.<sup>33</sup> This review rejects several hypotheses developed to account for the increased suicide risk among non-heterosexuals, including biases in self-reporting and failures to measure suicide attempts accurately. The review argues that methodological improvements in studies since 1997 have provided control groups, better representativeness of study samples, and more clarity in defining both suicide attempts and sexual orientation.

The review mentions a 2001 study<sup>34</sup> by Ritch Savin-Williams, a Cornell University professor of developmental psychology, that reported no statistically significant difference between heterosexual and LGB youths after eliminating false-positive reports of suicide attempts and blaming a "suffering suicidal' script" for leading to an over-reporting of suicidal behavior among gay youths. Plöderl and colleagues argue, however, that

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the Savin-Williams study's finding that there was no statistically significant difference between the suicide rates of LGB and heterosexual youths might be attributable to the small sample size, which yielded low statistical power.<sup>35</sup> The later work has not replicated this finding. Subsequent questionnaire or interview-based studies with stricter definitions of suicide attempts have found significantly increased rates of suicide attempts among non-heterosexuals. Several large-scale surveys of young people have found that the elevated risk of reported suicidal behavior increased with the severity of the attempts.<sup>36</sup> Finally, according to Plöderl and colleagues, comparing results of questionnaires with clinical interviews indicates that homosexual youth are less likely to over-report suicide attempts in surveys than heterosexual youth.

Plöderl and colleagues concluded that among psychiatric patients, homosexual or bisexual populations are over-represented in "serious suicide attempts," and that sexual orientation is one of the strongest predictors of suicide. Similarly, in nonclinical population-based studies, non-heterosexual status is found to be one of the strongest predictors of suicide attempts. The authors note:

The most exhaustive collation of published and unpublished international studies on the association of suicide attempts and sexual orientation with different methodologies has produced a very consistent picture: nearly all studies found increased incidences of self-reported suicide attempts among sexual minorities.<sup>37</sup>

In acknowledging the challenges of all such research, the authors suggest that "the major problem remains as to where one draws the line between a heterosexual or non-heterosexual orientation."<sup>38</sup>

A 1999 study by Richard Herrell and colleagues analyzed 103 middleaged male twin pairs from the Vietnam Era Twin Registry in Hines, Illinois, in which one twin, but not the other, reported having a male sex partner after the age of 18.<sup>39</sup> The study adopted several measures of suicidality and controlled for potential confounding factors such as substance abuse or depression. It found a "substantially increased lifetime prevalence of suicidal symptoms" in male twins who had sex with men compared with co-twins who did not, independent of the potential confounding effects of drug and alcohol abuse.<sup>40</sup> Though it is a relatively small study and relied on self-reporting for both same-sex behaviors and suicidal thoughts or behaviors, it is notable for using a probability sample (which eliminates selection bias), and for using the co-twin control method (which reduces the effects of genetics, age, race, and the like).

 $<sup>68 \</sup>sim \text{The New Atlantis}$ 

The study looked at middle-aged men; what the implications might be for adolescents is not clear.

In a 2011 study, Robin Mathy and colleagues analyzed the impact of sexual orientation on suicide rates in Denmark during the first twelve years after the legalization of same-sex registered domestic partnerships (RDPs) in that country, using data from death certificates issued between 1990 and 2001 as well as Danish census population estimates.<sup>41</sup> The researchers found that the age-adjusted suicide rate for same-sex RDP men was nearly eight times the rate for men in heterosexual marriages, and nearly twice the rate for men who had never married. For women, RDP status had a small, statistically insignificant effect on suicide mortality risk, and the authors conjectured that the impact of HIV status on the health of gay men might have contributed to this difference between the results for men and women. The study is limited by the fact that RDP status is an indirect measure of sexual orientation or behavior, and does not include those gays and lesbians who are not in a registered domestic partnership; the study also excluded individuals under the age of 18. Finally, the absolute number of individuals with current or past RDP status was relatively small, which may limit the study's conclusions.

Professor of pediatrics Gary Remafedi and colleagues published a 1991 study that looked at 137 males age 14–21 who self-identified as gay (88%) or bisexual (12%). Remafedi and colleagues attempted, with a casecontrolled approach, to examine which factors for this population were most predictive of suicide.<sup>42</sup> Compared to those who did not attempt suicide, those who did were significantly more likely to label themselves and identify publicly as bisexual or homosexual at younger ages, report sexual abuse, and report illicit drug use. The authors noted that the likelihood of a suicide attempt "diminished with advancing age at the time of bisexual or homosexual self-labeling." Specifically, "with each year's delay in selfidentification, the odds of a suicide attempt declined by more than 80%."<sup>43</sup> This study is limited by using a relatively small nonprobability sample, though the authors note that its result comports with their previous finding<sup>44</sup> of an inverse relationship between psychosocial problems and the age at which one identifies as homosexual.

In a 2010 study, Plöderl and colleagues solicited self-reported suicide attempts among 1,382 Austrian adults to confirm existing evidence that homosexual and bisexual individuals are at higher risk.<sup>45</sup> To sharpen the results, the authors developed more rigorous definitions of "suicide attempts" and assessed multiple dimensions of sexual orientation, distinguishing among sexual fantasies, preferred partners, self-identification,

recent sexual behavior, and lifetime sexual behavior. This study found an increased risk for suicide attempts for sexual minorities along all dimensions of sexual orientation. For women, the risk increases were largest for those with homosexual behaviors; for men, they were largest for homosexual or bisexual behavior in the previous twelve months and self-identification as homosexual or bisexual. Those reporting being unsure of their identity reported the highest percentage of suicide attempts (44%), although this group was small, comprising less than 1% of participants.

A 2016 meta-analysis by University of Toronto graduate student Travis Salway Hottes and colleagues aggregated data from thirty crosssectional studies on suicide attempts that together included 21,201 sexual minority adults.<sup>46</sup> These studies used either population-based sampling or community-based sampling. Since each sampling method has its own strengths and potential biases,<sup>47</sup> the researchers wanted to examine any differences in the rates of attempted suicide between the two sampling types. Of the LGB respondents to population-based surveys, 11% reported having attempted suicide at least once, compared to 4% of heterosexual respondents to these surveys.<sup>48</sup> Of the LGB respondents to communitybased surveys, 20% reported having attempted suicide.<sup>49</sup> Statistical analysis showed that the difference in the sampling methods accounted for 33% of the variation in the suicide figures reported by the studies.

The research on sexuality and the risk of suicide suggests that those who identify as gay, lesbian, bisexual, or transgender, or those who experience same-sex attraction or engage in same-sex sexual behavior are at substantially increased risk of suicidal ideation, suicide attempts, and completed suicide. In the section later in Part Two on the social stress model, we will examine—and raise questions about—one set of arguments put forward to explain these findings. Given the tragic consequences of inadequate or incomplete information in these matters and its effect on public policy and clinical care, more research into the reasons for elevated suicide risk among sexual minorities is desperately needed.

## **Sexuality and Intimate Partner Violence**

Several studies have examined the differences between rates of intimate partner violence (IPV) in same-sex couples and opposite-sex couples. The research literature examines rates of IPV *victimization* (being subjected to violence by a partner) and rates of IPV *perpetration* (committing violence against a partner). In addition to physical and sexual violence, some studies also examine psychological violence, which comprises verbal attacks,

<sup>70</sup>  $\sim$  The New Atlantis

threats, and similar forms of abuse. The weight of evidence indicates that the rate of intimate partner violence is significantly higher among samesex couples.

In 2014, London School of Hygiene and Tropical Medicine researcher Ana Buller and colleagues conducted a systematic review of 19 studies (with a meta-analysis of 17 of these studies) examining associations between intimate partner violence and health among men who have sex with men.<sup>50</sup> Combining the available data, they found that the pooled lifetime prevalence of any IPV was 48% (estimates from the studies were quite heterogeneous, ranging from 32% to 82%). For IPV within the previous five years, pooled prevalence was 32% (estimates ranging from 16% to 51%). IPV victimization was associated with increased rates of substance use (pooled odds ratio of 1.9), positive HIV status (pooled odds ratio of 1.5), and increased rates of depressive symptoms (pooled odds ratio of 1.5). IPV perpetration was also associated with increased rates of substance use (pooled odds ratio of 2.0). An important limitation of this meta-analysis was that the number of studies it included was relatively small. Also, the heterogeneity of the studies' results may undermine the precision of the meta-analysis. Further, most of the reviewed studies used convenience samples rather than probabilistic samples, and they used the word "partner" without distinguishing longterm relationships from casual encounters.

English psychologists Sabrina Nowinski and Erica Bowen conducted a 2012 review of 54 studies on the prevalence and correlates of intimate partner violence victimization among heterosexual and gay men.<sup>51</sup> The studies showed rates of IPV victimization for gay men ranging from 15% to 51%. Compared to heterosexual men, the review reports, "it appears that gay men experienced more total and sexual IPV, slightly less physical IPV, and similar levels of psychological IPV."52 The authors also report that according to estimates of IPV prevalence over the most recent twelve months, gay men "experienced less physical, psychological and sexual IPV" than heterosexual men, though the relative lack of twelve-month estimates may make this result unreliable. The authors note that "one of the most worrying findings is the prevalence of severe sexual coercion and abuse in male same-gender relationships,"<sup>53</sup> citing a 2005 study<sup>54</sup> on IPV in HIV-positive gay men. Nowinski and Bowen found positive HIV status to be associated with IPV in both gay and heterosexual relationships. An important limitation of their review is the fact that many of the same-sex IPV studies they examined were based on small convenience samples.

Catherine Finneran and Rob Stephenson of Emory University in 2012 conducted a systematic review of 28 studies examining IPV among men

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who have sex with men.<sup>55</sup> Every study in the review estimated rates of IPV for gay men that were similar to or higher than those for all women regardless of sexual orientation. The authors conclude that "the emergent evidence reviewed here demonstrates that IPV-psychological, physical, and sexual-occurs in male-male partnerships at alarming rates."56 Physical IPV victimization was reported most frequently, with rates ranging from 12% to 45%.57 The rate of sexual IPV victimization ranged from 5% to 31%, with 9 out of 19 studies reporting rates over 20%. Psychological IPV victimization was recorded in six studies, with rates ranging from 5% to 73%.58 Perpetration of physical IPV was reported in eight studies, with rates ranging from 4% to 39%. Rates of perpetration of sexual IPV ranged from 0.7% to 28%; four of the five studies reviewed reported rates of 9% or more. Only one study measured perpetration of psychological violence, and the estimated prevalence was 78%. Lack of consistent research design among the studies examined (for example, some differences regarding the exact definition of IPV, the correlates of IPV examined, and the recall periods used to measure violence) makes it impossible to calculate a pooled prevalence estimate, which would be useful given the lack of a national probability-based sample.

A 2013 study by UCLA's Naomi Goldberg and Ilan Meyer used a large probability sample of almost 32,000 individuals from the California Health Interview Survey to assess differences in intimate partner violence between various cohorts: heterosexual; self-identified gay, lesbian, and bisexual individuals; and men who have sex with men but did not identify as gay or bisexual, and women who have sex with women but did not identify as lesbian or bisexual.<sup>59</sup> All three LGB groups had greater lifetime and one-year prevalence of intimate partner violence than the heterosexual group, but this difference was only statistically significant for bisexual women and gay men. Bisexual women were more likely to have experienced lifetime IPV (52% of bisexual women vs. 22% of heterosexual women and 32% of lesbians) and to have experienced IPV in the preceding year (27% of bisexuals vs. 5% of heterosexuals and 10% of lesbians). For men, all three non-heterosexual groups had higher rates of lifetime and one-year IPV, but this was only statistically significant for gay men, who were more likely to have experienced IPV over a lifetime (27% of gay men vs. 11% of heterosexual men and 19.6% of bisexual men) and over the preceding year (12% of gay men vs. 5% of heterosexual men and 9% of bisexual men). The authors also tested whether binge drinking and psychological distress could explain the higher prevalence of IPV victimization in gay men and bisexual women; controlling for these

 $<sup>72 \</sup>sim \mathrm{The} \ \mathrm{New} \ \mathrm{Atlantis}$ 

variables revealed that they did not. This study is limited by the fact that other potentially confounding psychological variables (besides drinking and distress) were not controlled for, statistically or otherwise, and may have accounted for the findings.

To estimate the prevalence of battering victimization among gay partners, AIDS-prevention researcher Gregory Greenwood and colleagues published a 2002 study based on telephone interviews with a probability-based sample of 2,881 men who have sex with men (MSM) in four cities from 1996 to 1998.60 Of those interviewed, 34% reported experiencing psychological or symbolic abuse, 22% reported physical abuse, and 5% reported sexual abuse. Overall, 39% reported some type of battering victimization, and 18% reported more than one type of battering in the previous five years. Men younger than 40 were significantly more likely than men over 60 to report battering violence. The authors conclude that "the prevalence of battering within the context of intimate partner relationships was very high" among their sample of men who have sex with men, and that since lifetime rates are usually higher than those for a five-year recall, "it is likely that a substantially greater number of MSM than of heterosexual men have experienced lifetime victimization."61 The five-year prevalence of physical battering among this sample of urban MSM was also "significantly higher" than the annual rate of severe violence (3%) or total violence (12%) experienced in a representative sample of heterosexual women living with men, suggesting that the estimates of battering victimization for MSM in this study "are higher than or comparable to those reported for heterosexual women."62 This study was limited by its use of a sample from four cities, so it is not clear how well the results generalize to non-urban settings.

# **Transgender Health Outcomes**

The research literature for mental health outcomes in transgender individuals is more limited than the research on mental health outcomes in LGB populations. Because people identifying as transgender make up a very small proportion of the population, large population-based surveys and studies of such individuals are difficult if not impossible to conduct. Nevertheless, the limited available research strongly suggests that transgender people have increased risks of poor mental health outcomes. It appears that the rates of co-occurring substance use disorders, anxiety disorders, depression, and suicide tend to be higher for transgender people than for LGB individuals.

In 2015, Harvard pediatrics professor and epidemiologist Sari Reisner and colleagues conducted a retrospective matched-pair cohort study of mental health outcomes for 180 transgender subjects aged 12–29 years (106 female-to-male and 74 male-to-female), matched to non-transgender controls based on gender identity.<sup>63</sup> Transgender youth had an elevated risk of depression (50.6% vs. 20.6%)<sup>64</sup> and anxiety (26.7% vs. 10.0%).<sup>65</sup> Transgender youth also had higher risk of suicidal ideation (31.1% vs. 11.1%),<sup>66</sup> suicide attempts (17.2% vs. 6.1%),<sup>67</sup> and self-harm without lethal intent (16.7% vs. 4.4%)<sup>68</sup> relative to the matched controls. A significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%)<sup>69</sup> and outpatient mental health care (45.6% vs. 16.1%)<sup>70</sup> services. No statistically significant differences in mental health status were observed when comparing female-to-male transgender individuals to the male-to-female transgender individuals after adjusting for age, race/ethnicity, and hormone use.

This study had the merit of including individuals who presented to a community-based health clinic, and who thus were not identified solely as meeting the diagnostic criteria for gender identity disorder in the fourth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*, and were not selected from a population of patients presenting to a clinic for treatment of gender identity issues. However, Reisner and colleagues note that their study has the limitations typically found in the retrospective chart review study design, such as incomplete documentation and variation in the quality of information recorded by medical professionals.

A report from the American Foundation for Suicide Prevention and the Williams Institute, a think tank for LGBT issues at the UCLA School of Law, summarized findings on suicide attempts among transgender and gender-nonconforming adults from a large national sample of over 6,000 individuals.<sup>71</sup> This constitutes the largest study of transgender and gender-nonconforming adults to date, though it used a convenience sample rather than a population-based sample. (Large population-based samples are nearly impossible given the low overall prevalence in the general population of transgendered individuals.) Summarizing the major findings of this study, the authors write:

The prevalence of suicide attempts among respondents to the National Transgender Discrimination Survey (NTDS), conducted by the National Gay and Lesbian Task Force and National Center for Transgender Equality, is 41 percent, which vastly exceeds the 4.6

<sup>74</sup>  $\sim$  The New Atlantis

percent of the overall U.S. population who report a lifetime suicide attempt, and is also higher than the 10–20 percent of lesbian, gay and bisexual adults who report ever attempting suicide.<sup>72</sup>

The authors note that "respondents who said they had received transition-related health care or wanted to have it someday were more likely to report having attempted suicide than those who said they did not want it," however, "the survey did not provide information about the timing of reported suicide attempts in relation to receiving transition-related health care, which precluded investigation of transition-related explanations for these patterns."<sup>73</sup> The survey data suggested associations between suicide attempts, co-occurring mental health disorders, and experiences of discrimination or mistreatment, although the authors note some limitations of these outcomes: "The survey data did not allow us to determine a direct causal relationship between experiencing rejection, discrimination, victimization, or violence, and lifetime suicide attempts," although they did find evidence that stressors interacted with mental health factors "to produce a marked vulnerability to suicidal behavior in transgender and gender non-conforming individuals."<sup>74</sup>

A 2001 study by Kristen Clements-Nolle and colleagues of 392 male-tofemale and 123 female-to-male transgender persons found that 62% of the male-to-female and 55% of the female-to-male transgender persons were depressed at the time of the study, and 32% of each population had attempted suicide.<sup>75</sup> The authors note: "The prevalence of suicide attempts among male-to-female and female-to-male transgender persons in our study was much higher than that found in US household probability samples and a population-based sample of adult men reporting same-sex partners."<sup>76</sup>

# Explanations for the Poor Health Outcomes: The Social Stress Model

The greater prevalence of mental health problems in LGBT subpopulations is a cause for concern, and policymakers and clinicians should strive to reduce these risks. But to know what kinds of measures will help ameliorate them we must better understand their causes. At this time, the medical and social strategies for helping non-heterosexual populations in the United States are quite limited, and this may be due in part to the relatively limited explanations for the poor mental health outcomes offered by social scientists and psychologists.

Despite the limits of the scientific understanding of why nonheterosexual subpopulations are more likely to have such poor mental

health outcomes, much of the public effort to ameliorate these problems is motivated by a particular hypothesis called the *social stress model*. This model posits that discrimination, stigmatization, and other similar stresses contribute to poor mental health outcomes among sexual minorities. An implication of the social stress model is that reducing these stresses would ameliorate the mental health problems experienced by sexual minorities.

Sexual minorities face distinct social challenges such as stigma, overt discrimination and harassment, and, often, struggle with reconciling their sexual behaviors and identities with the norms of their families and communities. In addition, they tend to be subject to challenges similar to those of some other minority populations, arising from marginalization by or conflict with the larger part of society in ways that may adversely impact their health.<sup>77</sup> Many researchers classify these various challenges under the concept of *social stress* and believe that social stress contributes to the generally higher rates of mental health problems among LGBT subpopulations.<sup>78</sup>

In attempting to account for the mental health disparities between heterosexuals and non-heterosexuals, researchers occasionally refer to a social or minority stress *hypothesis*.<sup>79</sup> However, it is more accurate to refer to a social or minority stress *model*, because the postulated connection between social stress and mental health is more complex and less precise than anything that could be stated as a single hypothesis.<sup>80</sup> The term *stress* can have a number of meanings, ranging from a description of a physiological condition to a mental or emotional state of anger or anxiety to a difficult social, economic, or interpersonal situation. More questions arise when one thinks about various kinds of *stressors* that may disproportionately affect mental health in minority populations. We will discuss some of these aspects of the social stress model after a concise overview of the model as it has been presented in recent literature on LGBT mental health.

The social stress model attempts to explain why non-heterosexual people have, on average, higher incidences of poor mental health outcomes than the rest of the population. It does not put forth a complete explanation for the disparities between non-heterosexuals and heterosexuals, and it does not explain the mental health problems of a particular patient. Rather, it describes social factors that might directly or indirectly influence the health risks for LGBT people, which may only become apparent at a population level. Some of these factors may also influence heterosexuals, but LGBT people are probably disproportionately exposed to them.

In an influential 2003 article on the social stress model, psychiatric epidemiologist and sexual orientation law expert Ilan Meyer distinguished between *distal* and *proximate* minority stressors. Distal stressors do not

 $<sup>76 \</sup>sim \text{The New Atlantis}$ 

depend on the individual's "perceptions or appraisals," and thus "can be seen as independent of personal identification with the assigned minority status."81 For instance, if a man who was perceived to be gay by an employer was fired on that basis, this would be a distal stressor, since the stressful event of discrimination would have had nothing to do with whether the man actually identified as gay, but only with someone else's attitude and perception. Distal stressors tend to reflect social circumstances rather than the individual's reaction to those circumstances. Proximate stressors, in contrast, are more subjective and are closely related to the individual's self-identity as lesbian, gay, bisexual, or transgender. An example of a proximate stressor would be when a young woman personally identifies as being a lesbian, and chooses to hide that identity from her family members out of fear of disapproval, or because of an internal sense of shame. The effects of proximate stressors such as this one are highly dependent on the individual's self-understanding and unique social circumstances. In this section we describe the types of stressors postulated in the social stress model, starting at the distal and proceeding to the most proximate stressors, and examine some of the empirical evidence that has been offered on the links between the stressors and mental health outcomes.

**Discrimination and prejudice events.** Overt acts of mistreatment, ranging from violence to harassment and discrimination, are categorized together by researchers as "prejudice events." These are thought to be significant stressors for non-heterosexual populations.<sup>82</sup> Surveys of LGBT subpopulations have found that they tend to experience these kinds of prejudice events more frequently than the general population.<sup>83</sup>

The available evidence indicates that prejudice events likely contribute to mental health problems. A 1999 study by UC Davis professor of psychology Gregory Herek and colleagues using survey data from 2,259 LGB individuals in Sacramento found that self-identified lesbians and gays who experienced a bias crime in the preceding five years—a crime, such as assault, theft, or vandalism, motivated by the actual or perceived sexual identity of the victim—reported significantly higher levels of depressive symptoms, traumatic stress symptoms, and anxiety than lesbians and gays who had not experienced a bias crime over that same period.<sup>84</sup> Additionally, lesbians and gays who reported being the victims of bias crimes in the last five years showed significantly higher levels of depressive and traumatic stress symptoms than individuals who experienced non-bias crimes in the same period (though the two groups did not display significant differences in anxiety). Comparable significant correlations were not found for

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self-identified bisexuals, who constituted a much smaller portion of the survey respondents. The study also found that lesbians and gays subject to bias crimes were significantly more likely than other respondents to report feelings of vulnerability and a decreased sense of personal mastery or agency. Corroborating these findings on the harmful impact of bias crimes was a 2001 study by Northeastern University social scientist Jack McDevitt and colleagues that examined aggravated assaults using data from the Boston Police Department.<sup>85</sup> They found that bias crime victims tended to experience the effects of victimization more intensely and for a longer period of time than non-bias crime victims. (The study looked at bias-motivated assaults in general, rather than restricting its analysis to assaults motivated by LGBT bias, though a substantial portion of the subjects did experience assaults motivated by their non-heterosexual status.)

Similar patterns also appear among non-heterosexual adolescents, for whom maltreatment is particularly high.<sup>86</sup> In a 2011 study, University of Arizona social and behavioral scientist Stephen T. Russell and colleagues analyzed a survey of 245 young LGBT adults that retrospectively assessed school victimization due to actual or perceived LGBT status between the ages of 13 and 19. They found strong correlations between school victimization and poor mental health as young adults.<sup>87</sup> Victimization was assessed by asking yes-or-no questions, such as, "During my middle or high school years, while at school, I was pushed, shoved, slapped, hit, or kicked by someone who wasn't just kidding around," followed by a question of how often these events were related to the respondent's sexual identity. Respondents who reported high levels of school victimization due to their sexual identity were 2.6 times more likely to report depression as young adults and 5.6 times more likely to report that they had attempted suicide, compared to those who reported low levels of victimization. These differences were highly statistically significant, though the study is potentially limited by its use of retrospective surveys to measure incidents of victimization. A study by professor of social work Joanna Almeida and colleagues, which relied on the 2006 Boston Youth Survey (a biennial survey of high school students in Boston public schools), found that perceptions of having been victimized due to LGBT status accounted for increased symptoms of depression among LGBT students. For male LGBT students, but not females, the study also found a positive correlation between victimization and suicidal thoughts and self-harm.88

Differences in compensation suggest discrimination in the workplace, which can have both direct and indirect effects on mental health. M. V. Lee Badgett, a professor of economics at the University of Massachusetts,

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Amherst, analyzed data collected between 1989 and 1991 in the General Social Survey and found that non-heterosexual male employees received significantly lower compensation (11% to 27%) than heterosexuals, even after controlling for experience, education, occupation, and other factors.<sup>89</sup> According to a 2009 review by Badgett,<sup>90</sup> nine studies from the 1990s and early 2000s "consistently show that gay and bisexual men earned 10% to 32% less than heterosexual men," and that differences in occupation cannot account for much of the wage disparity. Researchers have also found that non-heterosexual women earn more than heterosexual women,<sup>91</sup> which may suggest either that patterns of discrimination differ for men and women, or that there are other factors associated with non-heterosexual behavior and self-identification in men and women influencing their respective earnings, such as a lower rate of child-rearing or being the family primary wage earner.

There is evidence that suggests that wage disparities can help explain some population-level disparities in mental health outcomes,<sup>92</sup> though it is difficult to tell if differences in mental health help explain the differences in wages. A 1999 study<sup>93</sup> by Craig Waldo on the relationship between workplace heterosexism—defined as negative social attitudes toward non-heterosexuals—and stress-related outcomes in 287 LGB individuals found that LGB individuals who experienced heterosexism in the workplace "exhibited higher levels of psychological distress and health-related problems, as well as decreased satisfaction with several aspects of their jobs." The cross-sectional data used by many of these studies make it impossible to infer causality, though both prospective studies and qualitative analyses of the impact of unemployment on mental health suggest that at least some of the correlations are likely accounted for by the psychological and material effects of unemployment.<sup>94</sup>

Stigma. Sociologists have for many years documented a range of adverse effects of stigma on individuals, ranging from issues with self-esteem to academic achievement.<sup>95</sup> Stigma is typically regarded as an attribute attaching to a person that reduces that person's worth to others in a particular social context.<sup>96</sup> These negative evaluations are in many cases widely shared among a cultural group and become the basis for excluding or differentially treating stigmatized individuals. For example, mental illness can become stigmatized when it is regarded as a character flaw in mentally ill people. One reason why stigma serves an important role in the social stress model is that it can be invoked as an explanation even in the absence of particular events of discrimination or maltreatment. For

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example, stigmatization of depression may take place when a depressed person conceals the depression on the expectation that friends and family members will regard it as a character flaw. Even when this concealment is successful, and there is therefore no actual discrimination or mistreatment by the individual's friends or family, anxiety over the attitudes others may have can affect the depressed person's emotional and mental well-being.

Researchers have found associations between the risk of poor mental health and stigma toward certain populations, though there has been little empirical research on the mental health effects of stigma on LGBT people in particular. Stigma is not easy to define or operationalize, making it a difficult and vague concept for empirical social scientists to study. Nevertheless, researchers have attempted to work with the concept using surveys of self-perceived devaluation by others and have found correlations between experiences of stigma and the risk of poor mental health status. One highly cited 1997 study by sociologist and epidemiologist Bruce Link and colleagues on the connection between stigma and mental health found a "strong and enduring" negative effect of stigma on the mental well-being of men who were suffering from a mental disorder and substance abuse.<sup>97</sup> In this study, the effects of stigma appeared to persist even after the men had received largely successful treatment for their original mental and substance abuse problems. The study found significant correlations between certain stigma variables-self-reported experiences of devaluation and rejection-and depressive symptoms before and after treatment, suggesting that the effects of stigma are relatively longlasting. This might simply indicate that people with depressive symptoms tend to report more stigma, but if that were the case, one would have expected reports of stigma to decline over the course of the treatment program, as depression did. However, since stigma reports stayed constant, the authors concluded that stigma must have had a causal role in shaping depressive symptoms. It is worth noting that this study found stigma variables to account uniquely for around 10% or slightly more of the variance in depressive symptoms-in other words, stigma had a minor effect on depressive symptoms, though such an effect might manifest itself in significant ways on a population level. Some other researchers have suggested that the effects of stigma are usually minor and transitory; for example, Vanderbilt sociologist Walter Gove argued that for the "vast majority of cases the stigma [experienced by mental patients] appears to be transitory and does not appear to pose a severe problem."98

Researchers have relatively recently begun pursuing both empirical and theoretical work<sup>99</sup> on how stigma affects the mental health of LGBT

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people, though there has been some controversy over the magnitude and duration of effects due to stigma. Some of the controversy may stem from the difficulty of defining and quantifying stigma as well as the variations in stigma across different social contexts. A 2013 study by Columbia University medical psychologist Walter Bockting and colleagues on mental health in 1,093 transgender people found a positive correlation between psychological distress and both enacted and felt stigma, which were measured using survey questions.<sup>100</sup> A 2003 study<sup>101</sup> by clinical psychologist Robin Lewis and colleagues of predictors of depressive symptoms in 201 LGB individuals found that stigma consciousness was significantly associated with depressive symptoms, where stigma consciousness was assessed using a ten-item questionnaire that assessed "the degree to which one expects to be judged on the basis of a stereotype."<sup>102</sup> However, depressive symptoms are often associated with negative cognition about the self, the world, and the future, and this may contribute to the subjective perception of stigmatization among individuals suffering from depression.<sup>103</sup> A 2011 study<sup>104</sup> by Bostwick that also used measures of stigma consciousness and depressive symptoms found a modest positive correlation between stigma scores and depressive symptoms in bisexual women, although the study was limited by having a relatively small sample size. However, a 2003 longitudinal study<sup>105</sup> of Norwegian adolescents by psychologist Lars Wichstrøm and colleague found that sexual orientation was associated with poor mental health status after accounting for a variety of psychological risk factors, including self-worth. While this study did not directly consider stigma as a risk factor, it suggests that psychological factors such as stigma consciousness alone likely cannot fully account for the disparities in mental health between heterosexuals and non-heterosexuals. Additionally, it is important to note that due to the cross-sectional design of these studies, causal inferences cannot be supported by the data-different kinds of data and more evidence would be needed to support conclusions about causal relationships. In particular, it is impossible to prove through these studies that stigma leads to poor mental health, as opposed to, for example, poor mental health leading people to report higher levels of stigma, or a third factor being responsible for both poor mental health and higher levels of stigma.

**Concealment.** Stigma may affect non-heterosexual individuals' decisions about whether to disclose or conceal their sexual orientation. LGBT people may decide to conceal their sexual orientation to protect themselves against possible bias or discrimination, to avoid a sense of shame, or to

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avoid a potential conflict between their social role and sexual desires or behaviors.<sup>106</sup> Particular contexts in which LGBT people may be more likely to conceal their sexual orientation include school, work, and other places in which they feel that disclosure could negatively affect the way that people regard them.

There is a large amount of evidence from psychological research indicating that concealment of an important aspect of one's identity may have adverse mental health consequences. In general, expressing one's emotions and sharing important aspects of one's life with others play large roles in maintaining mental health.<sup>107</sup> Recent decades have seen a growing body of research on the relationships between concealment and disclosure and mental health in LGBT subpopulations.<sup>108</sup> For example, a 2007 study<sup>109</sup> by Belle Rose Ragins and colleagues of workplace concealment and disclosure in 534 LGB individuals found that fear of disclosing was associated with psychological strain and other outcomes such as job satisfaction. However, the study also challenged the notion that disclosure leads to positive psychological and social outcomes, since employees' disclosure was not significantly associated with most of the outcome variables. The authors interpret this result by saying that "this study suggests that concealment may be a necessary and adaptive decision in an unsupportive or hostile environment, thus underscoring the importance of social context."<sup>110</sup> Due to the relatively rapid changes in social acceptance of same-sex marriage and of same-sex relationships more broadly in recent decades,111 it is possible that some of the research on the psychological effects of concealment and disclosure is outdated, because in general there may now be less pressure for those identifying as LGB to conceal their identities.

**Testing the model.** One of the implications of the social stress model is that reducing the amount of discrimination, prejudice, and stigmatization of sexual minorities would help reduce the rates of mental health problems for these populations. Some jurisdictions have sought to reduce these social stressors by passing anti-discrimination and hate-crime laws. If such policies are in fact successful at reducing these stressors then they could be expected to reduce the rates of mental health problems in LGB populations to the extent that the social stress model accurately accounts for the causes of these problems. So far, studies have not been designed in such a way that could allow them to test conclusively the hypothesis that social stress accounts for the high rates of poor mental health outcomes in non-heterosexual populations, but there is research that provides some data on a testable implication of the social stress model.

<sup>82</sup>  $\sim$  The New Atlantis

PART TWO: SEXUALITY, MENTAL HEALTH OUTCOMES, AND SOCIAL STRESS

A 2009 study by sociomedical scientist Mark Hatzenbuehler and colleagues investigated the association between psychiatric morbidity in LGB populations and two state-level policies that pertained to these populations: hate-crime laws that did not include sexual orientation as a protected category, and laws prohibiting employment discrimination based on sexual orientation.<sup>112</sup> The study used data on mental health outcomes from Wave 2 of the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), a nationally representative sample of 34,653 civilian, non-institutionalized adults, and measuring psychiatric disorders according to DSM-IV criteria.<sup>113</sup> Wave 2 of NESARC took place in 2004–2005. Of the sample, 577 respondents identified as lesbian, gay, or bisexual. The analysis of the data showed that LGB individuals living in states with no hate-crime laws and no non-discrimination laws tended to have higher odds of psychiatric morbidity (compared to LGB individuals in states with one or two protective laws), but the analysis found statistically significant correlations only for dysthymia (a less severe but more persistent form of depression), generalized anxiety disorder, and post-traumatic stress disorder, while the correlations between seven other psychiatric conditions investigated were not found to be statistically significant. No epidemiological inferences can be made due to the nature of the data, suggesting the need for more studies on this and similar topics.

Hatzenbuehler and colleagues attempted to improve on this crosssectional study by doing a prospective study, published in 2010, this time examining changes in psychiatric morbidity over the period in which certain states passed constitutional amendments defining marriage as a union between one man and one woman-amendments that were described by the study's authors as "bans on gay marriage."<sup>114</sup> The authors examined differences in psychiatric morbidity between Wave 1 of NESARC, which took place in 2001-2002, and Wave 2, which coincided with the 2004 and 2005 state-constitutional amendments. They observed that the prevalence in mood disorders in LGB respondents living in states that passed marriage amendments increased by 36.6% between Waves 1 and 2. Mood disorders for LGB respondents living in states that did not pass marriage amendments decreased by 23.6%, though this change was not statistically significant. The prevalence of certain disorders increased both in states that passed such amendments and in states that did not. Generalized anxiety disorder, for example, increased in both, but by a much larger and statistically significant magnitude in states that passed marriage amendments. Hatzenbuehler and colleagues found that drug-use disorders increased more in states that did not pass marriage amendments,

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and the increase was statistically significant only for those states. (Total substance abuse disorders increased in both cases, by a roughly similar amount.) As with the earlier cross-sectional study, for the majority of the psychiatric conditions investigated there were no significant correlations between the conditions and the social policies that were hypothesized to have an influence on mental health outcomes.

Some of the limitations of the study's findings noted by the authors include the following: healthier LGB respondents may have moved out of the states that would eventually pass marriage amendments into the states that would not; sexual orientation was only assessed during Wave 2 of NESARC, and there is some fluidity to sexual identity that may have led to misclassification of some LGB respondents; and the sample size of LGB respondents living in states that passed marriage amendments was relatively small, limiting the statistical power of the study.

One hypothesized causal mechanism for the change in mental health variables associated with the marriage amendments is that the public debate surrounding the amendments may have elevated the stress experienced by non-heterosexuals—a hypothesis that was put forward by psychologist Sharon Scales Rostosky and colleagues in a study of the attitudes of LGB adults in states that passed marriage amendments in 2006.115 The survey data collected during this study showed that LGB respondents living in states that passed marriage amendments in 2006 had higher levels of various kinds of psychological distress, including stress and depressive symptoms. The study also found that participation in LGBT activism during the election season was associated with increased psychological distress. It may be that part of the psychological distress recorded by this survey, which included perceived stress, depressive symptoms (but not diagnoses of depressive disorders), and what the researchers called "amendment-related affect," may have simply reflected the typical feelings of advocates when they experience political defeat on an issue that they care passionately about. Other key limitations of the study were its cross-sectional design and its reliance on volunteers for the survey (in contrast to the previous study by Hatzenbuehler and colleagues). The survey methodology may also have biased the results-the researchers advertised on websites and through listserv e-mail announcements that they were looking for survey respondents for a study on "attitudes and experiences of LGB...individuals regarding the debate" over gay marriage. As with many forms of convenience sampling, individuals with strong attitudes regarding the issues under investigation in the survey may have been more likely to respond.

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As for the effects of particular policies, the evidence is equivocal at best. The 2009 study by Hatzenbuehler and colleagues demonstrated significant correlations between the risk of some (though not all) mental health problems in the LGB subpopulation and state policies on hate crime and employment protections. Even for the aspects of mental health that this study found to be correlated with hate-crime or employment-protection policies, the study was unable to show an epidemiological relationship between policies and health outcomes.

## Conclusion

The social stress model probably accounts for some of the poor mental health outcomes experienced by sexual minorities, though the evidence supporting the model is limited, inconsistent and incomplete. Some of the central concepts of the model, such as stigmatization, are not easily operationalized. There is evidence linking some forms of mistreatment, stigmatization, and discrimination to some of the poor mental health outcomes experienced by non-heterosexuals, but it is far from clear that these factors account for all of the disparities between the heterosexual and non-heterosexual populations. Those poor mental health outcomes may be mitigated to some extent by reducing social stressors, but this strategy is unlikely to eliminate all of the disparities in mental health status between sexual minorities and the wider population. Other factors, such as the elevated rates of sexual abuse victimization among the LGBT population discussed in Part One, may also account for some of these mental health disparities, as research has consistently shown that "survivors of childhood sexual abuse are significantly at risk of a wide range of medical, psychological, behavioral, and sexual disorders."116

Just as it does a disservice to non-heterosexual subpopulations to ignore or downplay the statistically higher risks of negative mental health outcomes they face, so it does them a disservice to misattribute the causes of these elevated risks, or to ignore other potential factors that may be at work. Assuming that a single model can explain all of the mental health risks faced by non-heterosexuals can mislead clinicians and therapists charged with helping this vulnerable subpopulation. The social stress model deserves further research, but should not be assumed to offer a complete explanation of the causes of mental health disparities if clinicians and policymakers want to adequately address the mental health challenges faced by the LGBT community. More research is needed to explore the causes of, and solutions to, these important public health challenges.

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## Part Two: Sexuality, Mental Health Outcomes, and Social Stress

1. Michael King *et al.*, "A systematic review of mental disorder, suicide, and deliberate self harm in lesbian, gay and bisexual people," *BMC Psychiatry* 8 (2008): 70, http://dx.doi. org/10.1186/1471-244X-8-70.

2. The researchers who performed this meta-analysis initially found 13,706 papers by searching academic and medical research databases, but after excluding duplicates and other spurious search results examined 476 papers. After further excluding uncontrolled studies, qualitative papers, reviews, and commentaries, the authors found 111 data-based papers, of which they excluded 87 that were not population-based studies, or that failed to employ psychiatric diagnoses, or that used poor sampling. The 28 remaining papers relied on 25 studies (some of the papers examined data from the same studies), which King and colleagues evaluated using four quality criteria: (1) whether or not random sampling was used; (2) the representativeness of the study (measured by survey response rates); (3) whether the sample was drawn from the general population or from some more limited subset, such as university students; and (4) sample size. However, only one study met all four criteria. Acknowledging the inherent limitations and inconsistencies of sexual orientation concepts, the authors included information on how those concepts were operationalized in the studies analyzed-whether in terms of same-sex attraction (four studies), same-sex behavior (thirteen studies), self-identification (fifteen studies), score above zero on the Kinsey scale (three studies), two different definitions of sexual orientation (nine studies), three different definitions (one study). Eighteen of the studies used a specific time frame for defining the sexuality of their subjects. The studies were also grouped into whether or not they focused on lifetime or twelve-month prevalence, and whether the authors analyzed outcomes for LGB populations separately or collectively.

- 3. 95% confidence interval: 1.87-3.28.
- 4. 95% confidence interval: 1.69-2.48.
- 5. 95% confidence interval: 1.23-1.92.
- 6. 95% confidence interval: 1.23-1.86.
- 7. 95% confidence interval: 1.97-5.92.
- 8. 95% confidence interval: 2.32-7.88.

9. Wendy B. Bostwick *et al.*, "Dimensions of Sexual Orientation and the Prevalence of Mood and Anxiety Disorders in the United States," *American Journal of Public Health* 100, no. 3 (2010): 468–475, http://dx.doi.org/10.2105/AJPH.2008.152942.

10. Ibid., 470.

<sup>128</sup>  $\sim$  The New Atlantis

11. The difference in health outcomes between women who identify as lesbians and women who report exclusive same-sex sexual behaviors or attractions is a good illustration of how the differences between sexual identity, behavior, and attraction matter.

12. Susan D. Cochran and Vickie M. Mays, "Physical Health Complaints Among Lesbians, Gay Men, and Bisexual and Homosexually Experienced Heterosexual Individuals: Results From the California Quality of Life Survey," *American Journal of Public Health* 97, no. 11 (2007): 2048–2055, http://dx.doi.org/10.2105/AJPH.2006.087254.

13. Christine E. Grella *et al.*, "Influence of gender, sexual orientation, and need on treatment utilization for substance use and mental disorders: Findings from the California Quality of Life Survey," *BMC Psychiatry* 9, no. 1 (2009): 52, http://dx.doi. org/10.1186/1471-244X-9-52.

14. Theo G. M. Sandfort *et al.*, "Sexual Orientation and Mental and Physical Health Status: Findings from a Dutch Population Survey," *American Journal of Public Health* 96, (2006): 1119–1125, http://dx.doi.org/10.2105%2FAJPH.2004.058891.

15. Robert Graham *et al.*, Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities, Institute of Medicine, *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding* (Washington, D.C.: The National Academies Press, 2011), http://dx.doi. org/10.17226/13128.

16. Susan D. Cochran, J. Greer Sullivan, and Vickie M. Mays, "Prevalence of Mental Disorders, Psychological Distress, and Mental Health Services Use Among Lesbian, Gay, and Bisexual Adults in the United States," *Journal of Consulting and Clinical Psychology* 71, no. 1 (2007): 53–61, http://dx.doi.org/10.1037/0022-006X.71.1.53.

17. Lisa A. Razzano, Alicia Matthews, and Tonda L. Hughes, "Utilization of Mental Health Services: A Comparison of Lesbian and Heterosexual Women," *Journal of Gay & Lesbian Social Services* 14, no. 1 (2002): 51–66, http://dx.doi.org/10.1300/J041v14n01\_03.

18. Robert Graham et al., The Health of Lesbian, Gay, Bisexual, and Transgender People, 4.

19. Ibid., 190, see also 258-259.

20. Ibid., 211.

21. Esther D. Rothblum and Rhonda Factor, "Lesbians and Their Sisters as a Control Group: Demographic and Mental Health Factors," *Psychological Science* 12, no. 1 (2001): 63–69, http://dx.doi.org/10.1111/1467-9280.00311.

22. Stephen M. Horowitz, David L. Weis, and Molly T. Laflin, "Bisexuality, Quality of Life, Lifestyle, and Health Indicators," *Journal of Bisexuality* 3, no. 2 (2003): 5–28, http://dx.doi.org/10.1300/J159v03n02\_02.

23. By way of context, it may be worth noting that in the United States, the overall suicide rate has risen in recent years: "From 1999 through 2014, the age-adjusted suicide rate in the United States increased 24%, from 10.5 to 13.0 per 100,000 population, with the pace of increase greater after 2006." Sally C. Curtin, Margaret Warner, and Holly Hedegaard, "Increase in suicide in the United States, 1999–2014," National Center for

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Health Statistics, NCHS data brief no. 241 (April 22, 2016), http://www.cdc.gov/nchs/products/databriefs/db241.htm.

24. Ann P. Haas *et al.*, "Suicide and Suicide Risk in Lesbian, Gay, Bisexual, and Transgender Populations: Review and Recommendations," *Journal of Homosexuality* 58, no. 1 (2010): 10–51, http://dx.doi.org/10.1080/00918369.2011.534038.

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30. Robin M. Mathy, "Transgender Identity and Suicidality in a Nonclinical Sample: Sexual Orientation, Psychiatric History, and Compulsive Behaviors," *Journal of Psychology* & *Human Sexuality* 14, no. 4 (2003): 47–65, http://dx.doi.org/10.1300/J056v14n04\_03.

31. Yue Zhao *et al.*, "Suicidal Ideation and Attempt Among Adolescents Reporting 'Unsure' Sexual Identity or Heterosexual Identity Plus Same-Sex Attraction or Behavior: Forgotten Groups?," *Journal of the American Academy of Child & Adolescent Psychiatry* 49, no. 2 (2010): 104–113, http://dx.doi.org/10.1016/j.jaac.2009.11.003.

32. Wendy B. Bostwick *et al.*, "Dimensions of Sexual Orientation and the Prevalence of Mood and Anxiety Disorders in the United States."

33. Martin Plöderl *et al.*, "Suicide Risk and Sexual Orientation: A Critical Review," *Archives of Sexual Behavior* 42, no. 5 (2013): 715–727, http://dx.doi.org/10.1007/s10508-012-0056-y.

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35. For females in this study, eliminating false positive attempts substantially decreased the difference between orientations. For males, the "true suicide attempts" difference approached statistical significance: 2% of heterosexual males (1 of 61) and 9% of homosexual males (5 of 53) attempted suicide, resulting in an odds ratio of 6.2.

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36. Martin Plöderl et al., "Suicide Risk and Sexual Orientation," 716-717.

37. Ibid., 723.

38. Ibid.

39. Richard Herrell *et al.*, "Sexual Orientation and Suicidality: A Co-twin Control Study in Adult Men," *Archives of General Psychiatry* 56, no. 10 (1999): 867–874, http://dx.doi. org/10.1001/archpsyc.56.10.867.

40. Ibid., 872.

41. Robin M. Mathy *et al.*, "The association between relationship markers of sexual orientation and suicide: Denmark, 1990–2001," *Social Psychiatry and Psychiatric Epidemiology* 46, no. 2 (2011): 111–117, http://dx.doi.org/10.1007/s00127-009-0177-3.

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43. Ibid., 873.

44. Gary Remafedi, "Adolescent Homosexuality: Psychosocial and Medical Implications," *Pediatrics* 79, no. 3 (1987): 331–337, http://pediatrics.aappublications.org/content/79/3/331.

45. Martin Plöderl, Karl Kralovec, and Reinhold Fartacek, "The Relation Between Sexual Orientation and Suicide Attempts in Austria," *Archives of Sexual Behavior* 39, no. 6 (2010): 1403–1414, http://dx.doi.org/10.1007/s10508-009-9597-0.

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49. 95% confidence interval: 18-22%.

50. Ana Maria Buller *et al.*, "Associations between Intimate Partner Violence and Health among Men Who Have Sex with Men: A Systematic Review and Meta-Analysis," *PLOS Medicine* 11, no. 3 (2014): e1001609, http://dx.doi.org/10.1371/journal.pmed.1001609.

51. Sabrina N. Nowinski and Erica Bowen, "Partner violence against heterosexual and gay men: Prevalence and correlates," *Aggression and Violent Behavior* 17, no. 1 (2012): 36–52, http://dx.doi.org/10.1016/j.avb.2011.09.005. It is worth noting that the 54 studies that Nowinski and Bowen consider operationalize heterosexuality and homosexuality in various ways.

52. Ibid., 39.

53. Ibid., 50.

54. Shonda M. Craft and Julianne M. Serovich, "Family-of-Origin Factors and Partner Violence in the Intimate Relationships of Gay Men Who Are HIV Positive," *Journal of Interpersonal Violence* 20, no. 7 (2005): 777–791, http://dx.doi.org/10.1177/0886260505 277101.

55. Catherine Finneran and Rob Stephenson, "Intimate Partner Violence Among Men Who Have Sex With Men: A Systematic Review," *Trauma, Violence, & Abuse* 14, no. 2 (2013): 168–185, http://dx.doi.org/10.1177/1524838012470034.

56. Ibid., 180.

57. Although one study reported just 12%, the majority of studies (17 out of 24) showed that physical IPV was at least 22%, with nine studies recording rates of 31% or more.

58. Although Finneran and Stephenson say this measure was recorded in only six studies, the table they provide lists eight studies as measuring psychological violence, with seven of these showing rates 33% or higher, including five reporting rates of 45% or higher.

59. Naomi G. Goldberg and Ilan H. Meyer, "Sexual Orientation Disparities in History of Intimate Partner Violence: Results From the California Health Interview Survey," *Journal of Interpersonal Violence* 28, no. 5 (2013): 1109–1118, http://dx.doi.org/10.1177/0886260512459384.

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61. Ibid., 1967.

62. Ibid.

63. Sari L. Reisner *et al.*, "Mental Health of Transgender Youth in Care at an Adolescent Urban Community Health Center: A Matched Retrospective Cohort Study," *Journal of Adolescent Health* 56, no. 3 (2015): 274–279, http://dx.doi.org/10.1016/j.jadohealth.201 4.10.264.

- 64. Relative risk: 3.95.
- 65. Relative risk: 3.27.
- 66. Relative risk: 3.61.
- 67. Relative risk: 3.20.
- 68. Relative risk: 4.30.
- 69. Relative risk: 2.36.
- 70. Relative risk: 4.36.

71. Anne P. Haas, Philip L. Rodgers, and Jody Herman, "Suicide Attempts Among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey," Williams Institute, UCLA School of Law, January 2014, http://williamsinstitute.law.ucla.edu/wp-content/uploads/AFSP-Williams-Suicide-Report-

<sup>132</sup>  $\sim$  The New Atlantis

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72. Ibid., 2.

73. Ibid., 8.

74. Ibid., 13.

75. Kristen Clements-Nolle *et al.*, "HIV Prevalence, Risk Behaviors, Health Care Use, and Mental Health Status of Transgender Persons: Implications for Public Health Intervention," *American Journal of Public Health* 91, no. 6 (2001): 915–921, http://dx.doi. org/10.2105/AJPH.91.6.915.

76. Ibid., 919.

77. See, for example, Ilan H. Meyer, "Minority Stress and Mental Health in Gay Men," *Journal of Health and Social Behavior* 36 (1995): 38–56, http://dx.doi.org/10.2307/2137286; Bruce P. Dohrenwend, "Social Status and Psychological Disorder: An Issue of Substance and an Issue of Method," *American Sociological Review* 31, no. 1 (1966): 14–34, http://www.jstor.org/stable/2091276.

78. For overviews of the social stress model and mental health patterns among LGBT populations, see Ilan H. Meyer, "Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence," *Psychological Bulletin* 129, no. 5 (2003): 674–697, http://dx.doi.org/10.1037/0033-2909.129.5.674; Robert Graham *et al.*, *The Health of Lesbian, Gay, Bisexual, and Transgender People, op. cit*; Gregory M. Herek and Linda D. Garnets, "Sexual Orientation and Mental Health," *Annual Review of Clinical Psychology* 3 (2007): 353–375, http://dx.doi.org/10.1146/ annurev.clinpsy.3.022806.091510; Mark L. Hatzenbuehler, "How Does Sexual Minority Stigma 'Get Under the Skin'? A Psychological Mediation Framework," *Psychological Bulletin* 135, no. 5 (2009): 707–730, http://dx.doi.org/10.1037/a0016441.

79. See, for instance, Ilan H. Meyer, "The Right Comparisons in Testing the Minority Stress Hypothesis: Comment on Savin-Williams, Cohen, Joyner, and Rieger (2010)," *Archives of Sexual Behavior* 39, no. 6 (2010): 1217–1219.

80. This should not be taken to suggest that social stress is too vague a concept for empirical social science; the social stress model may certainly produce quantitative empirical hypotheses, such as hypotheses about correlations between stressors and specific mental health outcomes. In this context, the term "model" does not refer to a statistical model of the kind often used in social science research—the social stress model is a "model" in a metaphorical sense.

81. Meyer, "Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations," 676.

82. Meyer, "Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations," 680; Gregory M. Herek, J. Roy Gillis, and Jeanine C. Cogan, "Psychological Sequelae of Hate-Crime Victimization Among Lesbian, Gay, and Bisexual Adults," *Journal of Consulting and Clinical Psychology* 67, no. 6 (1999): 945–951, http://dx.doi. org/10.1037/0022-006X.67.6.945; Allegra R. Gordon and Ilan H. Meyer, "Gender Nonconformity as a Target of Prejudice, Discrimination, and Violence Against LGB

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85. Jack McDevitt *et al.*, "Consequences for Victims: A Comparison of Bias- and Non-Bias-Motivated Assaults," *American Behavioral Scientist* 45, no. 4 (2001): 697–713, http://dx.doi.org/10.1177/0002764201045004010.

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Part Three

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# **Gender Identity**

The concept of biological sex is well defined, based on the binary roles that males and females play in reproduction. By contrast, the concept of gender is not well defined. It is generally taken to refer to behaviors and psychological attributes that tend to be typical of a given sex. Some individuals identify as a gender that does not correspond to their biological sex. The causes of such cross-gender identification remain poorly understood. Research investigating whether these transgender individuals have certain physiological features or experiences in common with the opposite sex, such as brain structures or atypical prenatal hormone exposures, has so far been inconclusive. Gender dysphoria—a sense of incongruence between one's biological sex and one's gender, accompanied by clinically significant distress or impairment—is sometimes treated in adults by hormones or surgery, but there is little scientific evidence that these therapeutic interventions have psychological benefits. Science has shown that gender identity issues in children usually do not persist into adolescence or adulthood, and there is little scientific evidence for the therapeutic value of puberty-delaying treatments. We are concerned by the increasing tendency toward encouraging children with gender identity issues to transition to their preferred gender through medical and then surgical procedures. There is a clear need for more research in these areas.

As described in Part One, there is a widely held belief that *sexual orientation* is a well-defined concept, and that it is innate and fixed in each person—as it is often put, gay people are "born that way." Another emerging and related view is that *gender identity*—the subjective, internal sense of being a man or a woman (or some other gender category)—is also fixed at birth or at a very early age and can diverge from a person's biological sex. In the case of children, this is sometimes articulated by saying that a little boy may be trapped in a little girl's body, or vice versa.

In Part One we argued that scientific research does not give much support to the hypothesis that sexual orientation is innate and fixed. We will argue here, similarly, that there is little scientific evidence that gender identity is fixed at birth or at an early age. Though biological sex is innate, and gender identity and biological sex are related in complex ways, they

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are not identical; gender is sometimes defined or expressed in ways that have little or no biological basis.

## **Key Concepts and Their Origins**

To clarify what is meant by "gender" and "sex," we begin with a widely used definition, here quoted from a pamphlet published by the American Psychological Association (APA):

*Sex* is assigned at birth, refers to one's biological status as either male or female, and is associated primarily with physical attributes such as chromosomes, hormone prevalence, and external and internal anatomy. *Gender* refers to the socially constructed roles, behaviors, activities, and attributes that a given society considers appropriate for boys and men or girls and women. These influence the ways that people act, interact, and feel about themselves. While aspects of biological sex are similar across different cultures, aspects of gender may differ.<sup>1</sup>

This definition points to the obvious fact that there are social norms for men and women, norms that vary across different cultures and that are not simply determined by biology. But it goes further in holding that gender is wholly "socially constructed"—that it is detached from biological sex. This idea has been an important part of a feminist movement to reform or eliminate traditional gender roles. In the classic feminist book *The Second Sex* (1949), Simone de Beauvoir wrote that "one is not born, but becomes a woman."<sup>2</sup> This notion is an early version of the now familiar distinction between sex as a biological designation and gender as a cultural construct: though one is born, as the APA explains, with the "chromosomes, hormone prevalence, and external and internal anatomy" of a female, one is socially conditioned to take on the "roles, behaviors, activities, and attributes" of a woman.

Developments in feminist theory in the second half of the twentieth century further solidified the position that gender is socially constructed. One of the first to use the term "gender" as distinct from sex in the social-science literature was Ann Oakley in her 1972 book, *Sex, Gender and Society*.<sup>3</sup> In the 1978 book *Gender: An Ethnomethodological Approach*, psychology professors Suzanne Kessler and Wendy McKenna argued that "gender is a social construction, that a world of two 'sexes' is a result of the socially shared, taken for granted methods which members use to construct reality."<sup>4</sup>

Anthropologist Gayle Rubin expresses a similar view, writing in 1975 that "Gender is a socially imposed division of the sexes. It is a product of

the social relations of sexuality."<sup>5</sup> According to her argument, if it were not for this social imposition, we would still have males and females but not "men" and "women." Furthermore, Rubin argues, if traditional gender roles are socially constructed, then they can also be *de*constructed, and we can eliminate "obligatory sexualities and sex roles" and create "an androgynous and genderless (though not sexless) society, in which one's sexual anatomy is irrelevant to who one is, what one does, and with whom one makes love."<sup>6</sup>

The relationship between gender theory and the deconstruction or overthrowing of traditional gender roles is made even clearer in the works of the influential feminist theorist Judith Butler. In works such as *Gender Trouble: Feminism and the Subversion of Identity* (1990)<sup>7</sup> and *Undoing Gender* (2004)<sup>8</sup> Butler advances what she describes as "performativity theory," according to which being a woman or man is not something that one *is* but something that one *does*. "Gender is neither the causal result of sex nor as seemingly fixed as sex," as she put it.<sup>9</sup> Rather, gender is a constructed status radically independent from biology or bodily traits, "a free floating artifice, with the consequence that *man* and *masculine* might just as easily signify a female body as a male one, and *woman* and *feminine* a male body as easily as a female one."<sup>10</sup>

This view, that gender and thus gender identity are fluid and plastic, and not necessarily binary, has recently become more prominent in popular culture. An example is Facebook's move in 2014 to include 56 new ways for users to describe their gender, in addition to the options of male and female. As Facebook explains, the new options allow the user to "feel comfortable being your true, authentic self," an important part of which is "the expression of gender."<sup>11</sup> Options include *agender*, several *cis*- and *trans*- variants, *gender fluid, gender questioning, neither, other, pangender*, and *two-spirit*.<sup>12</sup>

Whether or not Judith Butler was correct in describing traditional gender roles of men and women as "performative," her theory of gender as a "free-floating artifice" does seem to describe this new taxonomy of gender. As these terms multiply and their meanings become more individualized, we lose any common set of criteria for defining what gender distinctions mean. If gender is entirely detached from the binary of biological sex, gender could come to refer to any distinctions in behavior, biological attributes, or psychological traits, and each person could have a gender defined by the unique combination of characteristics the person possesses. This *reductio ad absurdum* is offered to present the possibility that defining gender too broadly could lead to a definition that has little meaning.

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Alternatively, gender identity could be defined in terms of sex-typical traits and behaviors, so that being a boy means behaving in the ways boys typically behave-such as engaging in rough-and-tumble play and expressing an interest in sports and liking toy guns more than dolls. But this would imply that a boy who plays with dolls, hates guns, and refrains from sports or rough-and-tumble play might be considered to be a girl, rather than simply a boy who represents an exception to the typical patterns of male behavior. The ability to recognize exceptions to sex-typical behavior relies on an understanding of maleness and femaleness that is independent of these stereotypical sex-appropriate behaviors. The underlying basis of maleness and femaleness is the distinction between the reproductive roles of the sexes; in mammals such as humans, the female gestates offspring and the male impregnates the female. More universally, the male of the species fertilizes the egg cells provided by the female of the species. This conceptual basis for sex roles is binary and stable, and allows us to distinguish males from females on the grounds of their reproductive systems, even when these individuals exhibit behaviors that are not typical of males or females.

To illustrate how reproductive roles define the differences between the sexes even when behavior appears to be atypical for the particular sex, consider two examples, one from the diversity of the animal kingdom, and one from the diversity of human behavior. First, we look at the emperor penguin. Male emperor penguins provide more care for eggs than do females, and in this sense, the male emperor penguin could be described as more maternal than the female.<sup>13</sup> However, we recognize that the male emperor penguin is not in fact female but rather that the species represents an exception to the general, but not universal, tendency among animals for females to provide more care than males for offspring. We recognize this because sex-typical behaviors like parental care do not define the sexes; the individual's role in sexual reproduction does.

Even other sex-typical biological traits, such as chromosomes, are not necessarily helpful for defining sex in a universal way, as the penguin example further illustrates. As with other birds, the genetics of sex determination in the emperor penguin is different than the genetics of sex determination in mammals and many other animals. In humans, males have XY chromosomes and females have XX chromosomes; that is, males have a unique sex-determining chromosome that they do not share with females, while females have two copies of a chromosome that they share with males. But in birds, it is females, not males, that have and pass on the sex-specific chromosome.<sup>14</sup> Just as the observation that

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male emperor penguins nurture their offspring more than their partners did not lead zoologists to conclude that the egg-laying member of the emperor penguin species was in fact the male, the discovery of the ZW sex-determination system in birds did not lead geneticists to challenge the age-old recognition that hens are females and roosters are males. The only variable that serves as the fundamental and reliable basis for biologists to distinguish the sexes of animals is their role in reproduction, not some other behavioral or biological trait.

Another example that, in this case, only appears to be non-sex-typical behavior is that of Thomas Beatie, who made headlines as a man who gave birth to three children between 2008 and 2010.<sup>15</sup> Thomas Beatie was born a woman, Tracy Lehuanani LaGondino, and underwent a surgical and legal transition to living as a man before deciding to have children. Because the medical procedures he underwent did not involve the removal of his ovaries or uterus, Beatie was capable of bearing children. The state of Arizona recognizes Thomas Beatie as the father of his three children, even though, biologically, he is their mother. Unlike the case of the male emperor penguin's ostensibly maternal, "feminine" parenting behavior, Beatie's ability to have children does not represent an exception to the normal inability of males to bear children. The labeling of Beatie as a man despite his being biologically female is a personal, social, and legal decision that was made without any basis in biology; nothing whatsoever in biology suggests Thomas Beatie is a male.

In biology, an organism is male or female if it is structured to perform one of the respective roles in reproduction. This definition does not require any arbitrary measurable or quantifiable physical characteristics or behaviors; it requires understanding the reproductive system and the reproduction process. Different animals have different reproductive systems, but sexual reproduction occurs when the sex cells from the male and female of the species come together to form newly fertilized embryos. It is these reproductive roles that provide the conceptual basis for the differentiation of animals into the biological categories of male and female. There is no other widely accepted biological classification for the sexes.

But this definition of the biological category of sex is not universally accepted. For example, philosopher and legal scholar Edward Stein maintains that infertility poses a crucial problem for defining sex in terms of reproductive roles, writing that defining sex in terms of these roles would define "infertile males as females."<sup>16</sup> Since an infertile male cannot play the reproductive role for which males are structured, and an infertile

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female cannot play the reproductive role for which females are structured, according to this line of thinking, defining sex in terms of reproductive roles would not be appropriate, as infertile males would be classified as females, and infertile females as males. Nevertheless, while a reproductive system structured to serve a particular reproductive role may be impaired in such a way that it cannot perform its function, the system is still recognizably structured for that role, so that biological sex can still be defined strictly in terms of the structure of reproductive systems. A similar point can be made about heterosexual couples who choose not to reproduce for any of a variety of reasons. The male and female reproductive systems are generally clearly recognizable, regardless of whether or not they are being used for purposes of reproduction.

The following analogy illustrates how a system can be recognized as having a particular purpose, even when that system is dysfunctional in a way that renders it incapable of carrying out its purpose: Eyes are complex organs that function as processors of vision. However, there are numerous conditions affecting the eye that can impair vision, resulting in blindness. The eyes of the blind are still recognizably organs structured for the function of sight. Any impairments that result in blindness do not affect the purpose of the eye—any more than wearing a blindfold—but only its function. The same is true for the reproductive system. Infertility can be caused by many problems. However, the reproductive system continues to exist for the purpose of begetting children.

There are individuals, however, who are biologically "intersex," meaning that their sexual anatomy is ambiguous, usually for reasons of genetic abnormalities. For example, the clitoris and penis are derived from the same embryonic structures. A baby may display an abnormally large clitoris or an abnormally small penis, causing its biological sex to be difficult to determine long after birth.

The first academic article to use the term "gender" appears to be the 1955 paper by the psychiatry professor John Money of Johns Hopkins on the treatment of "intersex" children (the term then used was "hermaphrodites").<sup>17</sup> Money posited that gender identity, at least for these children, was fluid and that it could be constructed. In his mind, making a child identify with a gender only required constructing sex-typical genitalia and creating a gender-appropriate environment for the child. The chosen gender for these children was often female—a decision that was not based on genetics or biology, nor on the belief that these children were "really" girls, but, in part, on the fact that at the time it was easier surgically to construct a vagina then it was to construct a penis.

The most widely known patient of Dr. Money was David Reimer, a boy who was not born with an intersex condition but whose penis was damaged during circumcision as an infant.<sup>18</sup> David was raised by his parents as a girl named Brenda, and provided with both surgical and hormonal interventions to ensure that he would develop female-typical sex characteristics. However, the attempt to conceal from the child what had happened to him was not successful—he self-identified as a boy, and eventually, at the age of 14, his psychiatrist recommended to his parents that they tell him the truth. David then began the difficult process of reversing the hormonal and surgical interventions that had been performed to feminize his body. But he continued to be tormented by his childhood ordeal, and took his own life in 2004, at the age of 38.

David Reimer is just one example of the harm wrought by theories that gender identity can socially and medically be reassigned in children. In a 2004 paper, William G. Reiner, a pediatric urologist and child and adolescent psychiatrist, and John P. Gearhart, a professor of pediatric urology, followed up on the sexual identities of 16 genetic males affected by cloacal exstrophy—a condition involving a badly deformed bladder and genitals. Of the 16 subjects, 14 were assigned female sex at birth, receiving surgical interventions to construct female genitalia, and were raised as girls by their parents; 6 of these 14 later chose to identify as males, while 5 continued to identify as females and 2 declared themselves males at a young age but continued to be raised as females because their parents rejected the children's declarations. The remaining subject, who had been told at age 12 that he was born male, refused to discuss sexual identity.<sup>19</sup> So the assignment of female sex persisted in only 5 of the 13 cases with known results.

This lack of persistence is some evidence that the assignment of sex through genital construction at birth with immersion into a "genderappropriate" environment is not likely to be a successful option for managing the rare problem of genital ambiguity from birth defects. It is important to note that the ages of these individuals at last follow-up ranged from 9 to 19, so it is possible that some of them may have subsequently changed their gender identities.

Reiner and Gearhart's research indicates that gender is not arbitrary; it suggests that a biological male (or female) will probably not come to identify as the opposite gender after having been altered physically and immersed into the corresponding gender-typical environment. The plasticity of gender appears to have a limit.

What is clear is that biological sex is not a concept that can be reduced to, or artificially assigned on the basis of, the type of external genitalia

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alone. Surgeons are becoming more capable of constructing artificial genitalia, but these "add-ons" do not change the biological sex of the recipients, who are no more capable of playing the reproductive roles of the opposite biological sex than they were without the surgery. Nor does biological sex change as a function of the environment provided for the child. No degree of supporting a little boy in converting to be considered, by himself and others, to be a little girl makes him biologically a little girl. The scientific definition of biological sex is, for almost all human beings, clear, binary, and stable, reflecting an underlying biological reality that is not contradicted by exceptions to sex-typical behavior, and cannot be altered by surgery or social conditioning.

In a 2004 article summarizing the results of research related to intersex conditions, Paul McHugh, the former chief of psychiatry at Johns Hopkins Hospital (and the coauthor of this report), suggested:

We in the Johns Hopkins Psychiatry Department eventually concluded that human sexual identity is mostly built into our constitution by the genes we inherit and the embryogenesis we undergo. Male hormones sexualize the brain and the mind. Sexual dysphoria—a sense of disquiet in one's sexual role—naturally occurs amongst those rare males who are raised as females in an effort to correct an infantile genital structural problem.<sup>20</sup>

We now turn our attention to transgender individuals—children and adults—who choose to identify as a gender different from their biological sex, and explore the meaning of gender identity in this context and what the scientific literature tells us about its development.

## **Gender Dysphoria**

While biological sex is, with very few exceptions, a well-defined, binary trait (male versus female) corresponding to how the body is organized for reproduction, *gender identity* is a more subjective attribute. For most people, their own gender identity is probably not a significant concern; most biological males identify as boys or men, and most biological females identify as girls or women. But some individuals experience an incongruence between their biological sex and their gender identity. If this struggle causes them to seek professional help, then the problem is classified as "gender dysphoria."

Some male children raised as females, as described in Reiner and colleagues' 2004 study, came to experience problems with their gender

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identity when their subjective sense of being boys conflicted with being identified and treated as girls by their parents and doctors. The biological sex of the boys was not in question (they had an XY genotype), and the cause of gender dysphoria lay in the fact that they were genetically male, came to identify as male, but had been assigned female gender identities. This suggests that gender identity can be a complex and burdensome issue for those who choose (or have others choose for them) a gender identity opposite their biological sex.

But the cases of gender dysphoria that are the subject of much public debate are those in which individuals come to identify as genders different from those based on their biological sex. These people are usually identified, and describe themselves, as "transgender."\*

According to the fifth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, gender dysphoria is marked by "incongruence between one's experienced/ expressed gender and assigned gender," as well as "clinically significant distress or impairment in social, occupational, or other important areas of functioning."<sup>21</sup>

It is important to clarify that gender dysphoria is not the same as gender nonconformity or gender identity disorder. Gender nonconformity describes an individual who behaves in a manner contrary to the gender-specific norms of his or her biological sex. As the *DSM-5* notes, most transvestites, for instance, are not transgender—men who dress as women typically do not identify themselves as women.<sup>22</sup> (However, certain forms of transvestitism can be associated with late-onset gender dysphoria.<sup>23</sup>)

Gender identity disorder, an obsolete term from an earlier version of the *DSM* that was removed in its fifth edition, was used as a psychiatric diagnosis. If we compare the diagnostic criteria for gender dysphoria (the current term) and gender identity disorder (the former term), we see that both require the patient to display "a marked incongruence between one's

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<sup>\*</sup> A note on terminology: In this report, we generally use the term *transgender* to refer to persons for whom there is an incongruity between the gender identity they understand themselves to possess and their biological sex. We use the term *transsexual* to refer to individuals who have undergone medical interventions to transform their appearance to better correspond with that of their preferred gender. The most familiar colloquial term used to describe the medical interventions that transform the appearance of transgender individuals may be "sex change" (or, in the case of surgery, "sex-change operation"), but this is not commonly used in the scientific and medical literature today. While no simple terms for these procedures are completely satisfactory, in this report we employ the commonly used terms *sex reassignment* and *sex-reassignment surgery*, except when quoting a source that uses "gender reassignment" or some other term.

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experienced/expressed gender and assigned gender."<sup>24</sup> The key difference is that a diagnosis of gender dysphoria requires the patient additionally to experience a "clinically significant distress or impairment in social, occupational, or other important areas of functioning" associated with these incongruent feelings.<sup>25</sup> Thus the major set of diagnostic criteria used in contemporary psychiatry does not designate all transgender individuals as having a psychiatric disorder. For example, a biological male who identifies himself as a female is not considered to have a psychiatric disorder unless the individual is experiencing significant psychosocial distress at the incongruence. A diagnosis of gender dysphoria may be part of the criteria used to justify sex-reassignment surgery or other clinical interventions. Furthermore, a patient who has had medical or surgical modifications to express his or her gender identity may still suffer from gender dysphoria. It is the nature of the struggle that defines the disorder, not the fact that the expressed gender differs from the biological sex.

There is no scientific evidence that all transgender people have gender dysphoria, or that they are all struggling with their gender identities. Some individuals who are not transgender—that is, who do not identify as a gender that does not correspond with their biological sex-might nonetheless struggle with their gender identity; for example, girls who behave in some male-typical ways might experience various forms of distress without ever coming to identify as boys. Conversely, individuals who do identify as a gender that does not correspond with their biological sex may not experience clinically significant distress related to their gender identity. Even if only, say, 40% of individuals who identify as a gender that does not correspond with their biological sex experience significant distress related to their gender identity, this would constitute a public health issue requiring clinicians and others to act to support those with gender dysphoria, and hopefully, to reduce the rate of gender dysphoria in the population. There is no evidence to suggest that the other 60% in this hypothetical—that is, the individuals who identify as a gender that does not correspond with their biological sex but who do not experience significant distress—would require clinical treatment.

The DSM's concept of subjectively "experiencing" one's gender as incongruent from one's biological sex may require more critical scrutiny and possibly modification. The exact definition of gender dysphoria, however well-intentioned, is somewhat vague and confusing. It does not account for individuals who self-identify as transgender but do not experience dysphoria associated with their gender identity and who seek psychiatric care for functional impairment for problems unrelated to their

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gender identity, such as anxiety or depression. They may then be mislabeled as having gender dysphoria simply because they have a desire to be identified as a member of the opposite gender, when they have come to a satisfactory resolution, subjectively, with this incongruence and may be depressed for reasons having nothing to do with their gender identity.

The DSM-5 criteria for a diagnosis of gender dysphoria in children are defined in a "more concrete, behavioral manner than those for adolescents and adults."26 This is to say that some of the diagnostic criteria for gender dysphoria in children refer to behaviors that are stereotypically associated with the opposite gender. Clinically significant distress is still necessary for a diagnosis of gender dysphoria in children, but some of the other diagnostic criteria include, for instance, a "strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender."27 What of girls who are "tomboys" or boys who are not oriented toward violence and guns, who prefer quieter play? Should parents worry that their tomboy daughter is really a boy stuck in a girl's body? There is no scientific basis for believing that playing with toys typical of boys defines a child as a boy, or that playing with toys typical of girls defines a child as a girl. The DSM-5 criterion for diagnosing gender dysphoria by reference to gender-typical toys is unsound; it appears to ignore the fact that a child could display an *expressed* gender-manifested by social or behavioral traits-incongruent with the child's biological sex but without *identifying* as the opposite gender. Furthermore, even for children who do identify as a gender opposite their biological sex, diagnoses of gender dysphoria are simply unreliable. The reality is that they may have psychological difficulties in accepting their biological sex as their gender. Children can have difficulty with the expectations associated with those gender roles. Traumatic experiences can also cause a child to express distress with the gender associated with his or her biological sex.

Gender identity problems can also arise with intersex conditions (the presence of ambiguous genitalia due to genetic abnormalities), which we discussed earlier. These disorders of sex development, while rare, can contribute to gender dysphoria in some cases.<sup>28</sup> Some of these conditions include complete androgen insensitivity syndrome, where individuals with XY (male) chromosomes lack receptors for male sex hormones, leading them to develop the secondary sex characteristics of females, rather than males (though they lack ovaries, do not menstruate, and are consequently sterile).<sup>29</sup> Another hormonal disorder of sex development that can lead to individuals developing in ways that are not typical of their genetic sex include congenital adrenal hyperplasia, a condition that can

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masculinize XX (female) fetuses.<sup>30</sup> Other rare phenomena such as genetic mosaicism<sup>31</sup> or chimerism,<sup>32</sup> where some cells in the individual's bodies contain XX chromosomes and others contain XY chromosomes, can lead to considerable ambiguity in sex characteristics, including individuals who possess both male and female gonads and sex organs.

While there are many cases of gender dysphoria that are not associated with these identifiable intersex conditions, gender dysphoria may still represent a different type of intersex condition in which the primary sex characteristics such as genitalia develop normally while secondary sex characteristics associated with the brain develop along the lines of the opposite sex. Controversy exists over influences determining the nature of neurological, psychological, and behavioral sex differences. The emerging consensus is that there may be some differences in patterns of neurological development in- and ex-utero for men and women.<sup>33</sup> Therefore, in theory, transgender individuals could be subject to conditions allowing a more female-type brain to develop within a genetic male (having the XY chromosomal patterns), and vice versa. However, as we will show in the next section, the research supporting this idea is quite minimal.

As a way of surveying the biological and social science research on gender dysphoria, we can list some of the important questions. Are there biological factors that influence the development of a gender identity that does not correspond with one's biological sex? Are some individuals born with a gender identity different from their biological sex? Is gender identity shaped by environmental or nurturing conditions? How stable are choices of gender identity? How common is gender dysphoria? Is it persistent across the lifespan? Can a little boy who thinks he is a little girl change over the course of his life to regard himself as male? If so, how often can such people change their gender identities? How would someone's gender identity be measured scientifically? Does self-understanding suffice? Does a biological girl become a gender boy by believing, or at least stating, she is a little boy? Do people's struggles with a sense of incongruity between their gender identity and biological sex persist over the life course? Does gender dysphoria respond to psychiatric interventions? Should those interventions focus on affirming the gender identity of the patient or take a more neutral stance? Do efforts to hormonally or surgically modify an individual's primary or secondary sex characteristics help resolve gender dysphoria? Does modification create further psychiatric problems for some of those diagnosed with gender dysphoria, or does it typically resolve existing psychiatric problems? We broach a few of these critical questions in the following sections.

## Gender and Physiology

Robert Sapolsky, a Stanford professor of biology who has done extensive neuroimaging research, suggested a possible neurobiological explanation for cross-gender identification in a 2013 *Wall Street Journal* article, "Caught Between Male and Female." He asserted that recent neuroimaging studies of the brains of transgender adults suggest that they may have brain structures more similar to their gender identity than to their biological sex.<sup>34</sup> Sapolsky bases this assertion on the fact that there are differences between male and female brains, and while the differences are "small and variable," they "probably contribute to the sex differences in learning, emotion and socialization."<sup>35</sup> He concludes: "The issue isn't that sometimes people believe they are of a different gender than they actually are. Remarkably, instead, it's that sometimes people are born with bodies whose gender is different from what they actually are."<sup>36</sup> In other words, he claims that some people can have a female-type brain in a male body, or vice versa.

While this kind of neurobiological theory of cross-gender identification remains outside of the scientific mainstream, it has recently received scientific and popular attention. It provides a potentially attractive explanation for cross-gender identification, especially for individuals who are not affected by any known genetic, hormonal, or psychosocial abnormalities.<sup>37</sup> However, while Sapolsky may be right, there is fairly little support in the scientific literature for his contention. His neurological explanation for differences between male and female brains and those differences' possible relevance to cross-gender identification warrant further scientific consideration.

There are many small studies that attempt to define causal factors of the experience of incongruence between one's biological sex and felt gender. These studies are described in the following pages, each pointing to an influence that may contribute to the explanation for cross-gender identification.

Nancy Segal, a psychologist and geneticist, researched two case studies of identical twins discordant for female-to-male (FtM) transsexualism.<sup>38</sup> Segal notes that, according to another, earlier study that conducted nonclinical interviews with 45 FtM transsexuals, 60% suffered some form of childhood abuse, with 31% experiencing sexual abuse, 29% experiencing emotional abuse, and 38% physical abuse.<sup>39</sup> However, this earlier study did not include a control group and was limited by its small sample size, making it difficult to extract significant interactions, or generalizations, from the data.

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Segal's own first case study was of a 34-year-old FtM twin, whose identical twin sister was married and the mother of seven children.<sup>40</sup> Several stressful events had occurred during the twins' mother's pregnancy, and they were born five weeks prematurely. When they were eight years old, their parents divorced. The FtM twin exhibited gender-nonconforming behavior early and it persisted throughout childhood. She became attracted to other girls in junior high school and as a teenager attempted suicide several times. She reported physical abuse and emotional abuse at the hand of her mother. The twins were raised in a Mormon household, in which transsexuality was not tolerated.<sup>41</sup> The twin sister had never questioned her gender identity but did experience some depression. For Segal, the FtM twin's gender nonconformity and abuse in childhood were factors that contributed to gender dysphoria; the other twin was not subject to the same stressors in childhood, and did not develop issues around her gender identity. Segal's second case study also concerned identical twins with one twin transitioning from female to male.42 This FtM twin had early-onset nonconforming behaviors and attempted suicide as a young adult. At age 29 she underwent reassignment surgery, was well supported by family, met a woman, and married. As in the first case, the other twin was reportedly always secure in her female gender identity.

Segal speculates that each set of twins may have had uneven prenatal androgen exposures (though her study did not offer evidence to support this)<sup>43</sup> and concludes that "Transsexualism is unlikely to be associated with a major gene, but is likely to be associated with multiple genetic, epigenetic, developmental and experiential influences."<sup>44</sup> Segal is critical of the notion that the maternal abuse experienced by the FtM twin in her first case study may have played a causal role in the twin's "atypical gender identification" since the abuse "apparently *followed*" the twin's gender-atypical behaviors—though Segal acknowledges "it is possible that this abuse reinforced his already atypical gender identification."<sup>45</sup> These case studies, while informative, are not scientifically strong, and do not provide direct evidence for any causal hypotheses about the origins of atypical gender identification.

A source of more information—but also inadequate to make direct causal inferences—is a case analysis by Mayo Clinic psychiatrists J. Michael Bostwick and Kari A. Martin of an intersex individual born with ambiguous genitalia who was operated on and raised as a female.<sup>46</sup> By way of offering some background, the authors draw a distinction between gender identity disorder (an "inconsistency between perceived gender identity and phenotypic sex" that generally involves "no discernible neuroendocri-

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nological abnormality"<sup>47</sup>), and intersexuality (a condition in which biological features of both sexes are present). They also provide a summary and classification scheme of the various types of intersex disorders. After a thorough discussion of the various intersex developmental issues that can lead to a disjunction between the brain and body, the authors acknowledge that "Some adult patients with severe dysphoria—transsexuals—have neither history nor objective findings supporting a known biological cause of brain-body disjunction."<sup>48</sup> These patients require thorough medical and psychiatric attention to avoid gender dysphoria.

After this helpful summary, the authors state that "Absent psychosis or severe character pathology, patients' subjective assertions are presently the most reliable standards for delineating core gender identity."<sup>49</sup> But it is not clear how we could consider subjective assertions more reliable in establishing gender identity, unless gender identity is defined as a completely subjective phenomenon. The bulk of the article is devoted to describing the various objectively discernible and identifiable ways in which one's identity as a male or female is imprinted on the nervous and endocrine system. Even when something goes wrong with the development of external genitalia, individuals are more likely to act in accordance with their chromosomal and hormonal makeup.<sup>50</sup>

In 2011, Giuseppina Rametti and colleagues from various research centers in Spain used MRI to study the brain structures of 18 FtM transsexuals who exhibited gender nonconformity early in life and experienced sexual attraction to females prior to hormone treatment.<sup>51</sup> The goal was to learn whether their brain features corresponded more to their biological sex or to their sense of gender identity. The control group consisted of 24 male and 19 female heterosexuals with gender identities conforming to their biological sex. Differences were noted in the white matter microstructure of specific brain areas. In untreated FtM transsexuals, that structure was more similar to that of heterosexual males than to that of heterosexual females in three of four brain areas.<sup>52</sup> In a complementary study, Rametti and colleagues compared 18 MtF transsexuals to 19 female and 19 male heterosexual controls.53 These MtF transsexuals had white matter tract averages in several brain areas that fell between the averages of the control males and the control females. The values, however, were typically closer to the males (that is, to those that shared their biological sex) than to the females in most areas.<sup>54</sup> In controls the authors found that, as expected, the males had greater amounts of gray and white matter and higher volumes of cerebrospinal fluid than control females. The MtF transsexual brain volumes

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were all similar to those of male controls and significantly different from those of females.  $^{55}$ 

Overall, the findings of these studies by Rametti and colleagues do not sufficiently support the notion that transgender individuals have brains more similar to their preferred gender than to the gender corresponding with their biological sex. Both studies are limited by small sample sizes and lack of a prospective hypothesis—both analyzed the MRI data to find the gender differences and then looked to see where the data from transgender subjects fit.

Whereas both of these MRI studies looked at brain *structure*, a functional MRI study by Emiliano Santarnecchi and colleagues from the University of Siena and the University of Florence looked at brain *function*, examining gender-related differences in spontaneous brain activity during the resting state.<sup>56</sup> The researchers compared a single FtM individual (declared cross-gender since childhood), and control groups of 25 males and 25 females, with regard to spontaneous brain activity. The FtM individual demonstrated a "brain activity profile more close to his biological sex than to his desired one," and based in part on this result the authors concluded that "untreated FtM transsexuals show a functional connectivity profile comparable to female control subjects."<sup>57</sup> With a sample size of one, this study's statistical power is virtually zero.

In 2013, Hsaio-Lun Ku and colleagues from various medical centers and research institutes in Taiwan also conducted functional brain imaging studies. They compared the brain activity of 41 transsexuals (21 FtMs, 20 MtFs) and 38 matched heterosexual controls (19 males and 19 females).<sup>58</sup> Arousal response of each cohort while viewing neutral as compared to erotic films was compared between groups. All of the transsexuals in the study reported sexual attractions to members of their natal, biological sex, and exhibited more sexual arousal than heterosexual controls when viewing erotic films that depicted sexual activity between subjects sharing their biological sex. A "selfness" score was also incorporated into the study, in which the researchers asked participants to "rate the degree to which you identify yourself as the male or female in the film."<sup>59</sup> The transsexuals in the study identified with those of their preferred gender more than the controls identified with those of their biological gender, in both erotic films and neutral films. The heterosexual controls did not identify themselves with either males or females in either of the film types. Ku and colleagues claim to have demonstrated characteristic brain patterns for sexual attraction as related to biological sex but did not make meaningful neurobiological gender-identity comparisons among the three cohorts. In

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addition, they reported findings that transsexuals demonstrated psychosocial maladaptive defensive styles.

A 2008 study by Hans Berglund and colleagues from Sweden's Karolinska Institute and Stockholm Brain Institute used PET and fMRI scans to compare brain-area activation patterns in 12 MtF transgendered individuals who were sexually attracted to women with those of 12 heterosexual women and 12 heterosexual men.<sup>60</sup> The first set of subjects took no hormones and had not undergone sex-reassignment surgery. The experiment involved smelling odorous steroids thought to be female pheromones, and other sexually neutral odors such as lavender oil, cedar oil, eugenol, butanol, and odorless air. The results were varied and mixed between the groups for the various odors, which should not be surprising, since *post hoc* analyses usually lead to contradictory findings.

In summary, the studies presented above show inconclusive evidence and mixed findings regarding the brains of transgender adults. Brainactivation patterns in these studies do not offer sufficient evidence for drawing sound conclusions about possible associations between brain activation and sexual identity or arousal. The results are conflicting and confusing. Since the data by Ku and colleagues on brain-activation patterns are not universally associated with a particular sex, it remains unclear whether and to what extent neurobiological findings say anything meaningful about gender identity. It is important to note that regardless of their findings, studies of this kind cannot support any conclusion that individuals come to identify as a gender that does not correspond to their biological sex because of an innate, biological condition of the brain.

The question is not simply whether there are differences between the brains of transgender individuals and people identifying with the gender corresponding to their biological sex, but whether gender identity is a fixed, innate, and biological trait, even when it does not correspond to biological sex, or whether environmental or psychological causes contribute to the development of a sense of gender identity in such cases. Neurological differences in transgender adults might be the consequence of biological factors such as genes or prenatal hormone exposure, or of psychological and environmental factors such as childhood abuse, or they could result from some combination of the two. There are no serial, longitudinal, or prospective studies looking at the brains of cross-gender identifying children who develop to later identify as transgender adults. Lack of this research severely limits our ability to understand causal relationships between brain morphology, or functional activity, and the later development of gender identity different from biological sex.

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More generally, it is now widely recognized among psychiatrists and neuroscientists who engage in brain imaging research that there are inherent and ineradicable methodological limitations of *any* neuroimaging study that simply associates a particular trait, such as a certain behavior, with a particular brain morphology.<sup>61</sup> (And when the trait in question is not a concrete behavior but something as elusive and vague as "gender identity," these methodological problems are even more serious.) These studies cannot provide statistical evidence nor show a plausible biological mechanism strong enough to support *causal connections* between a brain feature and the trait, behavior, or symptom in question. To support a conclusion of causality, even epidemiological causality, we need to conduct prospective longitudinal panel studies of a fixed set of individuals across the course of sexual development if not their lifespan.

Studies like these would use serial brain images at birth, in childhood, and at other points along the developmental continuum, to see whether brain morphology findings were there from the beginning. Otherwise, we cannot establish whether certain brain features caused a trait, or whether the trait is innate and perhaps fixed. Studies like those discussed above of individuals who already exhibit the trait are incapable of distinguishing between *causes* and *consequences* of the trait. In most cases transgender individuals have been acting and thinking for years in ways that, through learned behavior and associated neuroplasticity, may have produced brain changes that could differentiate them from other members of their biological or natal sex. The only definitive way to establish epidemiological causality between a brain feature and a trait (especially one as complex as gender identity) is to conduct prospective, longitudinal, preferably randomly sampled and population-based studies.

In the absence of such prospective longitudinal studies, large representative population-based samples with adequate statistical controls for confounding factors may help narrow the possible causes of a behavioral trait and thereby increase the probability of identifying a neurological cause.<sup>62</sup> However, because the studies conducted thus far use small convenience samples, none of them is especially helpful for narrowing down the options for causality. To obtain a better study sample, we would need to include neuroimaging in large-scale epidemiological studies. In fact, given the small number of transgender individuals in the general population,<sup>63</sup> the studies would need to be prohibitively large to attain findings that would reach statistical significance.

Moreover, if a study found significant differences between these groups—that is, a number of differences higher than what would be

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expected by chance alone—these differences would refer to the average in a population of each group. Even if these two *groups* differed significantly for all 100 measurements, it would not necessarily indicate a biological difference among *individuals* at the extremes of the distribution. Thus, a randomly selected transgender individual and a randomly selected nontransgender individual might not differ on any of these 100 measurements. Additionally, since the probability that a randomly selected person from the general population will be transgender is quite small, statistically significant differences in the sample means are not sufficient evidence to conclude that a particular measurement is predictive of whether the person is transgender or not. If we measured the brain of an infant, toddler, or adolescent and found this individual to be closer to one cohort than another on these measures, it would not imply that this individual would grow up to identify as a member of that cohort. It may be helpful to keep this caveat in mind when interpreting research on transgender individuals.

In this context, it is important to note that there are no studies that demonstrate that any of the biological differences being examined have predictive power, and so all interpretations, usually in popular outlets, claiming or suggesting that a statistically significant difference between the brains of people who are transgender and those who are not is the cause of being transgendered or not—that is to say, that the biological differences determine the differences in gender identity—are unwarranted.

In short, the current studies on associations between brain structure and transgender identity are small, methodologically limited, inconclusive, and sometimes contradictory. Even if they were more methodologically reliable, they would be insufficient to demonstrate that brain structure is a cause, rather than an effect, of the gender-identity behavior. They would likewise lack predictive power, the real challenge for any theory in science.

For a simple example to illustrate this point, suppose we had a room with 100 people in it. Two of them are transgender and all others are not. I pick someone at random and ask you to guess the person's gender identity. If you know that 98 out of 100 of the individuals are not transgender, the safest bet would be to guess that the individual is not transgender, since that answer will be correct 98% of the time. Suppose, then, that you have the opportunity to ask questions about the neurobiology and about the natal sex of the person. Knowing the biology only helps in predicting whether the individual is transgender if it can improve on the original guess that the person is not transgender. So if knowing a characteristic of the individual's brain does not improve the ability to predict what group the patient belongs to, then the fact that the two groups differ at the mean is almost irrelevant.

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Improving on the original prediction is very difficult for a rare trait such as being transgender, because the probability of that prediction being correct is already very high. If there really were a clear difference between the brains of transgender and non-transgender individuals, akin to the biological differences between the sexes, then improving on the original guess would be relatively easy. Unlike the differences between the sexes, however, there are no biological features that can reliably identify transgender individuals as different from others.

The consensus of scientific evidence overwhelmingly supports the proposition that a physically and developmentally normal boy or girl is indeed what he or she appears to be at birth. The available evidence from brain imaging and genetics does not demonstrate that the development of gender identity as different from biological sex is innate. Because scientists have not established a solid framework for understanding the causes of cross-gender identification, ongoing research should be open to psychological and social causes, as well as biological ones.

## **Transgender Identity in Children**

In 2012, the *Washington Post* featured a story by Petula Dvorak, "Transgender at five,"<sup>64</sup> about a girl who at the age of 2 years began insisting that she was a boy. The story recounts her mother's interpretation of this behavior: "Her little girl's brain was different. Jean [her mother] could tell. She had heard about transgender people, those who are one gender physically but the other gender mentally." The story recounts this mother's distressed experiences as she began researching gender identity problems in children and came to understand other parents' experiences:

Many talked about their painful decision to allow their children to publicly transition to the opposite gender—a much tougher process for boys who wanted to be girls. Some of what Jean heard was reassuring: Parents who took the plunge said their children's behavior problems largely disappeared, schoolwork improved, happy kid smiles returned. But some of what she heard was scary: children taking puberty blockers in elementary school and teens embarking on hormone therapy before they'd even finished high school.<sup>65</sup>

The story goes on to describe how the sister, Moyin, of the transgender child Tyler (formerly Kathryn) made sense of her sibling's identity:

Tyler's sister, who's 8, was much more casual about describing her transgender sibling. "It's just a boy mind in a girl body," Moyin

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explained matter-of-factly to her second-grade classmates at her private school, which will allow Tyler to start kindergarten as a boy, with no mention of Kathryn. $^{66}$ 

The remarks from the child's sister encapsulate the popular notion regarding gender identity: transgender individuals, or children who meet the diagnostic criteria for gender dysphoria, are simply "a boy mind in a girl body," or vice versa. This view implies that gender identity is a persistent and innate feature of human psychology, and it has inspired a gender-affirming approach to children who experience gender identity issues at an early age.

As we have seen above in the overview of the neurobiological and genetic research on the origins of gender identity, there is little evidence that the phenomenon of transgender identity has a biological basis. There is also little evidence that gender identity issues have a high rate of persistence in children. According to the DSM-5, "In natal [biological] males, persistence [of gender dysphoria] has ranged from 2.2% to 30%. In natal females, persistence has ranged from 12% to 50%."67 Scientific data on persistence of gender dysphoria remains sparse due to the very low prevalence of the disorder in the general population, but the wide range of findings in the literature suggests that there is still much that we do not know about why gender dysphoria persists or desists in children. As the DSM-5 entry goes on to note, "It is unclear if children 'encouraged' or supported to live socially in the desired gender will show higher rates of persistence, since such children have not yet been followed longitudinally in a systematic manner."68 There is a clear need for more research in these areas, and for parents and therapists to acknowledge the great uncertainty regarding how to interpret the behavior of these children.

#### Therapeutic Interventions in Children

With the uncertainty surrounding the diagnosis of and prognosis for gender dysphoria in children, therapeutic decisions are particularly complex and difficult. Therapeutic interventions for children must take into account the probability that the children may outgrow cross-gender identification. University of Toronto researcher and therapist Kenneth Zucker believes that family and peer dynamics can play a significant role in the development and persistence of gender-nonconforming behavior, writing that

it is important to consider both predisposing and perpetuating factors that might inform a clinical formulation and the development of

<sup>106</sup>  $\sim$  The New Atlantis

a therapeutic plan: the role of temperament, parental reinforcement of cross-gender behavior during the sensitive period of gender identity formation, family dynamics, parental psychopathology, peer relationships and the multiple meanings that might underlie the child's fantasy of becoming a member of the opposite sex.<sup>69</sup>

Zucker worked for years with children experiencing feelings of gender incongruence, offering psychosocial treatments to help them embrace the gender corresponding with their biological sex—for instance, talk therapy, parent-arranged play dates with same-sex peers, therapy for cooccurring psychopathological issues such as autism spectrum disorder, and parent counseling.<sup>70</sup>

In a follow-up study by Zucker and colleagues of children treated by them over the course of thirty years at the Center for Mental Health and Addiction in Toronto, they found that gender identity disorder persisted in only 3 of the 25 girls they had treated.<sup>71</sup> (Zucker's clinic was closed by the Canadian government in  $2015.^{72}$ )

An alternative to Zucker's approach that emphasizes affirming the child's preferred gender identity has become more common among therapists.<sup>73</sup> This approach involves helping the children to self-identify even more with the gender label they prefer at the time. One component of the gender-affirming approach has been the use of hormone treatments for adolescents in order to delay the onset of sex-typical characteristics during puberty and alleviate the feelings of dysphoria the adolescents will experience as their bodies develop sex-typical characteristics that are at odds with the gender with which they identify. There is relatively little evidence for the therapeutic value of these kinds of puberty-delaying treatments, but they are currently the subject of a large clinical study sponsored by the National Institutes of Health.<sup>74</sup>

While epidemiological data on the outcomes of medically delayed puberty is quite limited, referrals for sex-reassignment hormones and surgical procedures appear to be on the rise, and there is a push among many advocates to proceed with sex reassignment at younger ages. According to a 2013 article in *The Times* of London, the United Kingdom saw a 50% increase in the number of children referred to gender dysphoria clinics from 2011 to 2012, and a nearly 50% increase in referrals among adults from 2010 to 2012.<sup>75</sup> Whether this increase can be attributed to rising rates of gender confusion, rising sensitivity to gender issues, growing acceptance of therapy as an option, or other factors, the increase itself is concerning, and merits further scientific inquiry into the family dynamics

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and other potential problems, such as social rejection or developmental issues, that may be taken as signs of childhood gender dysphoria.

A study of psychological outcomes following puberty suppression and sex-reassignment surgery, published in the journal *Pediatrics* in 2014 by child and adolescent psychiatrist Annelou L. C. de Vries and colleagues, suggested improved outcomes for individuals after receiving these interventions, with well-being improving to a level similar to that of young adults from the general population.<sup>76</sup> This study looked at 55 transgender adolescents and young adults (22 MtF and 33 FtM) from a Dutch clinic who were assessed three times: before the start of puberty suppression (mean age: 13.6 years), when cross-sex hormones were introduced (mean age: 16.7 years), and at least one year after sex-reassignment surgery (mean age: 20.7 years). The study did not provide a matched group for comparison—that is, a group of transgender adolescents who did not receive puberty-blocking hormones, cross-sex hormones, and/or sex-reassignment surgery—which makes comparisons of outcomes more difficult.

In the study cohort, gender dysphoria improved over time, body image improved on some measures, and overall functioning improved modestly. Due to the lack of a matched control group it is unclear whether these changes are attributable to the procedures or would have occurred in this cohort without the medical and surgical interventions. Measures of anxiety, depression, and anger showed some improvements over time, but these findings did not reach statistical significance. While this study suggested some improvements over time in this cohort, particularly the reported subjective satisfaction with the procedures, detecting significant differences would require the study to be replicated with a matched control group and a larger sample size. The interventions also included care from a multidisciplinary team of medical professionals, which could have had a beneficial effect. Future studies of this kind would ideally include long-term follow-ups that assess outcomes and functioning beyond the late teens or early twenties.

#### **Therapeutic Interventions in Adults**

The potential that patients undergoing medical and surgical sex reassignment may want to return to a gender identity consistent with their biological sex suggests that reassignment carries considerable psychological and physical risk, especially when performed in childhood, but also in adulthood. It suggests that the patients' pre-treatment beliefs about an ideal post-treatment life may sometimes go unrealized.

<sup>108</sup>  $\sim$  The New Atlantis

In 2004, Birmingham University's Aggressive Research Intelligence Facility (Arif) assessed the findings of more than one hundred follow-up studies of post-operative transsexuals.<sup>77</sup> An article in *The Guardian* summarized the findings:

Arif...concludes that none of the studies provides conclusive evidence that gender reassignment is beneficial for patients. It found that most research was poorly designed, which skewed the results in favour of physically changing sex. There was no evaluation of whether other treatments, such as long-term counselling, might help transsexuals, or whether their gender confusion might lessen over time. Arif says the findings of the few studies that have tracked significant numbers of patients over several years were flawed because the researchers lost track of at least half of the participants. The potential complications of hormones and genital surgery, which include deep vein thrombosis and incontinence respectively, have not been thoroughly investigated, either. "There is huge uncertainty over whether changing someone's sex is a good or a bad thing," says Dr Chris Hyde, director of Arif. "While no doubt great care is taken to ensure that appropriate patients undergo gender reassignment, there's still a large number of people who have the surgery but remain traumatized—often to the point of committing suicide."78

The high level of uncertainty regarding various outcomes after sexreassignment surgery makes it difficult to find clear answers about the effects on patients of reassignment surgery. Since 2004, there have been other studies on the efficacy of sex-reassignment surgery, using larger sample sizes and better methodologies. We will now examine some of the more informative and reliable studies on outcomes for individuals receiving sex-reassignment surgery.

As far back as 1979, Jon K. Meyer and Donna J. Reter published a longitudinal follow-up study on the overall well-being of adults who underwent sex-reassignment surgery.<sup>79</sup> The study compared the outcomes of 15 people who received surgery with those of 35 people who requested but did not receive surgery (14 of these individuals eventually received surgery later, resulting in three cohorts of comparison: operated, notoperated, and operated later). Well-being was quantified using a scoring system that assessed psychiatric, economic, legal, and relationship outcome variables. Scores were determined by the researchers after performing interviews with the subjects. Average follow-up time was approximately five years for subjects who had sex change surgery, and about two years for those subjects who did not.

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Compared to their condition before surgery, the individuals who had undergone surgery appeared to show some improvement in wellbeing, though the results had a fairly low level of statistical significance. Individuals who had no surgical intervention did display a statistically significant improvement at follow-up. However, there was no statistically significant difference between the two groups' scores of well-being at follow-up. The authors concluded that "sex reassignment surgery confers no objective advantage in terms of social rehabilitation, although it remains subjectively satisfying to those who have rigorously pursued a trial period and who have undergone it."<sup>80</sup> This study led the psychiatry department at Johns Hopkins Medical Center (JHMC) to discontinue surgical interventions for sex changes for adults.<sup>81</sup>

However, the study has important limitations. Selection bias was introduced in the study population, because the subjects were drawn from those individuals who sought sex-reassignment surgery at JHMC. In addition, the sample size was small. Also, the individuals who did not undergo sex-reassignment surgery but presented to JHMC for it did not represent a true control group. Random assignment of the surgical procedure was not possible. Large differences in the average follow-up time between those who underwent surgery and those who did not further reduces any capacity to draw valid comparisons between the two groups. Additionally, the study's methodology was also criticized for the somewhat arbitrary and idiosyncratic way it measured the well-being of its subjects. Cohabitation or any form of contact with psychiatric services were scored as equally negative factors as having been arrested.<sup>82</sup>

In 2011, Cecilia Dhejne and colleagues from the Karolinska Institute and Gothenburg University in Sweden published one of the more robust and well-designed studies to examine outcomes for persons who underwent sex-reassignment surgery. Focusing on mortality, morbidity, and criminality rates, the matched cohort study compared a total of 324 transsexual persons (191 MtFs, 133 FtMs) who underwent sex reassignment between 1973 and 2003 to two age-matched controls: people of the same sex as the transsexual person at birth, and people of the sex to which the individual had been reassigned.<sup>83</sup>

Given the relatively low number of transsexual persons in the general population, the size of this study is impressive. Unlike Meyer and Reter, Dhejne and colleagues did not seek to evaluate the patient satisfaction after sex-reassignment surgery, which would have required a control group of transgender persons who desired to have sex-reassignment surgery but did not receive it. Also, the study did not compare outcome

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variables before and after sex-reassignment surgery; only outcomes after surgery were evaluated. We need to keep these caveats in mind as we look at what this study found.

Dhejne and colleagues found statistically significant differences between the two cohorts on several of the studied rates. For example, the postoperative transsexual individuals had an approximately three times higher risk for psychiatric hospitalization than the control groups, even after adjusting for prior psychiatric treatment.84 (However, the risk of being hospitalized for substance abuse was not significantly higher after adjusting for prior psychiatric treatment, as well as other covariates.) Sexreassigned individuals had nearly a three times higher risk of all-cause mortality after adjusting for covariates, although the elevated risk was significant only for the time period of 1973-1988.85 Those undergoing surgery during this period were also at increased risk of being convicted of a crime.<sup>86</sup> Most alarmingly, sex-reassigned individuals were 4.9 times more likely to attempt suicide and 19.1 times more likely to die by suicide compared to controls.<sup>87</sup> "Mortality from suicide was strikingly high among sex-reassigned persons, including after adjustment for prior psychiatric morbidity."88

The study design precludes drawing inferences "as to the effectiveness of sex reassignment as a treatment for transsexualism," although Dhejne and colleagues state that it is possible that "things might have been even worse without sex reassignment."89 Overall, post-surgical mental health was quite poor, as indicated especially by the high rate of suicide attempts and all-cause mortality in the 1973-1988 group. (It is worth noting that for the transsexuals in the study who underwent sex reassignment from 1989 to 2003, there were of course fewer years of data available at the time the study was conducted than for those transsexuals from the earlier period. The rates of mortality, morbidity, and criminality in the later group may in time come to resemble the elevated risks of the earlier group.) In summary, this study suggests that sex-reassignment surgery may not rectify the comparatively poor health outcomes associated with transgender populations in general. Still, because of the limitations of this study mentioned above, the results also cannot establish that sex-reassignment surgery causes poor health outcomes.

In 2009, Annette Kuhn and colleagues from the University Hospital and University of Bern in Switzerland examined post-surgery quality of life in 52 MtF and 3 FtM transsexuals fifteen years after sex-reassignment surgery.<sup>90</sup> This study found considerably lower general life satisfaction in post-surgical transsexuals as compared with females who had at least one

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pelvic surgery in the past. The postoperative transsexuals reported lower satisfaction with their general quality of health and with some of the personal, physical, and social limitations they experienced with incontinence that resulted as a side effect of the surgery. Again, inferences cannot be drawn from this study regarding the efficacy of sex-reassignment surgery due to the lack of a control group of transgender individuals who did not receive sex-reassignment surgery.

In 2010, Mohammad Hassan Murad and colleagues from the Mayo Clinic published a systematic review of studies on the outcomes of hormonal therapies used in sex-reassignment procedures, finding that there was "very low quality evidence" that sex reassignment via hormonal interventions "likely improves gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life."91 The authors identified 28 studies that together examined 1,833 patients who underwent sex-reassignment procedures that included hormonal interventions (1,093 male-to-female, 801 female-to-male).<sup>92</sup> Pooling data across studies showed that, after receiving sex-reassignment procedures, 80% of patients reported improvement in gender dysphoria, 78% reported improvement in psychological symptoms, and 80% reported improvement in quality of life.93 None of the studies included the bias-limiting measure of randomization (that is, in none of the studies were sex-reassignment procedures assigned randomly to some patients but not to others), and only three of the studies included control groups (that is, patients who were not provided the treatment to serve as comparison cases for those who did).94 Most of the studies examined in Murad and colleagues' review reported improvements in psychiatric comorbidities and quality of life, though notably suicide rates remained higher for individuals who had received hormone treatments than for the general population, despite reductions in suicide rates following the treatments.<sup>95</sup> The authors also found that there were some exceptions to reports of improvements in mental health and satisfaction with sex-reassignment procedures; in one study, 3 of 17 individuals regretted the procedure with 2 of these 3 seeking reversal procedures,<sup>96</sup> and four of the studies reviewed reported worsening quality of life, including continuing social isolation, lack of improvement in social relationships, and dependence on government welfare programs.97

The scientific evidence summarized suggests we take a skeptical view toward the claim that sex-reassignment procedures provide the hopedfor benefits or resolve the underlying issues that contribute to elevated mental health risks among the transgender population. While we work to stop maltreatment and misunderstanding, we should also work to study

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PART THREE: GENDER IDENTITY

and understand whatever factors may contribute to the high rates of suicide and other psychological and behavioral health problems among the transgender population, and to think more clearly about the treatment options that are available.

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#### Part Three: Gender Identity

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86. MtF transsexuals in the study's 1973–1988 period showed a higher risk of crime compared to the female controls, suggesting that they maintain a male pattern for criminality. That study period's FtM transsexuals, however, did show a higher risk of crime compared to the female controls, perhaps related to the effects of exogenous testosterone administration.

87. 95% confidence intervals: 2.9-8.5 and 5.8-62.9, respectively.

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Conclusion

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Accurate, replicable scientific research results can and do influence our personal decisions and self-understanding, and can contribute to the public discourse, including cultural and political debates. When the research touches on controversial themes, it is particularly important to be clear about precisely what science has and has not shown. For complex, complicated questions concerning the nature of human sexuality, there exists at best provisional scientific consensus; much remains unknown, as sexuality is an immensely complex part of human life that defies our attempts at defining all its aspects and studying them with precision.

For questions that are easier to study empirically, however, such as those concerning the rates of mental health outcomes for identifiable subpopulations of sexual minorities, the research does offer some clear answers: these subpopulations show higher rates of depression, anxiety, substance abuse, and suicide compared to the general population. One hypothesis, the social stress model—which posits that stigma, prejudice, and discrimination are the primary causes of higher rates of poor mental health outcomes for these subpopulations—is frequently cited as a way to explain this disparity. While non-heterosexual and transgender individuals are often subject to social stressors and discrimination, science has not shown that these factors alone account for the entirety, or even a majority, of the health disparity between non-heterosexual and transgender subpopulations and the general population. There is a need for extensive research in this area to test the social stress hypothesis and other potential explanations for the health disparities, and to help identify ways of addressing the health concerns present in these subpopulations.

Some of the most widely held views about sexual orientation, such as the "born that way" hypothesis, simply are not supported by science. The literature in this area does describe a small ensemble of biological differences between non-heterosexuals and heterosexuals, but those biological differences are not sufficient to predict sexual orientation, the ultimate test of any scientific finding. The strongest statement that science offers to explain sexual orientation is that some biological factors appear, to an unknown extent, to predispose some individuals to a non-heterosexual orientation.

The suggestion that we are "born that way" is more complex in the case of gender identity. In one sense, the evidence that we are born with

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a given gender seems well supported by direct observation: males overwhelmingly identify as men and females as women. The fact that children are (with a few exceptions of intersex individuals) born either biologically male or female is beyond debate. The biological sexes play complementary roles in reproduction, and there are a number of population-level average physiological and psychological differences between the sexes. However, while biological sex is an innate feature of human beings, gender identity is a more elusive concept.

In reviewing the scientific literature, we find that almost nothing is well understood when we seek biological explanations for what causes some individuals to state that their gender does not match their biological sex. The findings that do exist often have sample-selection problems, and they lack longitudinal perspective and explanatory power. Better research is needed, both to identify ways by which we can help to lower the rates of poor mental health outcomes and to make possible more informed discussion about some of the nuances present in this field.

Yet despite the scientific uncertainty, drastic interventions are prescribed and delivered to patients identifying, or identified, as transgender. This is especially troubling when the patients receiving these interventions are children. We read popular reports about plans for medical and surgical interventions for many prepubescent children, some as young as six, and other therapeutic approaches undertaken for children as young as two. We suggest that no one can determine the gender identity of a two-year-old. We have reservations about how well scientists understand what it even means for a child to have a developed sense of his or her gender, but notwithstanding that issue, we are deeply alarmed that these therapies, treatments, and surgeries seem disproportionate to the severity of the distress being experienced by these young people, and are at any rate premature since the majority of children who identify as the gender opposite their biological sex will not continue to do so as adults. Moreover, there is a lack of reliable studies on the long-term effects of these interventions. We strongly urge caution in this regard.

We have sought in this report to present a complex body of research in a way that will be intelligible to a wide audience of both experts and lay readers alike. Everyone—scientists and physicians, parents and teachers, lawmakers and activists—deserves access to accurate information about sexual orientation and gender identity. While there is much controversy surrounding how our society treats its LGBT members, no political

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or cultural views should discourage us from understanding the related clinical and public health issues and helping people suffering from mental health problems that may be connected to their sexuality.

Our work suggests some avenues for future research in the biological, psychological, and social sciences. More research is needed to uncover the causes of the increased rates of mental health problems in the LGBT subpopulations. The social stress model that dominates research on this issue requires improvement, and most likely needs to be supplemented by other hypotheses. Additionally, the ways in which sexual desires develop and change across one's lifespan remain, for the most part, inadequately understood. Empirical research may help us to better understand relationships, sexual health, and mental health.

Critiquing and challenging both parts of the "born that way" paradigm—both the notion that sexual orientation is biologically determined and fixed, and the related notion that there is a fixed gender independent of biological sex—enables us to ask important questions about sexuality, sexual behaviors, gender, and individual and social goods in a different light. Some of these questions lie outside the scope of this work, but those that we have examined suggest that there is a great chasm between much of the public discourse and what science has shown.

Thoughtful scientific research and careful, circumspect interpretation of its results can advance our understanding of sexual orientation and gender identity. There is still much work to be done and many unanswered questions. We have attempted to synthesize and describe a complex body of scientific research related to some of these themes. We hope that this report contributes to the ongoing public conversation regarding human sexuality and identity. We anticipate that this report may elicit spirited responses, and we welcome them.

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### IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

# ALINA BOYDEN and SHANNON ANDREWS,

Plaintiffs,

v.

Case No. 17-CV-264

STATE OF WISCONSIN DEPARTMENT OF EMPLOYEE TRUST FUNDS, et al.,

Defendants.

## EXPERT REPORT OF DAVID V. WILLIAMS SUBMITTED ON BEHALF OF THE STATE DEFENDANTS

## EXPERT REPORT Gender Reassignment Benefits

19 April 2018

David V. Williams, Consultant

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# C Milliman

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I have reviewed the civil rights complaint for sex discrimination filed in United States District Court, W.D. Wisconsin No.: 17-cv-264; Alina Boyden, and Shannon Andrews Plaintiffs vs State of Wisconsin Department of Employee Trust Funds, State of Wisconsin Group Insurance Board, Robert Conlin (Secretary of the Department of Employee Trust Funds), Board of Regents of the University of Wisconsin System, Raymond Cross (President of the UW System), Rebecca Blank (Chancellor of UW – Madison), Robert Golden (Dean of the UW School of Medicine and Public Health), and Dean Health Plan, defendants. This report contains my opinions with respect to healthcare costs for surgical procedures, services and supplies related to surgery and hormone therapy associated with gender reassignment.

## **Professional Qualifications**

I am a Healthcare Consultant working in the Hartford, Connecticut office of Milliman, the largest independent actuarial consulting firm in the United States with offices worldwide. I have 30 years' experience in areas related to medical economics including director positions at two health plans. I hold a degree in Economics from Brigham Young University and have completed graduate course work in statistics, data mining, public health, and software development.

My employment as a Milliman Healthcare Consultant began in 1997. Milliman Healthcare Consultants consist of actuaries, medical professionals, information technology experts, and other professionals who serve clients that include health plans, insurance companies, healthcare providers, employers, governments, pharmaceutical companies, medical device manufacturers and others. Milliman qualifies consultants through a rigorous evaluation process that designates a consultant as an approved professional, which means the consultant is approved to work directly with clients, and/or has signature authority, which means the consultant may sign reports and approve other professional's work products: I am both an approved professional and have signature authority. My professional responsibilities include provider contracting, pricing, insurance premium rate-setting, return on investment analysis for wellness programs and medical devices, value-based insurance design, forecasting and budgeting of health plans, and medical claims data warehousing.

As a result of my technical experience in medical economics, benefit pricing, and data analysis, I have developed an understanding of benefit pricing techniques and approaches used in the healthcare industry.

I have previously serviced, and continue to work as an expert witness for Reasonable Fee Methodologies, particularly for fees paid by automobile related medical claims where there is no contract between the insurer and provider of care. I have developed an understanding of medical provider billing patterns across the healthcare industry.

The opinions set forth in this report are based on my education, training and experience including my knowledge of medical insurance, benefit design and benefit pricing as commonly used by employers in the U.S. market.

My practice is being compensated \$390 per hour for my services as an expert witness. I may use charts or tables attached to or included in the body of this report as demonstrative exhibits if I testify in this matter. I understand that the parties may obtain further information relating to the matters addressed in this report and that I may be asked to review further information. I reserve

the right to review, modify, or expand upon my opinions based on any further information provided to me. I may also develop additional charts or other exhibits to use in my testimony.

#### **Publications**

Milliman Reasonable Fee Methodology on behalf of United Services Automobile Association (USAA), 2012

Analysis of Medical Bill Audit Services prepared on behalf of United Services Automobile Association (USAA), June 21, 2004

Frykberg, RG., Williams DV., Negative-Pressure Wound Therapy and Diabetic Foot Amputations: A retrospective study of Payer Claims Data. J. Am Podiatr Med Assoc. Sept/Oct 97(5)2008, P. 351-9.

#### **Prior Expert Litigation Work**

Expert Report: 2012-02016-PAB-MJW; Lindsey Parks, representative of a class of injured persons insured with USAA, plaintiff, vs. USAA and AUTO INJURY SOLUTIONS, (AIS), defendants.

Deposition: MySpine, PS Plaintiff v USAA Casualty Insurance Company, et al. Defendant, Civil Action No. C12-1973RAJ

## Summary of Opinions

- 1. Examining retrospective claims data is the preferred starting point for pricing healthcare benefits for procedures, services, and supplies related to surgery and hormones therapy associated with gender reassignment. For purposes of this analysis, I used retrospective claims data from January 1, 2016 through December 31, 2016, from the Truven MarketScan® commercial research dataset.
- 2. In a population of 20,037,382 persons who likely had health insurance coverage for treatment associated with gender dysphoria, I identified 8200 persons, or 0.041% of the population, who had healthcare claims for treatments associated with gender dysphoria.
- 3. These real world data show a wide range of costs associated with gender dysphoria treatments among patients—from \$0 to \$311,000. The average cost of treatment per patient with gender dysphoria-related treatment is \$2,974. Using the same data, the average real world costs for persons who undergo gender reassignment surgery is \$21,302.
- 4. Because the real world data is only recently available and is limited to one year's claims experience, I blended the results with the cost information from Segal's January 23, 2017, report to Lisa Ellinger of the Wisconsin Department of Employee Trust Funds to arrive at an average cost per individual for individuals who had gender dysphoria-related surgical treatment to be \$35,000.
- 5. Given the relatively small proportion of members obtaining gender dysphoria treatments in the 2016 dataset and the widely varied costs associated with those treatments, I would expect volatile pricing for gender reassignment benefits from year to year. Therefore, it is fiscally prudent to add a risk margin to the final calculated benefit to account for the volatility in expected cost.
- 6. In my professional opinion, adding a risk margin of 50% for both the expected utilization of services and the average cost per person would be a reasonable way to price this risk margin. This results in total expected yearly cost of roughly \$301,600 and a per-member per-month ("PMPM") cost of \$0.15.

## Group Benefit Pricing Approach

Insurers typically price health plan benefits using historical data that includes an insured population and their historical medical claims. Health plans calculate the expected premium they charge to fully insured employers using these basic steps. Self-insured employers follow a similar process when setting budgets for health care benefit expenditures. In the absence of historical claims data, other published sources are sought.

Regardless of who takes the risk, new health plan benefits impose a cost that the employer pays, either through an increased premium that reflects the health plans' increased claims risk (for fully-insured employers) or through medical claims expenses directly imposed on the employer (for self-insured employers).

The following steps are used to estimate the cost of a benefit<sup>1</sup>:

- 1. Define the benefit by stating what services can be included and what services are excluded.
- 2. Gather enrollment data, also known as exposure data. This would be the number of covered employees and their dependents for an employer.
- 3. Calculate the average cost of the benefit, per patient, using historical base claim data for the covered services.
- 4. Estimate the number of the relevant healthcare services using a) how many individuals have the medical disorder at issue (here, gender dysphoria); b) how many of these individuals might seek covered treatments (here, procedures, services, and supplies related to surgery and sex hormones associated with gender reassignment); and c) for individuals who seek that treatment, the average cost of the treatment.
- 5. Add a reasonable risk margin based on uncertainties associated with the number of members who will seek the relevant treatments and the expected costs of those treatments.

## Define the Benefit

The 2017 and 2018 Uniform Benefits for Wisconsin state employees who receive health care coverage through their employment with the State contains the following coverage exclusion (hereafter, the "Exclusion"):

"Surgical Services: Procedures, services, and supplies related to surgery and sex hormones associated with gender reassignment."

I used a broad definition of gender reassignment surgery for this analysis that includes individuals with a diagnosis of gender dysphoria and services that may be related to gender reassignment surgery, both in preparation for surgery or post-surgical treatment. The following

<sup>&</sup>lt;sup>1</sup> For a more detailed description, see Group Insurance Chapter 33.

describes the basis for identifying, in the historical medical claims database<sup>2</sup> used here, individuals who submitted relevant claims.

Because the medical claims database used in this analysis contains claims associated with specific procedures, services, and supplies, I must determine which procedures, services, and supplies fall under the coverage exclusion described above. To do so, I reviewed benefit descriptions and medical policies for several health plans including:

- WPS Health Insurance Medical Affairs Policy. Service: Treatment of Gender Dysphoria. PUM 250-0039-1706. Medical Policy Committee approval 06/16/17; Effective Date: 08/21/17; Prior Authorization Needed: Yes.
- Blue Cross Blue Shield of Massachusetts: Medical Policy Transgender Services; Policy Number 189 updated effective 12/2017.
- Dean HealthPlan: Sex transformation Surgery (market-based) MP9465; October 31, 2016 Published/Effective 01/01/2017.
- Dean HealthPlan: Sex Transformation Surgery (standard) MP9469; Originated October 31, 2016; Revised April 19, 2017; Published/Effective 05/01/2017.

I used the Blue Cross Blue Shield of Massachusetts ("BCBSMA") Medical Policy for selecting specific services related to surgery. The BCBSMA policy includes the most specific coding for gender reassignment surgical services of the policies I reviewed and it is consistent in its general descriptions with the WPS and Dean medical policy descriptions. The procedures listed on BCBSMA medical policy refer to those items that are subject to prior authorization, and when billed, the claim must include a diagnosis code associated with gender dysphoria.<sup>3</sup>

But the BCBSMA medical policy also indicates that other coded procedures may also relate to gender dysphoria treatments; when referring to the listed gender dysphoria codes, it states that "[t]he following codes are included below for information purposes only; this is not an all - inclusive list." Likewise, the WPS medical policy states:

"Unless otherwise specified in the health plan, if a plan covers treatment for gender dysphoria, medically necessary services may include diagnostic evaluation, assessment, and treatment planning; psychotherapy; cross-sex hormone therapy; puberty suppressing medications; laboratory testing to monitor the safety of hormone therapy; and certain surgical treatments as listed in the Indications of Coverage section below, the Omnibus Pharmacy Policy for Treatments Reviewed by Medical Affairs, and Specialty Drug guidelines (Diplomat)"

To capture all surgically related services as described in these medical policies, including those not specified with lists of procedure codes, I have 1) created a "surgical bundle", and 2) listed other related services in the 'other' category.

As for the first described method, the combination of surgical procedures listed in the policy and the associated medically necessary services may be combined to form a surgical bundle. For purposes of this report, I define a surgical bundle as all related services incurred 7 days prior to

<sup>&</sup>lt;sup>2</sup> 2016 Truven Health MarketScan® Publication and Trademark Guidelines, commercial database. These data contain inpatient, outpatient and pharmacy claims and enrollment from large U.S. employers and health plans. (Hereafter, the "Database.")

<sup>&</sup>lt;sup>3</sup> These codes include ICD-10 codes F64.0 – F64.9 (DSM-5 codes 302.6 and 302.85).

the surgical procedure and 60 days after the medical procedure. CMS uses a similar method to calculate costs associated with a surgical procedure.<sup>4</sup>

As for the second described method, the "other" category includes services such as lab tests and office visits related to the surgical procedures and treatment for hormonal therapy. This category also captures surgical procedures not otherwise specifically listed in the BCBSMA medial policy.

The Exclusion also specifically applies to "sex hormones associated with gender reassignment."<sup>5</sup> I identify hormone therapy related to gender reassignment surgery by first identifying individuals with a gender dysphoria diagnosis, and then querying the pharmacy table for their associated prescriptions of the following therapeutic classes<sup>6</sup> of drugs:<sup>7</sup>

- 165: Hormones and Synthetics Substitutes. NEC.
- 167: Androgens and Combinations. NEC
- 170: Estrogens and Combinations. NEC
- 177: Progestins, NEC
- 246: Goandotrop Related Hormone Antagonist
- 262: Hormone-Modifying Therapy

## Gather Enrollment, or Exposure Data

The Database was queried to find 8,200 de-identified individuals with a gender dysphoria diagnosis, to which I will refer to as the "Study Population."

The next step is to determine the total members covered by relevant group health insurance plans that provide the defined benefit at issue. Because this analysis is meant to calculate the cost incurred by group health insurance plans that cover procedures, services, and supplies related to surgery and sex hormones associated with gender reassignment, members of plans that do not cover these treatments should be excluded from the total member population. Some individuals in the Database were presumably covered by plans that do not provide benefits for these treatments. However, the Database does not identify how many, if any, of the health plans or large employers exclude these benefits from their plan.

Therefore, I assume that if an individual's claim was paid that included a gender dysphoria diagnosis, then that individual was covered by a plan that provides benefits for gender dysphoria treatments. Using a data field that allows me to calculate the number of all members of plans that presumably provide these benefits, I summed the enrollment for plans that included at least one individual in the Study Population; this resulted in a total population of 20,037,382.

- <sup>6</sup> Based on the AHFS Pharmacologic-Therapeutic Classification System as supplied by MarketScan.
- <sup>7</sup> These correspond to the WPATH regimens at pp. 47-50.

<sup>&</sup>lt;sup>4</sup> Available at https://innovation.cms.gov/initiatives/Bundled-Payments/learning-area.html (last accessed April 19, 2018).

<sup>&</sup>lt;sup>5</sup> I understand, however, that the Exclusion is not applied to claims for sex hormones when those hormones are not associated with gender reassignment surgery.

The percentage of individuals who were identified in The Database as having sought medical treatment and having a diagnosis related to gender dysphoria is then:

8,200 / 20,037,382 = 0.041%

The Study Population ages range from 8 to 65 with a median of 23 and an average of 36.8.

29% of individuals in The Study Population were under age 18.

## Estimate Average Cost

Costs described here are the amounts allowed by contract between insurers and providers. I have included inpatient costs, outpatient costs and pharmacy costs in this estimate.

Selecting all 8,200 members with a gender dysphoria diagnosis yields a average cost of \$2,974 per member with a gender dysphoria diagnosis and a median of \$527; actual per-member costs for those with gender dysphoria range from \$0.00 to \$311,000.

#### TABLE 1A<sup>8</sup> SUMMARY OF COSTS OF STANDARD POPULATION BY CATEGORY

	Individuals		Total Cost	Cost per	
	Individuals	Total Cost		Person	
Counseling	4,519	\$	7,836,633	\$	1,734
Hormone Therapy	4,489	\$	2,947,095	\$	657
Reassignment Surgery	469	\$	7,257,523	\$	15,474
Other	6,973	\$	6,349,588	\$	911
Total	8,200	\$	24,390,839	\$	2,974

The resulting PMPM cost is calculated as the percentage of the population who are likely to receive health care services times the average cost of the service provided divided by twelve months, or  $8,200/20,037,282 \times 2,974/12 = 0.10$ 

The data lacks sufficient detail to determine which patients who have had counseling and hormone therapy are planning to or have had gender reassignment surgical procedures. I understand that counseling and hormone therapy would be covered under the Uniform Benefits at issue, if those services are unrelated to gender reassignment surgery. To address this uncertainty, table 1B isolates services for patients who are known to have had a surgical procedure.

<sup>&</sup>lt;sup>8</sup> Note that individuals may fall into several categories of services.

	Individuals To		Total Cost	Average	
	mulviduals		Total Cost		Cost
Counseling	259	\$	424,909	\$	1,641
Hormone Therapy	417	\$	229,705	\$	551
Reassignment Surgery	469	\$	7,318,440	\$	15,604
Other	458	\$	2,017,564	\$	4,405
Total	469	\$	9,990,618	\$	21,302

TABLE 1B SUMMARY OF COSTS FOR SURGICAL PATIENTS

The resulting PMPM (per member per month) cost is calculated as the percentage of the population who are likely to receive health care services times the average cost of the service provided divided by twelve months, or  $469/20,037,282 \times 21,302/12 = \$0.04$ 

As discussed further below, the "true" PMPM figure based on this data is somewhere between \$0.04 and \$0.10, since each set of calculations does not precisely track the coverage exclusion at issue.

The distribution of costs for surgical patients is as follows:

WITH A DIAGNOSIS OF GENDER DYSPHORIA/ GID					
Cost Dance		Cost Pango	Percent of	Percent	
	Cost Range		Individuals		
	\$	250	2.3%	0.0%	
	\$	1,000	7.0%	0.2%	
	\$	2,500	9.2%	0.7%	
	\$	5,000	11.5%	2.0%	
	\$	15,000	29.0%	13.8%	
	\$	30,000	24.1%	24.4%	
	\$	75,000	11.3%	24.8%	
	\$	150,000	4.3%	21.7%	
	\$	300,000	1.1%	9.2%	
	\$	500,000	0.2%	3.1%	

TABLE 1C RANGE OF CLAIMS COSTS FOR SURGICAL PATIENTS WITH A DIAGNOSIS OF GENDER DYSPHORIA/ GID

Further details regarding details of surgical costs and the age of the study population are provided in Tables 2 and 3, below.

SUMMARY SUF	GICAL PROCEDURE DETAILS			
Surgical Procedure Details	Individuals	Total Costs		
MTF	119	\$	930,822	
FTM	349	\$	2,797,955	
Both	123	\$	478,604	
Face	19	\$	238,436	
Other	26	\$	114,239	
Additional 'Bundled' Services		\$	1,542,811	
Facility Costs when Inpatient	39	\$	1,154,655	

TABLE 2 SUMMARY SURGICAL PROCEDURE DETAILS

TABLE 3 SUMMARY OF STUDY POPULATION BY AGE

Age	Pct of Individuals
<18	29%
18-40	56%
40-65	16%

## Estimate the Number of Expected Services

My review of prior studies of gender dysphoria prevalence and expected benefit utilization showed wide differences. These differences combine to produce uncertainty when attempting to calculate the expected healthcare costs for gender reassignment surgery and related services. Below I review prior studies to demonstrate the nature of the uncertainty.

#### SELF-REPORTING SURVEYS

The Centers for Disease Control and Prevention (CDC) 2014 Behavioral Risk Factor Surveillance System (BRFSS) estimated a prevalence rate of 0.6% as of 2011. The survey asked respondents whether they considered themselves to be transgender, and if yes, whether male-to-female, female-to-male, or gender nonconforming. This estimate was about twice that of a prior estimate of 0.3% from similar 2011 survey.

The DSM-5 manual describes the prevalence of gender dysphoria as follows:

- Natal adult males: 0.005% to 0.014%
- Natal adult females: 0.002% to 0.003%

The DSM-5 also opines that, "since not all adults seeking hormone treatment and surgical reassignment attend specialty clinics, these rates are likely modest underestimates."<sup>9</sup>

<sup>&</sup>lt;sup>9</sup> DSM Manual at p. 454.

Zuker (2017) pointed out the inaccuracies of self-reported studies to determine incidence of gender dysphoria. He states:

The "recent studies suggest that the prevalence of a self-reported transgender identity in children, adolescents and adults ranges from 0 to 1.3%, markedly higher than prevalence rates based on clinic-referred samples of adults. The stability of a self-reported transgender identity or a gender identity that departs from the traditional male-female binary among non-clinic based populations remains unknown and requires further study."

Identifying as gender dysmorphic does not necessarily mean the individual will seek related healthcare services or undergo gender transformation. Olyslager and Conway (2007) provide a useful framework to understand data available in claims based data sources:

P(TS) = the prevalence of transsexualism

P(SH) = the prevalence of transsexual people who have sought help from a healthcare provider P(HT) = the prevalence of those on hormone therapy

P(ST) = the prevalence of those who have socially transitioned, and

P(SRS) = the prevalence of those who have undergone gender (sex) reassignment surgery

 $\mathsf{P}(\mathsf{TS}) > \mathsf{P}(\mathsf{SH}) > \mathsf{P}(\mathsf{HT}) > \mathsf{P}(\mathsf{ST}) > \mathsf{P}(\mathsf{SRS})^{10}.$ 

A retrospective claims based data analysis for pricing will include individuals who have sought help from a healthcare provider (P(SH)), who are on hormone therapy (P(HT)), and who have undergone gender reassignment surgery (P(SRS)). The data will not identify individuals who have socially transitioned (P(ST)) but not sought help from a healthcare provider nor will it identify individuals who may identify as transgender or nongender conforming but have not sought help from a healthcare provider.

It should also be noted that the epidemiology definitions of prevalence and incidence may not be accurately reflected in a retrospective claims dataset consisting of one year's of incurred claims. There may be individuals who identify as transgender or nongender conforming who are included in the enrollment data who have not sought care from a healthcare provider as part of their health benefit.

#### CLAIMS BASED ANALYSIS

Naugle (2015) searched a 2012 medical claims dataset which found 0.004% of members had an insurance claim related to gender dysphoria. This analysis likely underestimates the true rate of gender dysphoria-related claims. In recent years many health plans and employers have begun to remove exclusions for gender reassignment benefits, which prompts another look at using health insurance claims data as a reliable source for estimating claims costs.

My analysis presents a more accurate picture of the true rate of gender dysphoria-related claims. This is because the Database used for this study represents an early look at the expected utilization of procedures, services, and supplies related to surgery and hormone therapy associated with gender reassignment and represents the first full year ICD-10

<sup>&</sup>lt;sup>10</sup> The authors point out that these ratios will be factors of many local conditions.

diagnosis codes are used after being first implemented in October 2015. Again, as calculated above, the 2016 medical claims dataset found 0.041% of members had an insurance claim with a diagnosis of gender dysphoria.

While the annual utilization figure found in The Database remains lower than the prevalence rates from the self-reported sources discussed above, the 0.041% utilization rate comes closer to describing the expected medical utilization for gender reassignment benefits than self-reported prevalence studies.

However, as discussed further below, recent movement to remove gender reassignment benefit exclusions and the relatively low prevalence of gender dysphoria, suggests continued caution when applying utilization estimates for pricing purposes. Accordingly, considerations for addressing the risk of underestimating the utilization rate are discussed below as a potential adjustment to the PMPM figures calculated above.

JANUARY 23, 2017, SEGAL REPORT FROM KIRSTEN R. SCHATTEN, ASA AND KENNETH C. VIEIRA, FSA TO LISA ELLINGER RE: TRANSGENDER COST ESTIMATE

Schatten and Viera state that there is a lack of information and data to provide specific information on estimated cost to the Plan. Schatten and Viera provide an estimated PMPM cost range of \$0.05 to \$0.13. The pricing formula and approach used in this report<sup>11</sup> is consistent with pricing principles.

However, there is no mention of the definition of the benefit or any adverse outcomes or comorbidities that may be associated with the procedures. The latter omission could cause the Segal report to underestimate the true costs of providing coverage for gender reassignment surgery.

## Summary & Risk Margin Discussion

As stated above, the expected utilization rate for surgical procedures, services and supplies related to surgery and hormone therapy associated with gender reassignment is a relatively small fraction of the total insured population. Additionally, there is a wide variance per individual cost (see table 1C). In an insured population of 167,543, the estimated number of individuals who obtain the more expensive gender reassignment surgery is between 3-4 individuals—although this estimate may vary from year to year.

From the summary above, the expected number of individuals obtaining gender dysphoriarelated treatment in a population of roughly 167,500 would be:

<sup>&</sup>lt;sup>11</sup> I independently calculated a PMPM of \$0.084 using the information available in the report.

		TABLE 5	
EXPECTED NUMBE	R OF GENDER	DYSPHORIC INDIVIDUALS OBTAINING CARE IN	A POPULATION OF
		167,500	
	36	Counseling	
	36	Hormone Therapy	
	4	Reassignment Surgery	
	55	Other	
	65	Total	

TABLE 5 E F

Individuals have complex health care needs and recommended treatment approaches and health care delivery will vary depending on patient complexity and preferences. Moreover, individuals may experience unforeseen complications resulting from gender reassignment procedures; any resulting complications will add to the costs of care for these particular patients.

Based on the claims analysis presented above, I observed that the expected average cost was for all individuals with a gender dysphoria diagnosis was \$2,974 with ranges from \$0.00 to \$311,000 and a median of \$527. The average cost for those who underwent gender reassignment surgery was \$21,302 per individual.

The implication of this wide range of average costs is that the expected total costs for a population of around 167,500 is highly variable. Considering the range of costs, it is plausible that in any given year, ETF and participating health plans could experience an adverse year of claims experience with more individuals seeking surgery than predicted who have higher than average surgical costs. Likewise, it would only take one individual with a catastrophic claim to significantly raise average and total costs.

Some of the reasons for this variability include:

- 1) Variability in the level of reconstruction: FTM surgical procedures may include mastectomy, male chest construction, hysterectomy and oophorectomy (removal of ovaries), urethraplasty, vaginectomy, scrotoplasty, and/or implantation of prostheses. MTF surgical procedures may include breast autmentation, penectomy, orchiectomy, vaginplasty, clitoraplasty, and vulvoplasty. These procedures may be one in combination (in one surgical episode) or individually over time, and may or may not include the full suite of possible reconstructions.
- Complications: These procedures are not risk free and could result in complications related to surgery or treatment that require further expensive treatment.
- 3) Location: Procedures performed in an ambulatory care setting or surgical center are less expensive than done in an inpatient setting.

For example, it is possible that, in a given year in ETF's population of around 167,500, eight individuals might submit claims for gender reassignment surgery (rather than three to four) at an average cost of \$100,000 (rather than the calculated average cost of around \$21,000). This would result in a total cost of \$800,000 in claims, a six fold increase from the average calculated above. In my professional experience, this would not be an unusual variance, and it therefore it must be acknowledged when pricing the benefit at issue.

I calculated above a range of PMPM costs from \$0.04 to \$0.10 using medical claims data from 2016, depending on the scope of services counted in the calculation. Based on these

calculations, I expect the value to be in-between \$0.04 and \$0.10 and therefore I use a midpoint of \$0.07.

The PMPM calculated above is \$0.07.  $0.07 \times 167,543 \times 12 = 140,736$  of expected cost to the Employee Trust Fund which is .01% of total premium based on Segal's report that the Wisconsin Department of Employee Trust Funds expended \$1.3 billion of non-Medicare premiums for 2017.

I observed that the average cost from the Database of those undergoing surgery of \$21,302 is lower than the values presented in the Segal study which were \$41,600 for MTF surgeries and \$64,200 for FTM surgeries.

Confident use of medical claims data for benefit pricing presumes several years of available data. Given that 2016 is the first year that a medical claims database contains sufficient claims for pricing gender reassignment benefits, it is prudent to blend it with other available data such as the pricing sources used in the Segal report.

I blend the average cost from the Database, \$21,302, with the weighted average<sup>12</sup> of Segal's cost estimates (0.66 x 41,600 + 0.34 x 64200 = \$49,284) by rounding the midpoint to the nearest thousand to obtain a blended cost estimate of \$35,000 for gender reassignment surgery and related services and supplies resulting in a PMPM of \$0.07.

In my professional opinion and given all the factors discussed in this section, adding a risk margin of 50% for both the expected utilization of services and the average cost per person would be a reasonable way to price a risk margin for these services.

The resulting PMPM would be  $0.15 (35,000 \times 1.5 \times .0023\%^{13} \times 1.5 / 12)$ . The expected yearly cost to ETF and participating health plans with this added contingency would be  $0.15 \times 12 \times 167,543 = 301,577$ .

This approach would cover most contingencies of high claim costs associated with a gender reassignment benefit, but it would result in excess revenue during an average or below average utilization year. The risk margin would be reviewed and adjusted annually based on the financial position of the plan at the time and additional, future claims data.

## **Other Considerations**

The 2016 study population from the Database used for my analysis has the following limitations:

1. It is possible there was pent up demand, meaning individuals who had not previously had access to transgender benefits through their employer decides to undergo transgender transformation with the first year of the exclusion removal. This would suggest a spike in utilization that would subside over time.

 $<sup>^{12}</sup>$  34% of the individuals who had surgery in the Database were male.  $^{13}$  469 / 20,0323,282

- 2. The treatment period is limited to one year, whereas treatment for gender reassignment surgery, including counseling and hormone treatment may be on-going. Therefore long term costs are not yet understood through the claims data.
- 3. If considering claims costs for surgical bundles that span 60 days, the annual costs and accompanying prevalence are limited to ten months from the first date of the procedure.

## Review of other estimates

EXPERT WITNESS REPORT OF STEPHANIE BUDGE, PH.D.

I reviewed the Cost of Transition-Related Care section in the Expert Witness Report of Stephanie Budge, Ph.D. found on page 22. The report relies on a cost effectiveness study for insurance companies to cover transition-related care. Padula, et al. (2016). The statistical analysis performed in the Padula study was a Quality of Life Year Cost-Effectiveness analysis using a Markov model based on a transgender discrimination survey, standard utility scores, and costs from disparate sources over different time periods.

These types of studies are not used in the actuarial sciences for benefit pricing purposes. They lack sufficiently detailed information to match the costs with the associated benefit descriptions for a specific time period.

The measured outcome in the Padula study is a Quality Adjusted Life Year at 5 year and 10 year horizons, which are too far out for benefit pricing purposes. The estimated costs are derived from an ad hoc survey<sup>14</sup>, and procedures were weighted in an undisclosed fashion by procedure prevalence<sup>15</sup> with a publication reference of 2007. Inputs with attached costs also include measures not included in standard health benefits including cost utilities for items such as job loss, depression, and attempted suicide. None of these study design elements would be used in a current pricing of medical benefits.

**Respectfully Submitted** 

av V. Willing

David V. Williams

Date: 19 April 2018

<sup>&</sup>lt;sup>14</sup> Padula, et al. (2016) at p.100.
<sup>15</sup> Paudla, et al. (2016) at p. 96.

### **Bibliography**

American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th Edition). Washington DC; American Psychiatric Association; 2013

Bernstein, GR., Brandel, SS.. Chapter 33: Estimating Medical Claims Costs. Group Insurance. Skwire DD. Principal Editor. ACTEX Publications, New Hartford, CT. 2016

Grant, Jaime M., Lisa A. Mottet, Justin Tanis, Jack Harrison, Jody L. Herman, and Mara Keisling. Injustice at Every Turn: A Report of the National Transgender.Discrimination Survey. Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force, 2011.

Naugle AL. Phillip S. Transgender healthcare coverage: Prevalence, recent trends, and considerations for payers. Milliman Insight, 2016

Padula, WV. Heru, S., Campbell, JD. Societal Implications of Health Insurance coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis. J Gen Intern Med 31(4): 394-401; doi: 10.1007/s11606-015-3529-6. 2015.

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Schatten, KR., Vieira, KC., Transgender Cost Estimate. Letter to Lisa Ellinger. January 23, 2017

Standards of Care for the Health of Transsexual, Transgender, and Gender nonconforming People. The World Professional Association for Transgender Health. 7th Edition. 2011.

Stephanie Budge, PhD. Expert Witness Report. 2/19/2018

Zuker, ZJ., Epidemiology of gender dysphoria and transgender identify, Sexual Health 2017; 14, 404-411. doi: 10.1071/SHI7067.

# Exhibit A

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# **CURRICULUM VITA**

#### David Williams Senior Healthcare Consultant

#### Milliman Inc.

80 Lamberton, Road Windsor, CT 06095 860-687-0120 / 860-882-3700 david.williams@milliman.com

#### WORK HISTORY AND EXPERIENCE

#### Milliman, Windsor, CT

Senior Healthcare Consultant (1999 – present)

- Consultant to medical device manufacturers seeking economic studies in support of FDA approval, pricing, and market potential. Ongoing
- Lead hospital contracting support for health plans. Ongoing
- Expert witness for UCR related medical billing disputes. Ongoing
- Consultant for risk bearing provider organizations and accountable care organizations. Ongoing
- Lead consultant for State of Connecticut employee benefits managing \$1.4 billion in medical claims.2006-2015
- Creator of CTHEP.COM, an employee internet portal that captures employee adherence to an innovative Value Based Insurance Design (VBI-D), 2012
- Developer of physician payment system for automobile related claims, 2009
- Project Manager GASBHelp.com, a sophisticated on-line reporting system to meet phase III GASB 45 requirements. 2008
- Office technology committee chair and HIPAA compliance officer.

#### MedSpan, Inc. Hartford CT

Director, Quality Management/Risk Share Arrangements (1994 – 1999)

- Executed and managed Medicare risk share agreements with ten physician hospital organizations.
- Responsible for Total Quality Management that resulted in NCQA accreditation. This was NCQA's first Physician Hospital Organization accreditation.
- Built a network of 23 hospitals with over 5,500 physicians for a newly created Health Maintenance Organization.
- Researched and implemented clinical guidelines and utilization management policies and procedures

#### **Kaiser Permanente**

Director, Medical Economics, Southern California and Northeast Regions, (1987-1994)

#### **EDUCATION**

BA, Economics – Brigham Young University, Provo, UT Masters courses, Managerial Economics; quantitative emphasis, BYU, Provo, UT Database Administration: Microsoft Professional Development Course Master Classes, Data Mining – Central Connecticut State University, on-line Master Classes, Public Health – UMASS, Amherst, on-line Predictive Modeling and Data Science using R – Coursera

#### **PROFESSIONAL PUBLICATIONS**

Expert Report: Lyndsey Parks plaintiff vs. USAA and Auto Injury Solutions (AIS) defendants. 2013

Negative-Pressure Wound Therapy and Diabetic Foot Amputations: A retrospective study of Payer Claims Data. Journal of the American Podiatric Medical Association, Sept/Oct 2007. P. 351

Demystifying the Medical Underwriting Cycle. Kaiser Foundation, 1990, unpublished manuscript.

#### SPEAKING ENGAGEMENTS

- 2018 MassMedic: Using Real World Data for Medical Device FDA Approval
- 2017 Milliman Forum: Tiered Network Analysis
- 2017 Milliman Forum: Advances and ROI in Wellness Programs and Wearables
- 2013 Milliman Forum: Big Data
- 2013 Milliman Forum: Value Based Insurance Design
- 2013 Milliman Forum: Advances in Wellness Programs
- 2012 Causality Actuarial Society Issues in Auto Injury Medical Reimbursement
- 2012 Milliman Forum: Value Based Insurance Design at the State of Connecticut
- 2010 Milliman Forum: Innovations in Physician Fee Schedules
- 2009 Milliman Forum: Wellness Programs
- 2005 Milliman Forum: Milliman Data Sources
- 2005 Florida HMO Association: Data Warehouse Basics
- 2005 KCI National Sales Conference: The Economic Value of the V.A.C. System
- 2004 National Pressure Ulcer Conference: Comorbid Conditions in Pressure Ulcers
- 2004 ISPOR: Avoiding Amputations using the V.A.C. System
- 2004 Milliman Forum: Milliman Data Sources
- 2002 Society of Actuaries: Advances in Data Warehousing
- 2002 Milliman Forum: Medical Device Economic Modeling
- 2001 Society of Actuaries: Issues in Healthcare Data Quality
- 2001 Milliman Forum: Auditing Using Claims Data
- 2000 Milliman Forum: Medical Data Warehousing
- 1995 New England HEDIS Coalition: Issues in HEDIS Reporting

#### ASSOCIATIONS AND VOLUNTEER WORK

Board of Directors: Farmington Valley Symphony Orchestra Friends of Music, Farmington Connecticut School District International Society for Pharmacoeconomics and Outcomes Research (ISPOR) MassMedic

#### LANGUAGES

Chinese Cantonese– conversationally fluent Chinese Mandarin – early intermediate level Case: 3:17-cv-00264-wmc Document #: 91-2 Filed: 06/06/18 Page 1 of 9

# Exhibit B





# Medical Affairs Policy

# Service: Treatment of Gender Dysphoria

PUM 250-0039-1706

Medical Policy Committee Approval	06/16/17
Effective Date	08/21/17
Prior Authorization Needed	Yes

**Disclaimer:** This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email <u>medical.policies@wpsic.com</u>.

#### **Description:**

Gender dysphoria is a condition in which there is a marked incongruence (discrepancy) between an individual's experienced/expressed gender and the assigned gender (biologic sex assigned at birth) and the associated gender role and/or primary and secondary sex characteristics.

Unless otherwise specified in the health plan, if a plan covers treatment for gender dysphoria, medically necessary services may include diagnostic evaluation, assessment, and treatment planning; psychotherapy; cross-sex hormone therapy; puberty suppressing medications; laboratory testing to monitor the safety of hormone therapy; and certain surgical treatments as listed in the Indications of Coverage section below, the Omnibus Pharmacy Policy for Treatments Reviewed by Medical Affairs, and Specialty Drug guidelines (Diplomat).

This policy is based on the World Professional Association for Transgender Health (WPATH) Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7<sup>th</sup> version, Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), American Psychiatric Association recommendations as well as other evidence based publications.

WPATH describes the transition from one gender to another in three stages:

- 1. Living in the gender role consistent with gender identity
- 2. The use of cross-sex hormone therapy after living in the new gender role for a least three months





3. Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months.

Clinical evidence for many of these services is limited and lacks long term safety data. Statistically robust randomized controlled trials are needed to address benefits versus clinical risks and long-term health outcomes. Expert consensus recommendations include that diagnosis be made by mental health professionals and that care is coordinated between the behavioral health professional, endocrinologists, and experienced surgeons.

This medical policy does not apply to individuals with ambiguous genitalia or disorders of sexual development, unless there is concurrent / concomitant diagnosed gender dysphoria.

#### **Indications of Coverage:**

When criteria below are met, the following gender reassignment surgical procedures may be considered medically necessary:

Note: In the absence of health plan limits, more than one gender transformation reassignment (which may include several staged surgeries) per lifetime will be considered experimental investigational and unproven

#### Female-to-Male (FtM)

- 1. Bilateral mastectomy or breast reduction
- 2. Hysterectomy (removal of uterus)
- 3. Metoidioplasty (creation of penis, using clitoris)
- 4. Penile prosthesis
- 5. Phalloplasty (creation of penis)
- 6. Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- 7. Scrotoplasty (creation of scrotum)
- 8. Testicular prostheses
- 9. Urethroplasty (reconstruction of male urethra)
- 10. Vaginectomy (removal of vagina)
- 11. Vulvectomy (removal of vulva)





12. Bilateral mastectomy or breast reduction may be done as a stand-alone procedure, without having genital reconstruction procedures. In those cases, the individual does not need to complete hormone therapy prior to procedure.

#### Male-to-Female (MtF)

- 1. Clitoroplasty (creation of clitoris)
- 2. Labiaplasty (creation of labia)
- 3. Orchiectomy (removal of testicles)
- 4. Penectomy (removal of penis)
- 5. Urethroplasty (reconstruction of female urethra)
- 6. Vaginoplasty (creation of vagina)
- A. Mastectomy for Female-to-Male (FtM) Patients
  - 1. Single letter of referral from a qualified mental health professional; and
  - 2. Persistent, well-documented gender dysphoria; and
  - 3. Capacity to make a fully informed decision and to consent for treatment; and
  - 4. Age of majority (18 years of age or older); and
  - 5. If significant medical or mental health concerns are present, they must be reasonably well controlled
- Note: A trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy
- **B.** Requirements for gonadectomy (hysterectomy and oophorectomy in female-to-male and orchiectomy in male-to-female)
  - 1. Two referral letters from qualified mental health professionals, one in a purely evaluative role; **and**
  - 2. Persistent, well-documented gender dysphoria; and
  - 3. Capacity to make a fully informed decision and to consent for treatment; and
  - 4. Age of majority (18 years or older); and





- 5. If significant medical or mental health concerns are present, they must be reasonably well controlled; **and**
- 6. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones)
- C. Genital reconstructive surgery
  - 1. Two referral letters from qualified mental health professionals, one in a purely evaluative role; **and**
  - 2. Persistent, well-documented gender dysphoria; and
  - 3. Capacity to make a fully informed decision and to consent for treatment; and
  - 4. Age of majority (age 18 years and older); and
  - 5. If significant medical or mental health concerns are present, they must be reasonably well controlled; **and**
  - 6. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); **and**
  - 7. Twelve months of living in a gender role that is congruent with their gender identity (real life experience)
- Note: Blepharoplasty, body contouring (liposuction of the waist), breast enlargement procedures such as augmentation mammoplasty and implants, face-lifting, facial bone reduction, feminization of torso, hair removal, lip enhancement, reduction thyroid chondroplasty, rhinoplasty, skin resurfacing (dermabrasion, chemical peel), and voice modification surgery (laryngoplasty, cricothyroid approximation or shortening of the vocal cords), which have been used in feminization, are considered cosmetic. Similarly, chin implants, lip reduction, masculinization of torso, and nose implants, which have been used to assist masculinization, are considered cosmetic.

\*Requirements for a Qualified Mental Health Professional:

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; **and** 





- 2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; **and**
- 3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; **and**
- 4. Knowledgeable about gender nonconforming identities and expressions; and the assessment and treatment of gender dysphoria; **and**
- 5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

#### **Limitations of Coverage:**

- **A.** Review health plan and endorsements for exclusions and prior authorization or benefit requirements.
- **B.** If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.
- **C.** If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- **D.** Certain ancillary procedures, including but not limited to the following, are exclusions of the health plan for all individuals or are considered cosmetic, when performed as part of gender reassignment:
  - 1. Abdominoplasty
  - 2. Blepharoplasty
  - 3. Body contouring (e.g., fat transfer, lipoplasty, panniculectomy)
  - 4. Breast enlargement, including augmentation mammaplasty and breast implants
  - 5. Brow lift
  - 6. Calf implants
  - 7. Cheek, chin and nose implants
  - 8. Injection of fillers or neurotoxins





- 9. Face/forehead lift and/or neck tightening
- 10. Facial bone remodeling for facial feminization
- 11. Hair removal (e.g., electrolysis or laser)
- 12. Hair transplantation
- 13. Lip augmentation
- 14. Lip reduction
- 15. Liposuction (suction-assisted lipectomy)
- 16. Mastopexy
- 17. Pectoral implants for chest masculinization
- 18. Reproductive services including, but not limited to, sperm or oocyte preservation, cryopreservation of fertilized embryos
- 19. Reversal of genital surgery or reversal of surgery to revise secondary sexual characteristics
- 20. Rhinoplasty
- 21. Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- 22. Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- 23. Voice modification surgery (e.g. laryngoplasty, glottoplasty or shortening of the vocal cords)
- 24. Voice lessons and voice therapy

#### **Documentation Required:**

- Referral letters from a qualified mental health professional as described in the indications containing all of the following:
  - 1. Client's general identifying characteristics (include pertinent clinical information such as preferred gender pronoun); **and**
  - 2. Results of the client's psychosocial assessment, including any diagnoses; and





- 3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date; **and**
- 4. An explanation that the WPATH criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery; and
- 5. A statement about the fact that informed consent has been obtained from the patient; **and**
- 6. A statement that the mental health professional is available for coordination of care and how contact can be made
- Medication Records
- Laboratory records if indicated

#### **References:**

- 1. Markwick L. Male, Female, Other: Transgender and the Impact in Primary Care. The Journal for Nurse Practitioners Vol 12, Issue 5, May 2016.
- 2. Hayes MTD Sex reassignment for the Treatment of gender Dysphoria. Publication Date May 15, 2014. Annual Review April 12, 2016.
- 3. Hayes MTD Hormone Therapy for the Treatment of Gender Dysphoria. Publication Date May 19, 2014. Annual Review April 15, 2016.
- 4. Hayes MTD Ancillary Procedures and Services for the Treatment of Gender Dysphoria. Publication Date May 9, 2014. Annual Review April 12, 2016.
- 5. World Professional Association for Transgender Health (WPATH): 2012 WPATH Standards of care for the health of transsexual, transgender, and gender nonconforming people, version 7
- 6. MCG 21<sup>st</sup> ed. ORG: B-010-IOP (BHG). Other Psychiatric disorders: Intensive Outpatient Program.
- MCG 21<sup>st</sup> ed. ORG: B-010-RES (BHG). Other Psychiatric disorders: Residential Care.

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# WPS/Arise Review History:

Implemented	08/21/17
Medical Policy	06/16/17
Committee	
Approval	
Reviewed	
Revised	
Developed	06/16/17

Approved by the Medical Director

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# Exhibit C



Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

### Medical Policy Transgender Services

#### **Table of Contents**

- Policy: Commercial
- Policy: Medicare
- <u>Authorization Information</u>
- Policy History

Description

- Information Pertaining to All Policies
- References
- Coding Information
- Endnotes

#### Policy Number: 189

BCBSA Reference Number: N/A NCD/LCD: N/A

**Related Policies** 

None

#### **Policy**<sup>1</sup>

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Please Note: According to the American Psychiatric Association, the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) defines gender dysphoria as a condition where a person's gender at birth is contrary to the one they identify with. This definition replaces the criteria for gender identity disorder which will no longer be used in DSM-5. However, ICD-10 codes continue to use the term gender identity disorder, and providers will need to submit claims for coverage using this diagnosis.

Mastectomy and/or creation of a male chest for female to male/gender neutral patients may be considered <u>MEDICALLY NECESSARY</u> when **ALL** of the following candidate criteria are met:

- The candidate is at least 18 years of age,
  - If the candidate is less than 18 years of age, then treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet this criterion.
- The candidate has been diagnosed with gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder), including meeting **ALL** of the following indications:
  - The desire to live and be accepted as a member of another sex other than one's assigned sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment
  - The new gender identity has been present for at least 12 months
  - The gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder) is not a symptom of another mental disorder.
- The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This includes members who identify as genders other than male or female.

 If the candidate does not meet the 12 month time frame criteria of 12 months of successful continuous full time real-life experience in their new gender noted above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria of 12 months of successful continuous full time real-life experience in their new gender may be waived.

Breast augmentation in male to female patients may be considered <u>MEDICALLY NECESSARY</u> when **ALL** of the following candidate criteria are met:

- The candidate is at least 18 years of age,
  - If the candidate is less than 18 years of age, then treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet this criterion.
- The candidate has been diagnosed with gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder), including meeting **ALL** of the following indications:
  - The desire to live and be accepted as a member of another sex other than one's assigned sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment
  - o The new gender identity has been present for at least 12 months
  - The gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder) is not a symptom of another mental disorder.
- For those candidates without a medical contraindication, the candidate has undergone a minimum of 12 months of continuous hormonal therapy that is provided under the supervision of a licensed clinician.
- The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This includes members who identify as genders other than male or female.
  - If the candidate does not meet the 12 month time frame criteria of 12 months of successful continuous full time real-life experience in their new gender noted above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria of 12 months of successful continuous full time real-life experience in their new gender may be waived.

Genital surgery in male to female, female to male, or gender neutral patients may be considered <u>MEDICALLY NECESSARY</u> when ALL of the following candidate criteria are met as documented by **two** treating clinicians:

- The candidate is at least 18 years of age,
  - If the candidate is less than 18 years of age, then treating clinicians must submit information indicating why it would be clinically inappropriate to require the candidate to meet this criterion.
- The candidate has been diagnosed with gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder), including meeting **ALL** of the following indications:
  - The desire to live and be accepted as a member of another sex other than one's assigned sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment
  - The new gender identity has been present for at least 12 months
  - The gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder) is not a symptom of another mental disorder.
- For those candidates without a medical contraindication, the candidate has undergone a minimum of 12 months of continuous hormonal therapy that is provided under the supervision of a licensed clinician.
- The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This includes members who identify as genders other than male or female.
  - If the candidate does not meet the 12 month time frame criteria of 12 months of successful continuous full time real-life experience in their new gender noted above, then the treating

clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria of 12 months of successful continuous full time real-life experience in their new gender may be waived.

Facial Feminization (typical components of facial feminization) or Masculinization may be considered **MEDICALLY NECESSARY** when **ALL** of the following candidate criteria are met:

- The candidate is at least 18 years of age,
  - If the candidate is less than 18 years of age, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet this criterion.
- The candidate has been diagnosed with gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder), including meeting **ALL** of the following indications:
  - The desire to live and be accepted as a member of another sex other than one's assigned sex, typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment
  - The new gender identity has been present for at least 12 months
  - The gender dysphoria (ICD-10 codes F64.0-F64.9 gender identity disorder) is not a symptom of another mental disorder.
- The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender.
  - If the candidate does not meet the 12 month time frame criteria of 12 months of successful continuous full time real-life experience in their new gender noted above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria of 12 months of successful continuous full time real-life experience in their new gender may be waived.
- Covered procedures when medical necessity criteria are met:
  - Forehead contouring
  - o Rhinoplasty
  - Mandible reconstruction
  - o Trachea shave
  - o Blepharoplasty
  - Brow lift
  - Cheek augmentation
  - Face lift or liposuction (only as needed in conjunction with one of the above procedures).

The following facial procedures are considered **INVESTIGATIONAL** and are not covered:

- Lip enhancement
- Neck lift
- Dermabrasion
- Chemical peel
- Hair transplant
- Electrolysis (except for genital surgery as noted below).

Electrolysis performed by a licensed dermatologist may be considered <u>MEDICALLY NECESSARY</u> for the removal of hair on a skin graft donor site prior to its use in genital sex reassignment surgery.

Oocyte, embryo, or sperm retrieval, freezing and storage for up to 24 months for transgender members prior to undergoing hormone therapy or genital sex reassignment surgery may be considered <u>MEDICALLY NECESSARY</u>. (See medical policy #<u>086</u>, Infertility Diagnosis and Treatment)

• Per subscriber certificate language, cryopreservation is limited to one cycle only.

GRS is **INVESTIGATIONAL** in the following circumstances:

- When one or more of the criteria above have not been met, OR
- Any services performed to reverse GRS, OR

• GRS procedures that are considered cosmetic are not covered unless otherwise specified in the member's individual subscriber certificate/benefit description.

#### **Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO	NO for Gender Reassignment Surgery
and POS)	YES for Oocyte, Embryo or Sperm retrieval, freezing and
	storage
Commercial PPO and Indemnity	NO for Gender Reassignment Surgery
	YES for Oocyte, Embryo or Sperm retrieval, freezing and
	storage
Medicare HMO Blue <sup>sM</sup>	NO for Gender Reassignment Surgery
	YES for Oocyte, Embryo or Sperm retrieval, freezing and
	storage
Medicare PPO Blue <sup>sM</sup>	No

#### Description

Gender reassignment surgery (GRS) is a treatment option for Gender Dysphoria, a condition in which a person feels a strong and persistent identification with a gender other than the one assigned at birth accompanied by a severe sense of discomfort with their own gender. People with gender dysphoria often report a feeling of being born as the wrong sex.

GRS is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities performed in conjunction with each other to help the candidate for gender reassignment achieve successful behavioral and medical outcomes. Before undertaking GRS, candidates need to undergo important medical and psychological evaluations, and begin medical therapies and behavioral trials to confirm that surgery is the most appropriate treatment choice.

FOLICY HISL	
Date	Action
12/2017	Medically necessary criteria revised. New investigational indications described.
	Clarified coding information. New references added. Effective 12/1/2017.
4/2017	Clarified coding information.
2/2017	Clarified coding information.
4/2016	Electrolysis added as medically necessary prior to sex reassignment surgery.
	Clarified coding information. Clarified cryopreservation statement. Effective 4/1/2016.
10/2015	Clarified coding information.
9/2015	Clarified coding information.
8/2015	Ongoing coverage on cryopreservation for transgender members added. Statement
	transferred from medical policy #086, Infertility Diagnosis and Treatment. 8/1/2015
4/2015	Coverage for facial surgical procedures and documentation requirement clarified.
	Effective 4/1/2015.
11/2014	Medically necessary statement clarified. Effective 11/14/2014.
10/2014	Coding information clarified.
9/2014	Coding information clarified.
8/2014	Updated criteria for SRS qualification. Added facial feminization to non-cosmetic
	surgery section. Coding information clarified. Effective 8/27/2014.

# Policy History

6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Language on benefit riders added.
4/2014	Coding information clarified.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
	No changes to policy statements.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology.
	No changes to policy statements.
12/2010	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology.
	No changes to policy statements.
1/2/2010	New policy, effective 1/2/2010, describing covered and non-covered services.

#### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

#### References

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#### CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria</u> on pp. 1-2 <u>MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

#### CPT Codes Male to Female Surgery

CPT codes:	Code Description
17380	Electrolysis epilation, each 30 minutes
19325	Mammaplasty, augmentation; with prosthetic implant
19350	Nipple/areola reconstruction
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19380	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
54120	Amputation of penis; partial
54125	Amputation of penis; complete
54300	Plastic operation of penis for straightening of chordee (eg, hypospadias), with or without mobilization of urethra
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55970	Intersex surgery; male to female
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state

### Facial Surgery (Male or Female)

#### **Brow Reconstruction**

CPT codes	Code Description
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft
	(includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction

#### **Brow Lift**

CPT codes	Code Description
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

#### Blepharoplasty

CPT codes	Code Description
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

#### Rhinoplasty

CPT codes	Code Description
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair

#### **Cheek Augmentation**

CPT codes	Code Description
21270	Malar augmentation, prosthetic material
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction

#### Jaw Reconstruction

CPT codes	Code Description
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction

#### **Chin Reconstruction**

CPT codes	Code Description
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction

#### Face Lift The following codes are covered when required as part of a medically necessary facial feminization procedure.

CPT codes	Code Description
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck

#### Liposuction

# The following codes are covered when required as part of a medically necessary facial feminization procedure.

CPT codes	Code Description
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

#### Trachea Shave

CPT codes	Code Description
31599	Unlisted procedure, larynx

#### Female to Male Surgery

CPT codes:	Code Description
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
19350	Nipple/areola reconstruction
53430	Urethroplasty, reconstruction of female urethra
54660	Insertion testicular prosthesis
55175	Scrotoplasty; simple
55180	Scrotoplasty; complex
55980	Intersex surgery; female to male
56620	Vulvectomy; simple
56625	Vulvectomy; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
56810	Perineoplasty, repair of perineum, nonobstetrical
57110	Vaginectomy; complete removal of vaginal wall
57111	Vaginectomy; with removal of paravaginal tissue (radical vaginectomy)
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 gms or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58275	Vaginal hysterectomy, with total or partial vaginectomy
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less;
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g

58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with
	removal of tube(s) and/or ovary(s)
50550	
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less;
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 grams or less; with
	removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams;
	with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of
	tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with
	removal of tube(s) and/or ovary(s)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT code above if above medical necessity criteria on pp. 1-2 are met:

#### ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis	
codes:	Code Description
F64.0	Transsexualism
F64.1	Gender identity disorder in adolescence and adulthood
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

The above <u>medical necessity criteria</u> on pp. 1-2 <u>MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

#### ICD-10 Procedure Codes Male to Female Surgery

ICD-10-PCS	
procedure	
codes:	Code Description
0VTC0ZZ	Resection of Bilateral Testes, Open Approach
0H0T0ZZ	Alteration of Right Breast, Open Approach
0H0T3ZZ	Alteration of Right Breast, Percutaneous Approach
0H0TXZZ	Alteration of Right Breast, External Approach
0H0U0ZZ	Alteration of Left Breast, Open Approach
0H0U3ZZ	Alteration of Left Breast, Percutaneous Approach
0H0UXZZ	Alteration of Left Breast, External Approach
0H0V07Z	Alteration of Bilateral Breast with Autologous Tissue Substitute, Open Approach
0H0V0JZ	Alteration of Bilateral Breast with Synthetic Substitute, Open Approach
0H0V0KZ	Alteration of Bilateral Breast with Nonautologous Tissue Substitute, Open Approach
0H0V0ZZ	Alteration of Bilateral Breast, Open Approach
0H0V37Z	Alteration of Bilateral Breast with Autologous Tissue Substitute, Percutaneous
	Approach
0H0V3JZ	Alteration of Bilateral Breast with Synthetic Substitute, Percutaneous Approach
0H0V3KZ	Alteration of Bilateral Breast with Nonautologous Tissue Substitute, Percutaneous
	Approach

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Alteration of Bilateral Breast, Percutaneous Approach
Alteration of Bilateral Breast, External Approach
Extraction of Hair, External Approach
Reattachment of Right Breast, External Approach
Reattachment of Left Breast, External Approach
Reattachment of Bilateral Breast, External Approach
Reattachment of Right Nipple, External Approach
Reattachment of Left Nipple, External Approach
Destruction of Clitoris, Open Approach
Destruction of Clitoris, External Approach
Drainage of Clitoris with Drainage Device, Open Approach
Drainage of Clitoris, Open Approach
Drainage of Clitoris with Drainage Device, External Approach
Drainage of Clitoris, External Approach
Excision of Clitoris, Open Approach, Diagnostic
Excision of Clitoris, Open Approach
Excision of Clitoris, External Approach, Diagnostic
Excision of Clitoris, External Approach
Extirpation of Matter from Clitoris, Open Approach
Extirpation of Matter from Clitoris, External Approach
Reattachment of Clitoris, External Approach
Release Clitoris, Open Approach
Release Clitoris, External Approach
Repair Vagina, Open Approach
Repair Clitoris, Open Approach
Repair Clitoris, External Approach
Resection of Clitoris, Open Approach
Resection of Clitoris, External Approach
Supplement Vagina with Autologous Tissue Substitute, Open Approach
Supplement Vagina with Synthetic Substitute, Open Approach
Supplement Vagina with Nonautologous Tissue Substitute, Open Approach
Supplement Vagina with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
Supplement Vagina with Synthetic Substitute, Percutaneous Endoscopic Approach
Supplement Vagina with Nonautologous Tissue Substitute, Percutaneous Endoscopic
Approach
Supplement Vagina with Autologous Tissue Substitute, Via Natural or Artificial Opening
Supplement Vagina with Synthetic Substitute, Via Natural or Artificial Opening
Supplement Vagina with Nonautologous Tissue Substitute, Via Natural or Artificial Opening
Supplement Vagina with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
Supplement Vagina with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
Supplement Vagina with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
Supplement Vagina with Autologous Tissue Substitute, External Approach
Supplement Vagina with Synthetic Substitute, External Approach
Supplement Vagina with Nonautologous Tissue Substitute, External Approach
Supplement Clitoris with Autologous Tissue Substitute, Open Approach
Supplement Clitoris with Synthetic Substitute, Open Approach

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0UUJX7Z	Supplement Clitoris with Autologous Tissue Substitute, External Approach
0UUJXJZ	Supplement Clitoris with Synthetic Substitute, External Approach
0UUJXKZ	Supplement Clitoris with Nonautologous Tissue Substitute, External Approach
0VT90ZZ	Resection of Right Testis, Open Approach
0VT94ZZ	Resection of Right Testis, Percutaneous Endoscopic Approach
0VTB0ZZ	Resection of Left Testis, Open Approach
0VTB4ZZ	Resection of Left Testis, Percutaneous Endoscopic Approach
0VTC4ZZ	Resection of Bilateral Testes, Percutaneous Endoscopic Approach
0VTS0ZZ	Resection of Penis, Open Approach
0VTS4ZZ	Resection of Penis, Percutaneous Endoscopic Approach
0VTSXZZ	Resection of Penis, External Approach
0W4M070	Creation of Vagina in Male Perineum with Autologous Tissue Substitute, Open
000400070	Approach
0W4M0J0	Creation of Vagina in Male Perineum with Synthetic Substitute, Open Approach
0W4M0K0	Creation of Vagina in Male Perineum with Nonautologous Tissue Substitute, Open
	Approach
0W4M0Z0	Creation of Vagina in Male Perineum, Open Approach

# Facial Surgery (Male or Female)

ICD-10-PCS	
procedure	
codes:	Code Description
080N0ZZ	Alteration of Right Upper Eyelid, Open Approach
080N3ZZ	Alteration of Right Upper Eyelid, Percutaneous Approach
080NXZZ	Alteration of Right Upper Eyelid, External Approach
080P0ZZ	Alteration of Left Upper Eyelid, Open Approach
080P3ZZ	Alteration of Left Upper Eyelid, Percutaneous Approach
080PXZZ	Alteration of Left Upper Eyelid, External Approach
080Q0ZZ	Alteration of Right Lower Eyelid, Open Approach
080Q3ZZ	Alteration of Right Lower Eyelid, Percutaneous Approach
080QXZZ	Alteration of Right Lower Eyelid, External Approach
080R0ZZ	Alteration of Left Lower Eyelid, Open Approach
080R3ZZ	Alteration of Left Lower Eyelid, Percutaneous Approach
080RXZZ	Alteration of Left Lower Eyelid, External Approach
090K0ZZ	Alteration of Nose, Open Approach
090K3ZZ	Alteration of Nose, Percutaneous Approach
090K4ZZ	Alteration of Nose, Percutaneous Endoscopic Approach
090KXZZ	Alteration of Nose, External Approach
09QM0ZZ	Repair Nasal Septum, Open Approach
09QM3ZZ	Repair Nasal Septum, Percutaneous Approach
09QM4ZZ	Repair Nasal Septum, Percutaneous Endoscopic Approach
0J040ZZ	Alteration of Anterior Neck Subcutaneous Tissue and Fascia, Open Approach
0J043ZZ	Alteration of Anterior Neck Subcutaneous Tissue and Fascia, Percutaneous Approach
0J050ZZ	Alteration of Posterior Neck Subcutaneous Tissue and Fascia, Open Approach
0J053ZZ	Alteration of Posterior Neck Subcutaneous Tissue and Fascia, Percutaneous Approach
0J060ZZ	Alteration of Chest Subcutaneous Tissue and Fascia, Open Approach
0J063ZZ	Alteration of Chest Subcutaneous Tissue and Fascia, Percutaneous Approach
0J070ZZ	Alteration of Back Subcutaneous Tissue and Fascia, Open Approach
0J073ZZ	Alteration of Back Subcutaneous Tissue and Fascia, Percutaneous Approach
0J080ZZ	Alteration of Abdomen Subcutaneous Tissue and Fascia, Open Approach
0J083ZZ	Alteration of Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

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0J090ZZ	Alteration of Buttock Subcutaneous Tissue and Fascia, Open Approach
0J093ZZ	Alteration of Buttock Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0D0ZZ	Alteration of Right Upper Arm Subcutaneous Tissue and Fascia, Open Approach
0J0D3ZZ	Alteration of Right Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0F0ZZ	Alteration of Left Upper Arm Subcutaneous Tissue and Fascia, Open Approach
0J0F3ZZ	Alteration of Left Upper Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0G0ZZ	Alteration of Right Lower Arm Subcutaneous Tissue and Fascia, Open Approach
0J0G3ZZ	Alteration of Right Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0H0ZZ	Alteration of Left Lower Arm Subcutaneous Tissue and Fascia, Open Approach
0J0H3ZZ	Alteration of Left Lower Arm Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0L0ZZ	Alteration of Right Upper Leg Subcutaneous Tissue and Fascia, Open Approach
0J0L3ZZ	Alteration of Right Upper Leg Subcutaneous Tissue and Fascia, Percutaneous
	Approach
0J0M0ZZ	Alteration of Left Upper Leg Subcutaneous Tissue and Fascia, Open Approach
0J0M3ZZ	Alteration of Left Upper Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0N0ZZ	Alteration of Right Lower Leg Subcutaneous Tissue and Fascia, Open Approach
0J0N3ZZ	Alteration of Right Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
0J0P0ZZ	Alteration of Left Lower Leg Subcutaneous Tissue and Fascia, Open Approach
0J0P3ZZ	Alteration of Left Lower Leg Subcutaneous Tissue and Fascia, Percutaneous Approach
08SN0ZZ	Reposition Right Upper Eyelid, Open Approach
08SN3ZZ	Reposition Right Upper Eyelid, Percutaneous Approach
08SNXZZ	Reposition Right Upper Eyelid, External Approach
08SP0ZZ	Reposition Left Upper Eyelid, Open Approach
08SP3ZZ	Reposition Left Upper Eyelid, Percutaneous Approach
08SPXZZ	Reposition Left Upper Eyelid, External Approach
08SQ0ZZ	Reposition Right Lower Eyelid, Open Approach
08SQ3ZZ	Reposition Right Lower Eyelid, Percutaneous Approach
08SQXZZ	Reposition Right Lower Eyelid, External Approach
08SR0ZZ	Reposition Left Lower Eyelid, Open Approach
08SR3ZZ	Reposition Left Lower Eyelid, Percutaneous Approach
08SRXZZ	Reposition Left Lower Eyelid, External Approach
0KS10ZZ	Reposition Facial Muscle, Open Approach
0KS14ZZ	Reposition Facial Muscle, Percutaneous Endoscopic Approach
0NNC0ZZ	Release Right Sphenoid Bone, Open Approach
0NNC3ZZ	Release Right Sphenoid Bone, Percutaneous Approach
0NNC4ZZ	Release Right Sphenoid Bone, Percutaneous Endoscopic Approach
0NND0ZZ	Release Left Sphenoid Bone, Open Approach
0NND3ZZ	Release Left Sphenoid Bone, Percutaneous Approach
0NND4ZZ	Release Left Sphenoid Bone, Percutaneous Endoscopic Approach
0NNF0ZZ	Release Right Ethmoid Bone, Open Approach
0NNF3ZZ	Release Right Ethmoid Bone, Percutaneous Approach
0NNF4ZZ	Release Right Ethmoid Bone, Percutaneous Endoscopic Approach
0NNG0ZZ	Release Left Ethmoid Bone, Open Approach
0NNG3ZZ	Release Left Ethmoid Bone, Percutaneous Approach
0NNG4ZZ	Release Left Ethmoid Bone, Percutaneous Endoscopic Approach
0NNH0ZZ	Release Right Lacrimal Bone, Open Approach
0NNH3ZZ	Release Right Lacrimal Bone, Percutaneous Approach

0NNH4ZZ	Release Right Lacrimal Bone, Percutaneous Endoscopic Approach
0NNJ0ZZ	Release Left Lacrimal Bone, Open Approach
0NNJ3ZZ	Release Left Lacrimal Bone, Percutaneous Approach
0NNJ4ZZ	Release Left Lacrimal Bone, Percutaneous Endoscopic Approach
0NNK0ZZ	Release Right Palatine Bone, Open Approach
0NNK3ZZ	Release Right Palatine Bone, Percutaneous Approach
0NNK4ZZ	Release Right Palatine Bone, Percutaneous Endoscopic Approach
0NNL0ZZ	Release Left Palatine Bone, Open Approach
0NNL3ZZ	Release Left Palatine Bone, Percutaneous Approach
0NNL4ZZ	Release Left Palatine Bone, Percutaneous Endoscopic Approach
0NNM0ZZ	Release Right Zygomatic Bone, Open Approach
0NNM3ZZ	Release Right Zygomatic Bone, Percutaneous Approach
0NNM4ZZ	Release Right Zygomatic Bone, Percutaneous Endoscopic Approach
0NNN0ZZ	Release Left Zygomatic Bone, Open Approach
0NNN3ZZ	Release Left Zygomatic Bone, Percutaneous Approach
0NNN4ZZ	Release Left Zygomatic Bone, Percutaneous Endoscopic Approach
0NNP0ZZ	Release Right Orbit, Open Approach
0NNP3ZZ	Release Right Orbit, Percutaneous Approach
0NNP4ZZ	Release Right Orbit, Percutaneous Endoscopic Approach
0NNQ0ZZ	Release Left Orbit, Open Approach
0NNQ3ZZ	Release Left Orbit, Percutaneous Approach
0NNQ4ZZ	Release Left Orbit, Percutaneous Endoscopic Approach
0NNR0ZZ	Release Right Maxilla, Open Approach
0NNR3ZZ	Release Right Maxilla, Percutaneous Approach
0NNR4ZZ	Release Right Maxilla, Percutaneous Endoscopic Approach
0NNS0ZZ	Release Left Maxilla, Open Approach
0NNS3ZZ	Release Left Maxilla, Percutaneous Approach
0NNS4ZZ	Release Left Maxilla, Percutaneous Endoscopic Approach
0NNT0ZZ	Release Right Mandible, Open Approach
0NNT3ZZ	Release Right Mandible, Percutaneous Approach
0NNT4ZZ	Release Right Mandible, Percutaneous Endoscopic Approach
0NNV0ZZ	Release Left Mandible, Open Approach
0NNV3ZZ	Release Left Mandible, Percutaneous Approach
0NNV4ZZ	Release Left Mandible, Percutaneous Endoscopic Approach
0NQC0ZZ	Repair Right Sphenoid Bone, Open Approach
0NQC3ZZ	Repair Right Sphenoid Bone, Percutaneous Approach
0NQC4ZZ	Repair Right Sphenoid Bone, Percutaneous Endoscopic Approach
0NQCXZZ	Repair Right Sphenoid Bone, External Approach
0NQD0ZZ	Repair Left Sphenoid Bone, Open Approach
0NQD3ZZ	Repair Left Sphenoid Bone, Percutaneous Approach
0NQD4ZZ	Repair Left Sphenoid Bone, Percutaneous Endoscopic Approach
0NQDXZZ	Repair Left Sphenoid Bone, External Approach
0NQF0ZZ	Repair Right Ethmoid Bone, Open Approach
0NQF3ZZ	Repair Right Ethmoid Bone, Percutaneous Approach
0NQF4ZZ	Repair Right Ethmoid Bone, Percutaneous Endoscopic Approach
0NQFXZZ	Repair Right Ethmoid Bone, External Approach
0NQG0ZZ	Repair Left Ethmoid Bone, Open Approach
0NQG3ZZ	Repair Left Ethmoid Bone, Percutaneous Approach
0NQG4ZZ	Repair Left Ethmoid Bone, Percutaneous Endoscopic Approach
ONQGXZZ	Repair Left Ethmoid Bone, External Approach
0NQH0ZZ	Repair Right Lacrimal Bone, Open Approach

0NQH3ZZ	Repair Right Lacrimal Bone, Percutaneous Approach
0NQH4ZZ	Repair Right Lacrimal Bone, Percutaneous Endoscopic Approach
0NQHXZZ	Repair Right Lacrimal Bone, External Approach
0NQJ0ZZ	Repair Left Lacrimal Bone, Open Approach
0NQJ3ZZ	Repair Left Lacrimal Bone, Percutaneous Approach
0NQJ4ZZ	Repair Left Lacrimal Bone, Percutaneous Endoscopic Approach
0NQJXZZ	Repair Left Lacrimal Bone, External Approach
0NQK0ZZ	Repair Right Palatine Bone, Open Approach
0NQK3ZZ	Repair Right Palatine Bone, Percutaneous Approach
0NQK4ZZ	Repair Right Palatine Bone, Percutaneous Endoscopic Approach
0NQKXZZ	Repair Right Palatine Bone, External Approach
0NQL0ZZ	Repair Left Palatine Bone, Open Approach
0NQL3ZZ	Repair Left Palatine Bone, Percutaneous Approach
0NQL4ZZ	Repair Left Palatine Bone, Percutaneous Endoscopic Approach
0NQLXZZ	Repair Left Palatine Bone, External Approach
0NQM0ZZ	Repair Right Zygomatic Bone, Open Approach
0NQM3ZZ	Repair Right Zygomatic Bone, Percutaneous Approach
0NQM4ZZ	Repair Right Zygomatic Bone, Percutaneous Endoscopic Approach
0NQMXZZ	Repair Right Zygomatic Bone, External Approach
0NQN0ZZ	Repair Left Zygomatic Bone, Open Approach
0NQN3ZZ	Repair Left Zygomatic Bone, Percutaneous Approach
0NQN4ZZ	Repair Left Zygomatic Bone, Percutaneous Endoscopic Approach
0NQNXZZ	Repair Left Zygomatic Bone, External Approach
0NQX0ZZ	Repair Hyoid Bone, Open Approach
0NQX3ZZ	Repair Hyoid Bone, Percutaneous Approach
0NQX4ZZ	Repair Hyoid Bone, Percutaneous Endoscopic Approach
ONQXXZZ	Repair Hyoid Bone, External Approach
	Replacement of Right Sphenoid Bone with Autologous Tissue Substitute, Open
0NRC07Z	Approach
0NRC0JZ	Replacement of Right Sphenoid Bone with Synthetic Substitute, Open Approach
	Replacement of Right Sphenoid Bone with Nonautologous Tissue Substitute, Open
0NRC0KZ	Approach
0100077	Replacement of Right Sphenoid Bone with Autologous Tissue Substitute,
0NRC37Z	Percutaneous Approach
	Replacement of Right Sphenoid Bone with Synthetic Substitute, Percutaneous
0NRC3JZ	Approach
0NRC3KZ	Replacement of Right Sphenoid Bone with Nonautologous Tissue Substitute,
UNRUSKZ	Percutaneous Approach
0NRC47Z	Replacement of Right Sphenoid Bone with Autologous Tissue Substitute,
	Percutaneous Endoscopic Approach
0NRC4JZ	Replacement of Right Sphenoid Bone with Synthetic Substitute, Percutaneous
01110-102	Endoscopic Approach
0NRC4KZ	Replacement of Right Sphenoid Bone with Nonautologous Tissue Substitute,
	Percutaneous Endoscopic Approach
0NRD07Z	Replacement of Left Sphenoid Bone with Autologous Tissue Substitute, Open
	Approach
0NRD0JZ	Replacement of Left Sphenoid Bone with Synthetic Substitute, Open Approach
0NRD0KZ	Replacement of Left Sphenoid Bone with Nonautologous Tissue Substitute, Open Approach
	Replacement of Left Sphenoid Bone with Autologous Tissue Substitute, Percutaneous
0NRD37Z	Approach

0NRD3KZ	Replacement of Left Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRD47Z	Replacement of Left Sphenoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRD4JZ	Replacement of Left Sphenoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRD4KZ	Replacement of Left Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRF07Z	Replacement of Right Ethmoid Bone with Autologous Tissue Substitute, Open Approach
0NRF0JZ	Replacement of Right Ethmoid Bone with Synthetic Substitute, Open Approach
0NRF0KZ	Replacement of Right Ethmoid Bone with Nonautologous Tissue Substitute, Open Approach
0NRF37Z	Replacement of Right Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRF3JZ	Replacement of Right Ethmoid Bone with Synthetic Substitute, Percutaneous Approach
0NRF3KZ	Replacement of Right Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRF47Z	Replacement of Right Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRF4JZ	Replacement of Right Ethmoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRF4KZ	Replacement of Right Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRG07Z	Replacement of Left Ethmoid Bone with Autologous Tissue Substitute, Open Approach
0NRG0JZ	Replacement of Left Ethmoid Bone with Synthetic Substitute, Open Approach
0NRG0KZ	Replacement of Left Ethmoid Bone with Nonautologous Tissue Substitute, Open Approach
0NRG37Z	Replacement of Left Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRG3JZ	Replacement of Left Ethmoid Bone with Synthetic Substitute, Percutaneous Approach
0NRG3KZ	Replacement of Left Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRG47Z	Replacement of Left Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRG4JZ	Replacement of Left Ethmoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRG4KZ	Replacement of Left Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRH07Z	Replacement of Right Lacrimal Bone with Autologous Tissue Substitute, Open Approach
0NRH0JZ	Replacement of Right Lacrimal Bone with Synthetic Substitute, Open Approach
0NRH0KZ	Replacement of Right Lacrimal Bone with Nonautologous Tissue Substitute, Open Approach
0NRH37Z	Replacement of Right Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRH3JZ	Replacement of Right Lacrimal Bone with Synthetic Substitute, Percutaneous Approach
0NRH3KZ	Replacement of Right Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRH47Z	Replacement of Right Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach

0NRH4JZ	Replacement of Right Lacrimal Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRH4KZ	Replacement of Right Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRJ07Z	Replacement of Left Lacrimal Bone with Autologous Tissue Substitute, Open Approach
0NRJ0JZ	Replacement of Left Lacrimal Bone with Synthetic Substitute, Open Approach
0NRJ0KZ	Replacement of Left Lacrimal Bone with Nonautologous Tissue Substitute, Open Approach
0NRJ37Z	Replacement of Left Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRJ3JZ	Replacement of Left Lacrimal Bone with Synthetic Substitute, Percutaneous Approach
0NRJ3KZ	Replacement of Left Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRJ47Z	Replacement of Left Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRJ4JZ	Replacement of Left Lacrimal Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRJ4KZ	Replacement of Left Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRK07Z	Replacement of Right Palatine Bone with Autologous Tissue Substitute, Open Approach
0NRK0JZ	Replacement of Right Palatine Bone with Synthetic Substitute, Open Approach
0NRK0KZ	Replacement of Right Palatine Bone with Nonautologous Tissue Substitute, Open Approach
0NRK37Z	Replacement of Right Palatine Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRK3JZ	Replacement of Right Palatine Bone with Synthetic Substitute, Percutaneous Approach
0NRK3KZ	Replacement of Right Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRK47Z	Replacement of Right Palatine Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRK4JZ	Replacement of Right Palatine Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRK4KZ	Replacement of Right Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRL07Z	Replacement of Left Palatine Bone with Autologous Tissue Substitute, Open Approach
0NRL0JZ	Replacement of Left Palatine Bone with Synthetic Substitute, Open Approach
0NRL0KZ	Replacement of Left Palatine Bone with Nonautologous Tissue Substitute, Open Approach
0NRL37Z	Replacement of Left Palatine Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRL3JZ	Replacement of Left Palatine Bone with Synthetic Substitute, Percutaneous Approach
0NRL3KZ	Replacement of Left Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRL47Z	Replacement of Left Palatine Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRL4JZ	Replacement of Left Palatine Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRL4KZ	Replacement of Left Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRM07Z	Replacement of Right Zygomatic Bone with Autologous Tissue Substitute, Open Approach
0NRM0JZ	Replacement of Right Zygomatic Bone with Synthetic Substitute, Open Approach

0NRM0KZ	Replacement of Right Zygomatic Bone with Nonautologous Tissue Substitute, Open Approach
0NRM37Z	Replacement of Right Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRM3JZ	Replacement of Right Zygomatic Bone with Synthetic Substitute, Percutaneous Approach
0NRM3KZ	Replacement of Right Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRM47Z	Replacement of Right Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRM4JZ	Replacement of Right Zygomatic Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRM4KZ	Replacement of Right Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRN07Z	Replacement of Left Zygomatic Bone with Autologous Tissue Substitute, Open Approach
0NRN0JZ	Replacement of Left Zygomatic Bone with Synthetic Substitute, Open Approach
0NRN0KZ	Replacement of Left Zygomatic Bone with Nonautologous Tissue Substitute, Open Approach
0NRN37Z	Replacement of Left Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRN3JZ	Replacement of Left Zygomatic Bone with Synthetic Substitute, Percutaneous Approach
0NRN3KZ	Replacement of Left Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRN47Z	Replacement of Left Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRN4JZ	Replacement of Left Zygomatic Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRN4KZ	Replacement of Left Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRP0KZ	Replacement of Right Orbit with Nonautologous Tissue Substitute, Open Approach
0NRP3KZ	Replacement of Right Orbit with Nonautologous Tissue Substitute, Percutaneous Approach
0NRP4KZ	Replacement of Right Orbit with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRQ0KZ	Replacement of Left Orbit with Nonautologous Tissue Substitute, Open Approach
0NRQ3KZ	Replacement of Left Orbit with Nonautologous Tissue Substitute, Percutaneous Approach
0NRQ4KZ	Replacement of Left Orbit with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRR07Z	Replacement of Right Maxilla with Autologous Tissue Substitute, Open Approach
0NRR0JZ	Replacement of Right Maxilla with Synthetic Substitute, Open Approach
0NRR0KZ	Replacement of Right Maxilla with Nonautologous Tissue Substitute, Open Approach
0NRR37Z	Replacement of Right Maxilla with Autologous Tissue Substitute, Percutaneous Approach
0NRR3JZ	Replacement of Right Maxilla with Synthetic Substitute, Percutaneous Approach
0NRR3KZ	Replacement of Right Maxilla with Nonautologous Tissue Substitute, Percutaneous Approach
0NRR47Z	Replacement of Right Maxilla with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRR4JZ	Replacement of Right Maxilla with Synthetic Substitute, Percutaneous Endoscopic Approach

0NRR4KZ	Replacement of Right Maxilla with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRS07Z	Replacement of Left Maxilla with Autologous Tissue Substitute, Open Approach
0NRS0JZ	Replacement of Left Maxilla with Synthetic Substitute, Open Approach
0NRS0KZ	Replacement of Left Maxilla with Nonautologous Tissue Substitute, Open Approach
0NRS37Z	Replacement of Left Maxilla with Autologous Tissue Substitute, Percutaneous Approach
0NRS3JZ	Replacement of Left Maxilla with Synthetic Substitute, Percutaneous Approach
0NRS3KZ	Replacement of Left Maxilla with Nonautologous Tissue Substitute, Percutaneous Approach
0NRS47Z	Replacement of Left Maxilla with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRS4JZ	Replacement of Left Maxilla with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRS4KZ	Replacement of Left Maxilla with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRX07Z	Replacement of Hyoid Bone with Autologous Tissue Substitute, Open Approach
0NRX0JZ	Replacement of Hyoid Bone with Synthetic Substitute, Open Approach
0NRX0KZ	Replacement of Hyoid Bone with Nonautologous Tissue Substitute, Open Approach
0NRX37Z	Replacement of Hyoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NRX3JZ	Replacement of Hyoid Bone with Synthetic Substitute, Percutaneous Approach
0NRX3KZ	Replacement of Hyoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NRX47Z	Replacement of Hyoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NRX4JZ	Replacement of Hyoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NRX4KZ	Replacement of Hyoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUC07Z	Supplement Right Sphenoid Bone with Autologous Tissue Substitute, Open Approach
0NUC0JZ	Supplement Right Sphenoid Bone with Synthetic Substitute, Open Approach
0NUC0KZ	Supplement Right Sphenoid Bone with Nonautologous Tissue Substitute, Open Approach
0NUC37Z	Supplement Right Sphenoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUC3JZ	Supplement Right Sphenoid Bone with Synthetic Substitute, Percutaneous Approach
0NUC3KZ	Supplement Right Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUC47Z	Supplement Right Sphenoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUC4JZ	Supplement Right Sphenoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUC4KZ	Supplement Right Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUD07Z	Supplement Left Sphenoid Bone with Autologous Tissue Substitute, Open Approach
0NUD0JZ	Supplement Left Sphenoid Bone with Synthetic Substitute, Open Approach
0NUD0KZ	Supplement Left Sphenoid Bone with Nonautologous Tissue Substitute, Open Approach
0NUD37Z	Supplement Left Sphenoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUD3JZ	Supplement Left Sphenoid Bone with Synthetic Substitute, Percutaneous Approach
0NUD3KZ	Supplement Left Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach

0NUD47Z	Supplement Left Sphenoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUD4JZ	Supplement Left Sphenoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUD4KZ	Supplement Left Sphenoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUF07Z	Supplement Right Ethmoid Bone with Autologous Tissue Substitute, Open Approach
0NUF0JZ	Supplement Right Ethmoid Bone with Synthetic Substitute, Open Approach
UNUFUJZ	Supplement Right Ethmoid Bone with Nonautologous Tissue Substitute, Open
0NUF0KZ	Approach
0NUF37Z	Supplement Right Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUF3JZ	Supplement Right Ethmoid Bone with Synthetic Substitute, Percutaneous Approach
0NUF3KZ	Supplement Right Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUF47Z	Supplement Right Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUF4JZ	Supplement Right Ethmoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUF4KZ	Supplement Right Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUG07Z	Supplement Left Ethmoid Bone with Autologous Tissue Substitute, Open Approach
0NUG0JZ	Supplement Left Ethmoid Bone with Synthetic Substitute, Open Approach
0NUG0KZ	Supplement Left Ethmoid Bone with Nonautologous Tissue Substitute, Open Approach
0NUG37Z	Supplement Left Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUG3JZ	Supplement Left Ethmoid Bone with Synthetic Substitute, Percutaneous Approach
0NUG3KZ	Supplement Left Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUG47Z	Supplement Left Ethmoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUG4JZ	Supplement Left Ethmoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUG4KZ	Supplement Left Ethmoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUH07Z	Supplement Right Lacrimal Bone with Autologous Tissue Substitute, Open Approach
0NUH0JZ	Supplement Right Lacrimal Bone with Synthetic Substitute, Open Approach
0NUH0KZ	Supplement Right Lacrimal Bone with Nonautologous Tissue Substitute, Open Approach
0NUH37Z	Supplement Right Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUH3JZ	Supplement Right Lacrimal Bone with Synthetic Substitute, Percutaneous Approach
0NUH3KZ	Supplement Right Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUH47Z	Supplement Right Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUH4JZ	Supplement Right Lacrimal Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUH4KZ	Supplement Right Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUJ07Z	Supplement Left Lacrimal Bone with Autologous Tissue Substitute, Open Approach
ONUJOJZ	Supplement Left Lacrimal Bone with Synthetic Substitute, Open Approach
UNUJUJZ	Supplement Left Lacinnal Done with Synthetic Substitute, Open Apploach

0NUJ37Z	Supplement Left Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUJ3JZ	Supplement Left Lacrimal Bone with Synthetic Substitute, Percutaneous Approach
0NUJ3KZ	Supplement Left Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUJ47Z	Supplement Left Lacrimal Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUJ4JZ	Supplement Left Lacrimal Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUJ4KZ	Supplement Left Lacrimal Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUK07Z	Supplement Right Palatine Bone with Autologous Tissue Substitute, Open Approach
0NUK0JZ	Supplement Right Palatine Bone with Synthetic Substitute, Open Approach
0NUK0KZ	Supplement Right Palatine Bone with Nonautologous Tissue Substitute, Open Approach
0NUK37Z	Supplement Right Palatine Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUK3JZ	Supplement Right Palatine Bone with Synthetic Substitute, Percutaneous Approach
0NUK3KZ	Supplement Right Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUK47Z	Supplement Right Palatine Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUK4JZ	Supplement Right Palatine Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUK4KZ	Supplement Right Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUL07Z	Supplement Left Palatine Bone with Autologous Tissue Substitute, Open Approach
0NUL0JZ	Supplement Left Palatine Bone with Synthetic Substitute, Open Approach
0NUL0KZ	Supplement Left Palatine Bone with Nonautologous Tissue Substitute, Open Approach
0NUL37Z	Supplement Left Palatine Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUL3JZ	Supplement Left Palatine Bone with Synthetic Substitute, Percutaneous Approach
0NUL3KZ	Supplement Left Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUL47Z	Supplement Left Palatine Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUL4JZ	Supplement Left Palatine Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUL4KZ	Supplement Left Palatine Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUM07Z	Supplement Right Zygomatic Bone with Autologous Tissue Substitute, Open Approach
0NUM0JZ	Supplement Right Zygomatic Bone with Synthetic Substitute, Open Approach
0NUM0KZ	Supplement Right Zygomatic Bone with Nonautologous Tissue Substitute, Open Approach
0NUM37Z	Supplement Right Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUM3JZ	Supplement Right Zygomatic Bone with Synthetic Substitute, Percutaneous Approach
0NUM3KZ	Supplement Right Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUM47Z	Supplement Right Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUM4JZ	Supplement Right Zygomatic Bone with Synthetic Substitute, Percutaneous Endoscopic Approach

0NUM4KZ	Supplement Right Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUN07Z	Supplement Left Zygomatic Bone with Autologous Tissue Substitute, Open Approach
0NUN0JZ	Supplement Left Zygomatic Bone with Synthetic Substitute, Open Approach
0NUN0KZ	Supplement Left Zygomatic Bone with Nonautologous Tissue Substitute, Open Approach
0NUN37Z	Supplement Left Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Approach
0NUN3JZ	Supplement Left Zygomatic Bone with Synthetic Substitute, Percutaneous Approach
0NUN3KZ	Supplement Left Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Approach
0NUN47Z	Supplement Left Zygomatic Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUN4JZ	Supplement Left Zygomatic Bone with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUN4KZ	Supplement Left Zygomatic Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUP07Z	Supplement Right Orbit with Autologous Tissue Substitute, Open Approach
0NUP0KZ	Supplement Right Orbit with Nonautologous Tissue Substitute, Open Approach
0NUP37Z	Supplement Right Orbit with Autologous Tissue Substitute, Percutaneous Approach
0NUP3KZ	Supplement Right Orbit with Nonautologous Tissue Substitute, Percutaneous Approach
0NUP47Z	Supplement Right Orbit with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUP4KZ	Supplement Right Orbit with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUQ07Z	Supplement Left Orbit with Autologous Tissue Substitute, Open Approach
0NUQ0KZ	Supplement Left Orbit with Nonautologous Tissue Substitute, Open Approach
0NUQ37Z	Supplement Left Orbit with Autologous Tissue Substitute, Percutaneous Approach
0NUQ3KZ	Supplement Left Orbit with Nonautologous Tissue Substitute, Percutaneous Approach
0NUQ47Z	Supplement Left Orbit with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUQ4KZ	Supplement Left Orbit with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUR07Z	Supplement Right Maxilla with Autologous Tissue Substitute, Open Approach
0NUR0JZ	Supplement Right Maxilla with Synthetic Substitute, Open Approach
0NUR0KZ	Supplement Right Maxilla with Nonautologous Tissue Substitute, Open Approach
0NUR37Z	Supplement Right Maxilla with Autologous Tissue Substitute, Percutaneous Approach
0NUR3JZ	Supplement Right Maxilla with Synthetic Substitute, Percutaneous Approach
0NUR3KZ	Supplement Right Maxilla with Nonautologous Tissue Substitute, Percutaneous Approach
0NUR47Z	Supplement Right Maxilla with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUR4JZ	Supplement Right Maxilla with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUR4KZ	Supplement Right Maxilla with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUS07Z	Supplement Left Maxilla with Autologous Tissue Substitute, Open Approach
0NUS0JZ	Supplement Left Maxilla with Synthetic Substitute, Open Approach
0NUS0KZ	Supplement Left Maxilla with Nonautologous Tissue Substitute, Open Approach
0NUS37Z	Supplement Left Maxilla with Autologous Tissue Substitute, Percutaneous Approach
0NUS3JZ	Supplement Left Maxilla with Synthetic Substitute, Percutaneous Approach

0NUS3KZ	Supplement Left Maxilla with Nonautologous Tissue Substitute, Percutaneous		
0NUS47Z	Approach Supplement Left Maxilla with Autologous Tissue Substitute, Percutaneous Endoscopic		
0NUS4JZ	Approach Supplement Left Maxilla with Synthetic Substitute, Percutaneous Endoscopic Approach		
	Supplement Left Maxilla with Synthetic Substitute, Percutaneous Endoscopic Approact Supplement Left Maxilla with Nonautologous Tissue Substitute, Percutaneous		
0NUS4KZ	Endoscopic Approach		
0NUX07Z	Supplement Hyoid Bone with Autologous Tissue Substitute, Open Approach		
0NUX0JZ	Supplement Hyoid Bone with Synthetic Substitute, Open Approach		
0NUX0KZ	Supplement Hyoid Bone with Nonautologous Tissue Substitute, Open Approach		
0NUX37Z	Supplement Hyoid Bone with Autologous Tissue Substitute, Percutaneous Approach		
0NUX3JZ	Supplement Hyoid Bone with Synthetic Substitute, Percutaneous Approach		
0NUX3KZ	Supplement Hyoid Bone with Nonautologous Tissue Substitute, Percutaneous Approach		
0NUX47Z	Supplement Hyoid Bone with Autologous Tissue Substitute, Percutaneous Endoscopic Approach		
0NUX4JZ	Supplement Hyoid Bone with Synthetic Substitute, Percutaneous Endoscopic Approach		
0NUX4KZ	Supplement Hyoid Bone with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach		
0RNC0ZZ	Release Right Temporomandibular Joint, Open Approach		
0RNC3ZZ	Release Right Temporomandibular Joint, Percutaneous Approach		
0RNC4ZZ	Release Right Temporomandibular Joint, Percutaneous Endoscopic Approach		
0RND0ZZ	Release Left Temporomandibular Joint, Open Approach		
0RND3ZZ	Release Left Temporomandibular Joint, Percutaneous Approach		
0RND4ZZ	Release Left Temporomandibular Joint, Percutaneous Endoscopic Approach		
0W0407Z	Alteration of Upper Jaw with Autologous Tissue Substitute, Open Approach		
0W040JZ	Alteration of Upper Jaw with Synthetic Substitute, Open Approach		
0W040KZ	Alteration of Upper Jaw with Nonautologous Tissue Substitute, Open Approach		
0W040ZZ	Alteration of Upper Jaw, Open Approach		
0W0437Z	Alteration of Upper Jaw with Autologous Tissue Substitute, Percutaneous Approach		
0W043JZ	Alteration of Upper Jaw with Synthetic Substitute, Percutaneous Approach		
0W043KZ	Alteration of Upper Jaw with Nonautologous Tissue Substitute, Percutaneous Approach		
0W043ZZ	Alteration of Upper Jaw, Percutaneous Approach		
0W0447Z	Alteration of Upper Jaw with Autologous Tissue Substitute, Percutaneous Endoscopic Approach		
0W044JZ	Alteration of Upper Jaw with Synthetic Substitute, Percutaneous Endoscopic Approach		
0W044KZ	Alteration of Upper Jaw with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach		
0W044ZZ	Alteration of Upper Jaw, Percutaneous Endoscopic Approach		
0W0507Z	Alteration of Lower Jaw with Autologous Tissue Substitute, Open Approach		
0W050JZ	Alteration of Lower Jaw with Synthetic Substitute, Open Approach		
0W050KZ	Alteration of Lower Jaw with Nonautologous Tissue Substitute, Open Approach		
0W050ZZ	Alteration of Lower Jaw, Open Approach		
0W0537Z	Alteration of Lower Jaw with Autologous Tissue Substitute, Percutaneous Approach		
0W053JZ	Alteration of Lower Jaw with Synthetic Substitute, Percutaneous Approach		
0W053KZ	Alteration of Lower Jaw with Nonautologous Tissue Substitute, Percutaneous Approach		
0W053ZZ	Alteration of Lower Jaw, Percutaneous Approach		
0W0547Z	Alteration of Lower Jaw with Autologous Tissue Substitute, Percutaneous Endoscopic Approach		

0W054JZ	Alteration of Lower Jaw with Synthetic Substitute, Percutaneous Endoscopic Approach		
0W054KZ	Alteration of Lower Jaw with Nonautologous Tissue Substitute, Percutaneous		
	Endoscopic Approach		
0W054ZZ	Alteration of Lower Jaw, Percutaneous Endoscopic Approach		
0W020ZZ	Alteration of Face, Open Approach		
0W0207Z	Alteration of Face with Autologous Tissue Substitute, Open Approach		
0W020JZ	Alteration of Face with Synthetic Substitute, Open Approach		
0W020KZ	Alteration of Face with Nonautologous Tissue Substitute, Open Approach		
0W023ZZ	Alteration of Face, Percutaneous Approach		
0W0247Z	Alteration of Face with Autologous Tissue Substitute, Percutaneous Endoscopic		
	Approach		
0W024JZ	Alteration of Face with Synthetic Substitute, Percutaneous Endoscopic Approach		
0W024KZ	Alteration of Face with Nonautologous Tissue Substitute, Percutaneous Endoscopic		
	Approach		
0W024ZZ	Alteration of Face, Percutaneous Endoscopic Approach		
0NS104Z	Reposition Right Frontal Bone with Internal Fixation Device, Open Approach		
0NS204Z	Reposition Left Frontal Bone with Internal Fixation Device, Open Approach		

#### Female to Male Surgery

ICD-10-PCS			
procedure			
codes:	Code Description		
0VTC0ZZ	Resection of Bilateral Testes, Open Approach		
0H0T0ZZ	Alteration of Right Breast, Open Approach		
0H0T3ZZ	Alteration of Right Breast, Percutaneous Approach		
0H0TXZZ	Alteration of Right Breast, External Approach		
0H0U0ZZ	Alteration of Left Breast, Open Approach		
0H0U3ZZ	Alteration of Left Breast, Percutaneous Approach		
0H0UXZZ	Alteration of Left Breast, External Approach		
0H0V07Z	Alteration of Bilateral Breast with Autologous Tissue Substitute, Open Approach		
0H0V0JZ	Alteration of Bilateral Breast with Synthetic Substitute, Open Approach		
0H0V0KZ	Alteration of Bilateral Breast with Nonautologous Tissue Substitute, Open Approach		
0H0V0ZZ	Alteration of Bilateral Breast, Open Approach		
0H0V37Z	Alteration of Bilateral Breast with Autologous Tissue Substitute, Percutaneous Approach		
0H0V3JZ	Alteration of Bilateral Breast with Synthetic Substitute, Percutaneous Approach		
0H0V3KZ	Alteration of Bilateral Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0H0V3ZZ	Alteration of Bilateral Breast, Percutaneous Approach		
0H0VXZZ	Alteration of Bilateral Breast, External Approach		
0HDSXZZ	Extraction of Hair, External Approach		
0HMTXZZ	Reattachment of Right Breast, External Approach		
0HMUXZZ	Reattachment of Left Breast, External Approach		
0HMVXZZ	Reattachment of Bilateral Breast, External Approach		
0HMWXZZ	Reattachment of Right Nipple, External Approach		
0HMXXZZ	Reattachment of Left Nipple, External Approach		
0HNT0ZZ	Release Right Breast, Open Approach		
0HNT3ZZ	Release Right Breast, Percutaneous Approach		
0HNT7ZZ	Release Right Breast, Via Natural or Artificial Opening		
0HNT8ZZ	Release Right Breast, Via Natural or Artificial Opening Endoscopic		
0HNTXZZ	Release Right Breast, External Approach		
0HNU0ZZ	Release Left Breast, Open Approach		

	Deleges Left Dresst Derevtensous Annus est		
0HNU3ZZ	Release Left Breast, Percutaneous Approach		
0HNU7ZZ	Release Left Breast, Via Natural or Artificial Opening		
0HNU8ZZ	Release Left Breast, Via Natural or Artificial Opening Endoscopic		
0HNUXZZ	Release Left Breast, External Approach		
0HNV0ZZ	Release Bilateral Breast, Open Approach		
0HNV3ZZ	Release Bilateral Breast, Percutaneous Approach		
0HNV7ZZ	Release Bilateral Breast, Via Natural or Artificial Opening		
0HNV8ZZ	Release Bilateral Breast, Via Natural or Artificial Opening Endoscopic		
OHNVXZZ	Release Bilateral Breast, External Approach		
0HNW0ZZ	Release Right Nipple, Open Approach		
0HNW3ZZ	Release Right Nipple, Percutaneous Approach		
0HNW7ZZ	Release Right Nipple, Via Natural or Artificial Opening		
0HNW8ZZ	Release Right Nipple, Via Natural or Artificial Opening Endoscopic		
OHNWXZZ	Release Right Nipple, External Approach		
0HNX0ZZ	Release Left Nipple, Open Approach		
0HNX3ZZ	Release Left Nipple, Percutaneous Approach		
0HNX7ZZ	Release Left Nipple, Via Natural or Artificial Opening		
0HNX8ZZ	Release Left Nipple, Via Natural or Artificial Opening Endoscopic		
0HNXXZZ	Release Left Nipple, External Approach		
0HQT0ZZ	Repair Right Breast, Open Approach		
0HQT3ZZ	Repair Right Breast, Percutaneous Approach		
0HQT7ZZ	Repair Right Breast, Via Natural or Artificial Opening		
0HQT8ZZ	Repair Right Breast, Via Natural or Artificial Opening Endoscopic		
0HQTXZZ	Repair Right Breast, External Approach		
0HQU0ZZ	Repair Left Breast, Open Approach		
0HQU3ZZ	Repair Left Breast, Percutaneous Approach		
0HQU7ZZ	Repair Left Breast, Via Natural or Artificial Opening		
0HQU8ZZ	Repair Left Breast, Via Natural or Artificial Opening Endoscopic		
0HQUXZZ	Repair Left Breast, External Approach		
0HQV0ZZ	Repair Bilateral Breast, Open Approach		
0HQV3ZZ	Repair Bilateral Breast, Percutaneous Approach		
0HQV7ZZ	Repair Bilateral Breast, Via Natural or Artificial Opening		
0HQV8ZZ	Repair Bilateral Breast, Via Natural or Artificial Opening Endoscopic		
0HQVXZZ	Repair Bilateral Breast, External Approach		
0HQW0ZZ	Repair Right Nipple, Open Approach		
0HQW3ZZ	Repair Right Nipple, Percutaneous Approach		
0HQW7ZZ	Repair Right Nipple, Via Natural or Artificial Opening		
0HQW8ZZ	Repair Right Nipple, Via Natural or Artificial Opening Endoscopic		
OHQWXZZ	Repair Right Nipple, External Approach		
0HQX0ZZ	Repair Left Nipple, Open Approach		
0HQX3ZZ	Repair Left Nipple, Percutaneous Approach		
0HQX7ZZ	Repair Left Nipple, Via Natural or Artificial Opening		
0HQX8ZZ	Repair Left Nipple, Via Natural or Artificial Opening Endoscopic		
OHQXXZZ	Repair Left Nipple, External Approach		
OHQYOZZ	Repair Supernumerary Breast, Open Approach		
0HQY3ZZ	Repair Supernumerary Breast, Percutaneous Approach		
0HQY7ZZ	Repair Supernumerary Breast, Via Natural or Artificial Opening		
0HQY8ZZ	Repair Supernumerary Breast, Via Natural of Artificial Opening Endoscopic		
OHQYXZZ	Repair Supernumerary Breast, Via Natural of Artificial Opening Endoscopic		
0HRT07Z	Replacement of Right Breast with Autologous Tissue Substitute, Open Approach		
0HRT0/Z	Replacement of Right Breast with Nonautologous Tissue Substitute, Open Approach		

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0HRT37Z	Replacement of Right Breast with Autologous Tissue Substitute, Percutaneous Approach		
0HRT3KZ	Replacement of Right Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HRTXJZ	Replacement of Right Breast with Synthetic Substitute, External Approach		
0HRU07Z	Replacement of Left Breast with Autologous Tissue Substitute, Open Approach		
0HRU0KZ	Replacement of Left Breast with Nonautologous Tissue Substitute, Open Approach		
0HRU37Z	Replacement of Left Breast with Autologous Tissue Substitute, Percutaneous Approach		
0HRU3KZ	Replacement of Left Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HRUXJZ	Replacement of Left Breast with Synthetic Substitute, External Approach		
0HRV07Z	Replacement of Bilateral Breast with Autologous Tissue Substitute, Open Approach		
0HRV0KZ	Replacement of Bilateral Breast with Nonautologous Tissue Substitute, Open Approach		
0HRV37Z	Replacement of Bilateral Breast with Autologous Tissue Substitute, Percutaneous Approach		
0HRV3KZ	Replacement of Bilateral Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HRVXJZ	Replacement of Bilateral Breast with Synthetic Substitute, External Approach		
0HRW07Z	Replacement of Right Nipple with Autologous Tissue Substitute, Open Approach		
0HRW0JZ	Replacement of Right Nipple with Synthetic Substitute, Open Approach		
0HRW0KZ	Replacement of Right Nipple with Nonautologous Tissue Substitute, Open Approach		
0HRW37Z	Replacement of Right Nipple with Autologous Tissue Substitute, Percutaneous Approach		
0HRW3JZ	Replacement of Right Nipple with Synthetic Substitute, Percutaneous Approach		
0HRW3KZ	Replacement of Right Nipple with Nonautologous Tissue Substitute, Percutaneous Approach		
0HRWX7Z	Replacement of Right Nipple with Autologous Tissue Substitute, External Approach		
OHRWXJZ	Replacement of Right Nipple with Synthetic Substitute, External Approach		
0HRWXKZ	Replacement of Right Nipple with Nonautologous Tissue Substitute, External Approach		
0HRX07Z	Replacement of Left Nipple with Autologous Tissue Substitute, Open Approach		
OHRXOJZ	Replacement of Left Nipple with Synthetic Substitute, Open Approach		
0HRX0KZ	Replacement of Left Nipple with Nonautologous Tissue Substitute, Open Approach		
0HRX37Z	Replacement of Left Nipple with Autologous Tissue Substitute, Percutaneous Approach		
0HRX3JZ	Replacement of Left Nipple with Synthetic Substitute, Percutaneous Approach		
0HRX3KZ	Replacement of Left Nipple with Nonautologous Tissue Substitute, Percutaneous Approach		
0HRXX7Z	Replacement of Left Nipple with Autologous Tissue Substitute, External Approach		
OHRXXJZ	Replacement of Left Nipple with Synthetic Substitute, External Approach		
0HRXXKZ	Replacement of Left Nipple with Nonautologous Tissue Substitute, External Approach		
0HUT07Z	Supplement Right Breast with Autologous Tissue Substitute, Open Approach		
OHUTOJZ	Supplement Right Breast with Synthetic Substitute, Open Approach		
OHUTOKZ	Supplement Right Breast with Nonautologous Tissue Substitute, Open Approach		
0HUT37Z	Supplement Right Breast with Autologous Tissue Substitute, Open Approach		
0HUT3JZ	Supplement Right Breast with Synthetic Substitute, Percutaneous Approach		
0HUT3KZ	Supplement Right Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HUT77Z	Supplement Right Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0HUT7JZ	Supplement Right Breast with Synthetic Substitute, Via Natural or Artificial Opening		
UTUTIJZ	Supplement right breast with Synthetic Substitute, via Matural of Artificial Opening		

0HUT7KZ	Supplement Right Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening		
0HUT87Z	Supplement Right Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUT8JZ	Supplement Right Breast with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic		
0HUT8KZ	Supplement Right Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUTX7Z	Supplement Right Breast with Autologous Tissue Substitute, External Approach		
0HUTXJZ	Supplement Right Breast with Synthetic Substitute, External Approach		
0HUTXKZ	Supplement Right Breast with Nonautologous Tissue Substitute, External Approach		
0HUU07Z	Supplement Left Breast with Autologous Tissue Substitute, Open Approach		
0HUU0JZ	Supplement Left Breast with Synthetic Substitute, Open Approach		
0HUU0KZ	Supplement Left Breast with Nonautologous Tissue Substitute, Open Approach		
0HUU37Z	Supplement Left Breast with Autologous Tissue Substitute, Percutaneous Approach		
0HUU3JZ	Supplement Left Breast with Synthetic Substitute, Percutaneous Approach		
0HUU3KZ	Supplement Left Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HUU77Z	Supplement Left Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0HUU7JZ	Supplement Left Breast with Synthetic Substitute, Via Natural or Artificial Opening		
0HUU7KZ	Supplement Left Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening		
0HUU87Z	Supplement Left Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUU8JZ	Supplement Left Breast with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic		
0HUU8KZ	Supplement Left Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUUX7Z	Supplement Left Breast with Autologous Tissue Substitute, External Approach		
0HUUXJZ	Supplement Left Breast with Synthetic Substitute, External Approach		
0HUUXKZ	Supplement Left Breast with Nonautologous Tissue Substitute, External Approach		
0HUV07Z	Supplement Bilateral Breast with Autologous Tissue Substitute, Open Approach		
0HUV0JZ	Supplement Bilateral Breast with Synthetic Substitute, Open Approach		
0HUV0KZ	Supplement Bilateral Breast with Nonautologous Tissue Substitute, Open Approach		
0HUV37Z	Supplement Bilateral Breast with Autologous Tissue Substitute, Percutaneous Approach		
0HUV3JZ	Supplement Bilateral Breast with Synthetic Substitute, Percutaneous Approach		
0HUV3KZ	Supplement Bilateral Breast with Nonautologous Tissue Substitute, Percutaneous Approach		
0HUV77Z	Supplement Bilateral Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0HUV7JZ	Supplement Bilateral Breast with Synthetic Substitute, Via Natural or Artificial Opening		
0HUV7KZ	Supplement Bilateral Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening		
0HUV87Z	Supplement Bilateral Breast with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUV8JZ	Supplement Bilateral Breast with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic		
0HUV8KZ	Supplement Bilateral Breast with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUVX7Z	Supplement Bilateral Breast with Autologous Tissue Substitute, External Approach		
OHUVXJZ	Supplement Bilateral Breast with Synthetic Substitute, External Approach		

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0HUVXKZ	Supplement Bilateral Breast with Nonautologous Tissue Substitute, External Approach		
0HUW07Z	Supplement Right Nipple with Autologous Tissue Substitute, Open Approach		
0HUW0JZ	Supplement Right Nipple with Synthetic Substitute, Open Approach		
0HUW0KZ	Supplement Right Nipple with Nonautologous Tissue Substitute, Open Approach		
0HUW37Z	Supplement Right Nipple with Autologous Tissue Substitute, Percutaneous Approach		
0HUW3JZ	Supplement Right Nipple with Synthetic Substitute, Percutaneous Approach		
0HUW3KZ	Supplement Right Nipple with Nonautologous Tissue Substitute, Percutaneous Approach		
0HUW77Z	Supplement Right Nipple with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0HUW7JZ	Supplement Right Nipple with Synthetic Substitute, Via Natural or Artificial Opening		
0HUW7KZ	Supplement Right Nipple with Nonautologous Tissue Substitute, Via Natural or Artificial Opening		
0HUW87Z	Supplement Right Nipple with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUW8JZ	Supplement Right Nipple with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic		
0HUW8KZ	Supplement Right Nipple with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUWX7Z	Supplement Right Nipple with Autologous Tissue Substitute, External Approach		
0HUWXJZ	Supplement Right Nipple with Synthetic Substitute, External Approach		
0HUWXKZ	Supplement Right Nipple with Nonautologous Tissue Substitute, External Approach		
0HUX07Z	Supplement Left Nipple with Autologous Tissue Substitute, Open Approach		
0HUX0JZ	Supplement Left Nipple with Synthetic Substitute, Open Approach		
0HUX0KZ	Supplement Left Nipple with Nonautologous Tissue Substitute, Open Approach		
0HUX37Z	Supplement Left Nipple with Autologous Tissue Substitute, Percutaneous Approach		
0HUX3JZ	Supplement Left Nipple with Synthetic Substitute, Percutaneous Approach		
0HUX3KZ	Supplement Left Nipple with Nonautologous Tissue Substitute, Percutaneous Approach		
0HUX77Z	Supplement Left Nipple with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0HUX7JZ	Supplement Left Nipple with Synthetic Substitute, Via Natural or Artificial Opening		
0HUX7KZ	Supplement Left Nipple with Nonautologous Tissue Substitute, Via Natural or Artificial Opening		
0HUX87Z	Supplement Left Nipple with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUX8JZ	Supplement Left Nipple with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic		
0HUX8KZ	Supplement Left Nipple with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic		
0HUXX7Z	Supplement Left Nipple with Autologous Tissue Substitute, External Approach		
0HUXXJZ	Supplement Left Nipple with Synthetic Substitute, External Approach		
0HUXXKZ	Supplement Left Nipple with Nonautologous Tissue Substitute, External Approach		
0U5J0ZZ	Destruction of Clitoris, Open Approach		
0U5JXZZ	Destruction of Clitoris, External Approach		
0U9J00Z	Drainage of Clitoris with Drainage Device, Open Approach		
0U9J0ZZ	Drainage of Clitoris, Open Approach		
0U9JX0Z	Drainage of Clitoris with Drainage Device, External Approach		
0U9JXZZ	Drainage of Clitoris, External Approach		
0UBJ0ZX	Excision of Clitoris, Open Approach, Diagnostic		
0UBJ0ZZ	Excision of Clitoris, Open Approach		
0UBJXZX	Excision of Clitoris, External Approach, Diagnostic		

0UBJXZZ	Excision of Clitoris, External Approach		
0UCJ0ZZ	Extirpation of Matter from Clitoris, Open Approach		
OUCJXZZ	Extirpation of Matter from Clitoris, External Approach		
OUMJXZZ	Reattachment of Clitoris, External Approach		
OUNJOZZ	Release Clitoris, Open Approach		
OUNJXZZ	Release Clitoris, External Approach		
0UQG0ZZ	Repair Vagina, Open Approach		
0UQJ0ZZ	Repair Vagina, Open Approach Repair Clitoris, Open Approach		
OUQJXZZ	Repair Clitoris, Open Approach Repair Clitoris, External Approach		
OUTJOZZ	Resection of Clitoris, Open Approach		
OUTJXZZ	Resection of Clitoris, Open Approach Resection of Clitoris, External Approach		
0UUG07Z	Supplement Vagina with Autologous Tissue Substitute, Open Approach		
0UUG0JZ	Supplement Vagina with Synthetic Substitute, Open Approach		
0UUG0KZ	Supplement Vagina with Synthetic Substitute, Open Approach		
	Supplement Vagina with Autologous Tissue Substitute, Percutaneous Endoscopic		
0UUG47Z	Approach		
0UUG4JZ	Supplement Vagina with Synthetic Substitute, Percutaneous Endoscopic Approach		
	Supplement Vagina with Nonautologous Tissue Substitute, Percutaneous Endoscopic		
0UUG4KZ	Approach		
0UUG77Z	Supplement Vagina with Autologous Tissue Substitute, Via Natural or Artificial Openir		
0UUG7JZ	Supplement Vagina with Synthetic Substitute, Via Natural or Artificial Opening		
	Supplement Vagina with Nonautologous Tissue Substitute, Via Natural or Artificial		
0UUG7KZ	Opening		
01110077	Supplement Vagina with Autologous Tissue Substitute, Via Natural or Artificial Opening		
0UUG87Z	Endoscopic		
0UUG8JZ	Supplement Vagina with Synthetic Substitute, Via Natural or Artificial Opening		
000032	Endoscopic		
0UUG8KZ	Supplement Vagina with Nonautologous Tissue Substitute, Via Natural or Artificial		
	Opening Endoscopic		
0UUGX7Z	Supplement Vagina with Autologous Tissue Substitute, External Approach		
0UUGXJZ	Supplement Vagina with Synthetic Substitute, External Approach		
0UUGXKZ	Supplement Vagina with Nonautologous Tissue Substitute, External Approach		
0UUJ07Z	Supplement Clitoris with Autologous Tissue Substitute, Open Approach		
OUUJOJZ	Supplement Clitoris with Synthetic Substitute, Open Approach		
0UUJ0KZ	Supplement Clitoris with Nonautologous Tissue Substitute, Open Approach		
0UUJX7Z	Supplement Clitoris with Autologous Tissue Substitute, External Approach		
0UUJXJZ	Supplement Clitoris with Synthetic Substitute, External Approach		
0UUJXKZ	Supplement Clitoris with Nonautologous Tissue Substitute, External Approach		
0VT90ZZ	Resection of Right Testis, Open Approach		
0VT94ZZ	Resection of Right Testis, Percutaneous Endoscopic Approach		
0VTB0ZZ	Resection of Left Testis, Open Approach		
0VTB4ZZ	Resection of Left Testis, Percutaneous Endoscopic Approach		
0VTC4ZZ	Resection of Bilateral Testes, Percutaneous Endoscopic Approach		
0VTS0ZZ	Resection of Penis, Open Approach		
0VTS4ZZ	Resection of Penis, Percutaneous Endoscopic Approach		
0VTSXZZ	Resection of Penis, External Approach		
014/41074	Creation of Penis in Female Perineum with Autologous Tissue Substitute, Open		
0W4N071	Approach		
0W4N0J1	Creation of Penis in Female Perineum with Synthetic Substitute, Open Approach		
0W4N0K1	Creation of Penis in Female Perineum with Nonautologous Tissue Substitute, Open		
	Approach		
0W4N0Z1	Creation of Penis in Female Perineum, Open Approach		

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#### Endnotes

<sup>1</sup> Based on local expert opinion

# Exhibit D



Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

Sex Transformation Surgery (market-based)

MP9465

Covered Service:	Yes, when member has the Sex Transformation Surgery Rider and meets criteria below.	
Prior Authorization Required:	Yes-as shown below	
Additional Information:	The medical policy criteria herein govern coverage determinations for certain Sex Transformation Surgeries for those members covered under a certificate that includes a Sex Transformation Surgery rider. The medical policy applies only to those Sex Transformation Surgery services covered under the rider. All Sex Transformation Surgery services not covered under the rider are governed by MP9469, Sex Transformation Surgery (standard).	
	Sex Transformation Surgeries for those members covered under a certificate that does not include a Sex Transformation Surgery Rider are governed by MP9469, Sex Transformation Surgery (standard).	
	Authorization may <u>only</u> be granted if the member is an active participant in a recognized gender identity treatment program.	
	Sex Transformation Surgery is defined as a surgery performed for the treatment of a confirmed gender dysphoria diagnosis.	
Medicare Policy:	Does not apply.	
BadgerCare Plus Policy:	Does not apply.	

#### Dean Health Plan Medical Policy:

- 1.0 **All** Sex Transformation Surgeries **require** prior authorization through the Quality and Care Management Division and are considered medically appropriate when **all** the following are met:
  - 1.1 Letter of referral for surgery from the individual's qualified mental health professional competent in the assessment and treatment of gender dysphoria, which includes:
    - 1.1.1 Letter of referral should include **all** the following information:
      - 1.1.1.1 Member's general identifying characteristics; and



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## Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

- 1.1.1.2 Results of the client's psychosocial assessment, including any diagnoses; and
- 1.1.1.3 The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date; and
- 1.1.1.4 An explanation that the World Professional Association for Transgender Health (WPATH) criteria for surgery have been met, and a brief description of the clinical rationale for supporting the member's request for surgery; and
- 1.1.1.5 A statement about the fact that informed consent has been obtained from the member.
- 1.1.2 One letter of referral is required for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty); **and**
- 1.1.3 One independent letter of referral is required for genital surgery
- 1.2 Persistent, well-documented gender dysphoria; and
- 1.3 Capacity to make a fully informed decision and to consent to treatment; and
- 1.4 Age of majority (18 years of age or older); and
- 1.5 If significant medical or mental health concerns are present, conditions must be reasonably well-controlled; **and**
- 1.6 The member may be required to complete twelve months of continuous and compliant hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); **and** 
  - 1.6.1 If required documentation of at least 12 months of continuous hormonal sex reassignment therapy; **and**
  - 1.6.2 The physician responsible for endocrine transition therapy must medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery.
- 1.7 The treatment plan must conform to identifiable external sources including the World Professional Association for Transgender Health Association (WPATH), and/or professional society guidance.



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# Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

	Committee/Source	Date(s)
Originated:	Medical Policy Committee/Quality and Care Management Division	October 31, 2016
Revised:		

**Reviewed:** 

Published/Effective: 01/01/2017

# Exhibit E



Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

Sex Transformation Surgery (standard)

**MP9469** 

- Covered Service: No
- Prior Authorization Required: Not covered

AdditionalThe medical policy criteria herein govern coverage of the<br/>identified categories of Sex Transformation Surgery for<br/>treatment of persons with gender dysphoria.

For those members covered under a certificate that includes a market-based Sex Transformation Surgery Rider, certain Sex Transformation Surgery services may be governed by MP9465 Sex Transformation Surgery (market-based).

Sex Transformation Surgery is defined as a surgery performed for the treatment of a confirmed gender dysphoria diagnosis.

**Medicare Policy:** Dean Health Plan makes coverage determinations on an individual claim basis.

BadgerCare PlusDean Health Plan covers when BadgerCare Plus also coversPolicy:the benefit.

#### Dean Health Plan Medical Policy:

- 1.0 Quality and Care Management has determined the following after review of current medical literature and studies regarding the identified categories of Sex Transformation Surgery:
- 2.0 Based upon lack of published evidence showing conclusively the long-term safety and positive impact on health outcomes, the following categories of Sex Transformation Surgery should be considered not medically necessary:
  - 2.1 Male to Female transition (55970):
    - 2.1.1 Breast augmentation (19324, 19325, 19340, 19342, 19350)
    - 2.1.2 Orchiectomy (54520, 54522, 54690)
    - 2.1.3 Penectomy (54125)
    - 2.1.4 Vaginoplasty (57335)
    - 2.1.5 Colovaginoplasty (55899, 57291, 57292, 58999)
    - 2.1.6 Clitoroplasty (56805)



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Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

- 2.1.7 Labiaplasty (55899, 58999)
- 2.2 Female to Male transition (55980):
  - 2.2.1Breast reduction/mastectomy (19301, 19303, 19304, 19318)
  - 2.2.2Hysterectomy (58150, 58180, 58260-58262, 58275, 58285, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573)
  - 2.2.3 Salpingo-oophrectomy (58661, 58720)
  - 2.2.4 Colpectomy / vaginectomy (57106, 57107, 57110, 57111)
  - 2.2.5 Metoidioplasty (55899, 58999)
  - 2.2.6 Phalloplasty (55899, 58999)
  - 2.2.7 Urethroplasty (53430)
  - 2.2.8 Scrotoplasty (55175, 55180)
  - 2.2.9 Placement of erectile prosthesis (54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417)
  - 2.2.10 Vulvectomy (56625)
- 3.0 The following procedures, which may be requested as part of sex transformation surgery, are non-covered benefits because they are generally performed to enhance body appearance and are not reconstructive in nature. This is not an all-inclusive list. Please see MP9022 Plastic and Reconstructive Surgery for additional information:
  - 3.1 Abdominoplasty
  - 3.2 Blepharoplasty or brow ptosis surgery
  - 3.3 Body contouring (including liposuction or subcutaneous injection of filling material)
  - 3.4 Calf implants
  - 3.5 Cheek (malar) implants, nose implants or chin implants
  - 3.6 Face lift or neck lift (rhytidectomy)
  - 3.7 Facial bone reduction
  - 3.8 Feminization of torso
  - 3.9 Hair transplant or removal
  - 3.10 Lip reduction or enhancement
  - 3.11 Masculinization of torso (pectoral implants)
  - 3.12 Mastopexy
  - 3.13 Reduction thyroid chondroplasty
  - 3.14 Removal of excess or redundant skin



A member of SSM Health

## Coverage of any medical intervention discussed in a Dean Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate.

- 3.15 Rhinoplasty
- 3.16 Skin resurfacing (including dermabrasion, chemical peel or chemical exfoliation)
- 3.17 Voice modification surgery (including laryngoplasty, cricothyroid approximation or vocal cord shortening)
- 4.0 Surgical Procedures accompanying a diagnosis of gender dysphoria that have not been listed above must be reviewed by a Medical Director for medical necessity.

	Committee/Source	Date(s)
Originated:	Medical Policy Committee/Quality and Care Management Division	October 31, 2016
Revised:	Medical Policy Committee/Quality and Care Management Division	April 19, 2017
Reviewed:	Medical Policy Committee/Quality and Care Management Division	April 19, 2017

Published/Effective: 05/01/2017

#### EXPERT WITNESS REPORT OF LOREN S. SCHECHTER, M.D.

I, Loren S. Schechter, M.D., have been retained by counsel for the Plaintiffs as an expert in the above-captioned lawsuit to provide an expert opinion on: 1) the standards of care for treating individuals diagnosed with gender dysphoria: 2) the safety and efficacy of gender confirming surgeries as treatment for gender dysphoria and 3) the similarities between surgical techniques to treat gender dysphoria and surgical techniques to treat other medical conditions.

I am a board certified plastic surgeon. I specialize in performing gender confirming surgeries (including chest reconstruction surgeries, genital reconstruction surgeries, and other procedures to feminize or masculinize the body, as described in more detail below),<sup>1</sup> and I am a recognized expert in this field.

I have personal knowledge of the matters stated in this report. I may further supplement these opinions in response to information produced by Defendants in discovery and in response to additional information from Defendants' experts.

#### I. <u>Background and Qualifications</u>

The information provided regarding my professional background, experiences, publications, and presentations are detailed in my curriculum vitae. A true and correct copy of my CV is attached to this report as Exhibit A.

<sup>&</sup>lt;sup>1</sup> I refer to this family of procedures as "gender confirmation" or "gender affirming surgeries" because they are one of the therapeutic tools used to enable people to live comfortably in accordance with their gender identities. Out of the myriad labels I've heard for these procedures—"sex reassignment surgery," "gender reassignment surgery," and "sex change operation," to name but a few—none is as accurate when it comes to describing what is actually taking place as "gender confirmation" or "gender affirmation surgery." Most, if not all, the other names used for these procedures suggest that a person is making a choice to switch genders, or that there is a single "surgery" involved. From the hundreds of discussions I have had with patients over the years, nothing could be further from the truth. This is not about choice; it's about using one or more surgical procedures as therapeutic tools to enable people to live authentically.

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I received my medical degree from the University of Chicago, Pritzker School of Medicine. I completed my residency and chief residency in plastic and reconstructive surgery and a fellowship in reconstructive microsurgery at the University of Chicago Hospitals.

I am currently a Visiting Clinical Professor of Surgery at the University of Illinois at Chicago. I also maintain a clinical practice in plastic surgery in Illinois where I treat patients from around the country, including from Wisconsin, as well as from around the world.

I have been performing gender confirming surgeries for over 18 years. For the past four or five years, I have been performing approximately 100-150 gender confirming procedures every year. I have performed over 500 gender confirming surgeries during my medical career. Currently, approximately 85-90 percent of the patients in my clinical practice are transgender individuals seeking gender confirmation surgeries.

I was a contributing author to the Seventh Version (current) of the World Professional Association for Transgender Health's (WPATH) *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*<sup>2</sup> (hereafter, "WPATH SOC"). In particular, I wrote the section focused on the relationship of the surgeon with the treating mental health professional and the physician prescribing hormone therapy. WPATH is in the midst of drafting the eighth version of the WPATH SOC. I am the co-lead on the surgical and postoperative care chapter in the eighth version.

The WPATH SOC provides clinical guidance for health professionals based on the best available science and expert professional consensus. The purpose of the WPATH SOC is to assist health providers in delivering medical care to transgender people in order to provide them

<sup>&</sup>lt;sup>2</sup> Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7 World Professional Association for Transgender Health 1 (2011).

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with safe and effective pathways to achieving lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment.

In addition, I have written a number of peer-reviewed journal articles and chapters in professional textbooks about gender confirmation surgeries. In 2016, I published *Surgical Management of the Transgender Patient*, the first surgical atlas (a reference guide for surgeons on how to perform surgical procedures using safe, well-established techniques) dedicated to gender confirming surgeries. A full and complete list of my publications is included in my CV.

I am a guest reviewer for the *Journal of Plastic and Reconstructive Surgery*, the *Journal of Reconstructive Microsurgery*, and the *Journal of Sexual Medicine*. I also serve on the editorial board of both *Transgender Health* and the *International Journal of Transgenderism*. Each of these publications is a peer-reviewed medical journal.

I am actively involved in training other surgeons to perform gender confirming surgeries. Last year I started the surgical fellowship in gender surgery at Weiss Memorial Hospital in Chicago. I am also the Medical Director of the Center for Gender Confirmation Surgery at Weiss Memorial Hospital. In addition, I am the site director for a fellowship in reconstructive urology and gender surgery at Weiss Memorial Hospital, under the auspices of the Department of Urology at the University of Illinois at Chicago.

I have given dozens of public addresses, seminars, and lectures on gender confirming surgery, including many through the American Society of Plastic Surgeons. I have also taught a number of courses through WPATH's Global Education Initiative, which provides training courses toward a member certification program in transgender health for practitioners around the world. In addition, I recently co-directed the first live surgery course in gender confirming procedures at Mount Sinai Hospital in New York City.

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I am also a former member of the Board of Governors of the American College of Surgeons and a current member of the Board of Directors of WPATH.

I am being compensated at an hourly rate of \$450/hour plus expenses for my time spent preparing this report and providing local testimony (including deposition or providing hearing testimony by telephone or video-teleconference). I will be compensated a flat daily rate of \$7000 for any out-of-town deposition or hearing testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

In the previous four years, I was retained as an expert witness by the defense in *Willis v. Flagg*, a medical malpractice case heard in Cook County (IL) Circuit Court. In that case, I testified as an expert witness at trial. I was also retained as an expert witness by the defense in *Carver v. VanRaalte*, a medical malpractice case heard in Rock Island County (IL) Circuit Court. Again, I testified as an expert witness at trial. I do not remember giving expert testimony at a trial or at a deposition in any other case in the last four years.

#### II. <u>Basis for Opinions</u>

My opinions contained in this report are based on: (1) my clinical experience as a surgeon performing gender confirming surgeries for patients; (2) my knowledge of the peer-reviewed research, including my own, regarding gender confirming surgeries, which reflects the clinical advancements in these procedures and the corresponding growth in research related to their safety and effectiveness in treating gender dysphoria; (3) my work as a contributing author of the WPATH SOC; and (4) my work as an author and teacher of surgical techniques used in gender confirming surgeries.

#### III. Discussion

### A. The Standards Of Care For Treating Individuals Diagnosed With Gender Dysphoria

#### 1. Background on Gender Identity and Gender Dysphoria

The term "transgender" is used to describe a diverse group of individuals whose gender identity, or internal sense of being male or female (or both or neither), differs from the sex they were assigned at birth.

Many transgender individuals experience gender dysphoria at some point in their lives. Gender dysphoria is defined as distress caused by a discrepancy between a person's gender identity and that person's primary and/or secondary sexual characteristics.

Gender dysphoria is a serious medical condition recognized by the International Classification of Diseases-10 (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) published by the American Psychiatric Association. Individuals diagnosed with gender dysphoria have an intense and persistent discomfort with the primary and/or secondary sex characteristics of the sex they were assigned at birth.

Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide.

Appropriate medical care, including mental health services, hormone therapy, and gender confirming surgeries, can help alleviate gender dysphoria. Gender confirming surgeries, which bring a person's body into better alignment with their gender identity, have been shown to be an effective treatment for gender dysphoria.

#### 2. Gender Confirming Surgeries are Standard, Medically Accepted Treatments for Gender Dysphoria and Are Medically Necessary for Many Transgender People

The World Professional Association for Transgender Health is a non-profit professional and educational organization devoted to transgender health. WPATH's mission is "to promote evidence-based care, education, research, advocacy, public policy, and respect in transgender health." WPATH, Mission and Vision, https://www.wpath.org/about/mission-and-vision.

WPATH publishes *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*. The WPATH SOC are based on the best available scientific evidence and expert professional consensus.

WPATH published the first version of the standards of care in 1979. The guidelines have since been updated, the most current version being the seventh edition. These updates reflect the significant advances made in the understanding, management, and care of transgender individuals.

The WPATH SOC are widely recognized guidelines for the clinical management of transgender individuals with gender dysphoria. Most surgeons who regularly treat individuals experiencing gender dysphoria, including myself, practice in accordance with the WPATH SOC.

As indicated in the WPATH SOC, effective treatment options for gender dysphoria include psychotherapy, hormone therapy to feminize or masculinize the body, and various surgical procedures to align a person's primary and/or secondary sex characteristics with the person's gender identity. (SOC at 9-10).

Surgery is often the last and most considered of the treatment options. Not every transgender person wants, requires, or qualifies for every available surgical procedure. In fact, the SOC notes that "[t]he number and sequence of surgical procedures may vary from patient to

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patient, according to their clinical needs." (SOC at 58). Evidence shows that while some transgender individuals do not require surgery, "for many others surgery is essential and medically necessary to alleviate their gender dysphoria. For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity." (SOC at 54-55).

For transgender women (women who were assigned male at birth and have a female gender identity), surgical treatment options that are generally accepted in the medical community and are consistent with the WPATH SOC include, but are not limited to:

- Chest reconstruction surgery: augmentation mammoplasty (breast implants);
- Genital reconstruction surgeries: penectomy (removal of the penis), orchiectomy (removal of the testes), vaginoplasty, clitoroplasty, and/or vulvoplasty (creation of female genitalia); and
- Other surgeries to feminize the body, such as: reduction thyroid chondroplasty (reduction of the Adam's apple), voice modification surgery, suction-assisted lipoplasty and/or lipofilling (contour modeling) of the waist, hair transplantation, and facial feminization procedures. (SOC at 57)

For transgender men (men who were assigned female at birth and have a male gender

identity), surgical treatment options that are generally accepted in the medical community and

are consistent with the WPATH SOC include, but are not limited to:

- Chest reconstruction surgery: subcutaneous mastectomy, creation of a male chest;
- Genital reconstruction surgeries: hysterectomy/salpingo-oophorectomy (removal of the uterus and ovaries), reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or a phalloplasty (creation of a penis), vaginectomy (removal of the vagina), scrotoplasty (creation of the scrotum), and implantation of erection and/or testicular prostheses; and
- Other surgeries to masculinize the body, such as: liposuction, lipofilling, pectoral implants, and body contouring procedures. (SOC at 57).

Surgeons generally consider surgeries performed to treat gender dysphoria as

reconstructive. This is true even though the same surgical procedures might be considered

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cosmetic when performed on someone without a diagnosis of gender dysphoria. As discussed further below, some of these procedures are similar to other reconstructive procedures performed for other diagnoses (*e.g.*, breast cancer). No particular surgery is inherently cosmetic or inherently reconstructive; rather, the underlying diagnosis determines whether the procedure is considered cosmetic or reconstructive. Because these medically necessary procedures help transgender individuals to live and present in a manner more consistent with their gender identity and therefore reduce their dysphoria, the professional medical consensus recognizes that these are appropriately categorized as reconstructive procedures.

The WPATH SOC sets forth criteria for initiation of surgical treatment. For adults seeking chest and/or genital reconstruction procedures, the criteria are:

- The patient has the capacity to make fully informed decisions and to consent for treatment.
- If the patient has other significant medical or mental health concerns, they are reasonably well-controlled prior to surgery.
- The patient has persistent gender dysphoria as documented by at least one mental health professional for chest reconstruction surgeries and two such professionals for genital reconstruction surgeries.
- Prior to genital reconstruction surgery, the patient has undergone 12 continuous months of hormone therapy, unless hormone therapy is not clinically indicated for that patient.<sup>3</sup> The purpose of the prerequisite is to introduce a period of estrogen or testosterone suppression before the patient undergoes a surgical intervention.
- Prior to certain genital reconstruction procedures metoidoplasty, phalloplasty, or vaginoplasty the patient has lived for 12 continuous months in a gender role that is congruent with their gender identity. The prerequisite ensures that the patient has ample opportunity to experience and socially adjust in their desired gender role, before undergoing this surgery.<sup>4</sup> (SOC at 60).

<sup>&</sup>lt;sup>3</sup> While not an explicit criterion, the WPATH SOC recommends that individuals undergo 12 months of continuous hormone therapy prior to breast augmentation surgery to obtain the best possible outcome. (SOC at 59).

<sup>&</sup>lt;sup>4</sup> While not an explicit criterion, the WPATH SOC also recommend that these individuals see a mental health or other medical professional during this 12 month period. (SOC at 60).

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The Endocrine Society—the leading professional organization devoted to research on hormones and the clinical practice of endocrinology—has also issued clinical guidelines for the treatment of transgender individuals.<sup>5</sup> The guidelines indicate that for many transgender individuals, gender confirming surgery is a necessary and effective treatment.<sup>6</sup>

The broader medical community, including the American Medical Association, American Psychological Association, American Psychiatric Association, American College of Obstetricians and Gynecologists, American Academy of Family Physicians, and World Health Organization, recognizes that gender confirming surgery is standard, appropriate, and necessary treatment for many people with gender dysphoria.

#### **B.** The Safety and Efficacy of Gender Confirming Surgeries as Treatment for Gender Dysphoria and Their Acceptance in the Medical Field

The available peer-reviewed literature concludes that when performed in accordance with the SOC, gender confirmation surgery is effective in alleviating gender dysphoria.

For example, one peer-reviewed study of transgender men found that 91% of a sample who received phalloplasty reported that the surgery was effective in aligning their physical appearance with their male gender identity.<sup>7</sup>Another peer-reviewed study of transgender men who received chest reconstruction found that the procedure improved psychosocial well-being and physical well-being among participants.<sup>8</sup>

<sup>&</sup>lt;sup>5</sup> Hembree, W.C., et al., (2017): Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J. Clin. Endocrinology & Metabolism, 102, 3869.
<sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> Leriche, A., Timsit, M., Morel-Journel, N., Bouillot, A., Dembele, D., & Ruffion, A. (2008): Long-term outcome of forearm flee-flap phalloplasty in the treatment of transsexualism. BJU International, 101(10), 1297-1300. doi:10.1111/j.1464-410x.2007.07362; *see also* Morrison, S. D., Shakir, A., Vyas, K. S., Kirby, J., Crane, C. N. & Lee, G. K. (2016): Phalloplasty: A Review of Techniques and Outcomes (concluding that "[P]halloplasty is highly efficacious and beneficial to patients").

<sup>&</sup>lt;sup>8</sup> Agarwal, A. et al., (2018): Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test, 71, 651-657.

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Similarly, a peer-reviewed study of transgender women found that those who underwent breast augmentation surgeries experienced statistically significant improvements in their psychosocial well-being.<sup>9</sup>Another peer-reviewed study of transgender women who had vaginoplasty found that study participants' mean improvement in quality of life after surgery was 7.9 on a scale from -10 to 10.<sup>10</sup>Another study of transgender women found that surgical interventions were highly correlated with alleviating gender dysphoria.<sup>11</sup>

Dr. Mayer seems to suggest in his report that a woman who is transgender might choose "after a period of time, to adopt a male gender identity" and would then seek "surgery to remasculinize her face." (Mayer Report, p.9, ¶32). Neither the research in the field nor my own clinical experience provides support for this suggestion. In fact, research demonstrates that while regret of any type is rare (.6% in transgender women and .3% of transgender men<sup>12</sup>), what researchers term "true regrets" as opposed to regrets due to lack of social acceptance, comprise an even smaller percentage (approximately half this group, roughly .3% in transwomen and .15% in transmen).<sup>13</sup>

<sup>11</sup> Hess, J., Neto, R., Panic, L., Rubben, H. & Senf, W. (2014): Satisfaction with Male-to-Female Gender Reassignment Surgery (among survey respondents, the majority (90.2%) said that their expectations for life as a woman were fulfilled after surgery. A similarly high percentage (85.4%) saw themselves as women).

<sup>&</sup>lt;sup>9</sup> Weigert, R., Frison, E., Sessiecq, Q., Mutairi, K. A., & Casoli, V. (2013): Patient Satisfaction with Breasts and Psychosocial, Sexual, and Physical Well-Being after Breast Augmentation in Male-to-Female Transsexuals. Plastic and Reconstructive Surgery, 132(6), 1421-1429, doi:10.1097/01.prs.0000434415.70711.49.

<sup>&</sup>lt;sup>10</sup> Horbach, S. E. R., Bouman, M., Smit, J. M., Ozer, M., Buncamper, M. & Mullender, M. G. (2015): Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques.

<sup>&</sup>lt;sup>12</sup> The Amsterdam Cohort of Gender Dysphoria Study 1972-2015 (2018): Trends in Prevalence, Treatment, And Regrets, Wiepjes, et. al. The Journal of Sexual Medicine 15, 582.

<sup>&</sup>lt;sup>13</sup> The Amsterdam Cohort of Gender Dysphoria Study 1972-2015 (2018): Trends in Prevalence, Treatment, And Regrets, Wiepjes, et. al. The Journal of Sexual Medicine 15, 585, (researchers classified "social regrets" as those experienced by individuals who still identified as transwomen, but reported feeling "ignored by surroundings" or regretted "loss of relatives," and classified "true regrets" as those experienced by individuals who "thought gender-affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment" *Id.* at 587).

### C. The Similarities Between Surgeries to Treat Gender Dysphoria and Surgeries to Treat Other Medical Conditions.

When performing gender confirming surgery, surgeons use many of the same procedures that they use to treat other medical conditions. For example, surgeons regularly perform mastectomies and chest/breast reconstruction, hysterectomies/salpingo-oophorectomies, and orchiectomies to treat individuals with cancer, or a genetic predisposition to cancer (BRCA 1, 2 genes in the case of prophylactic mastectomy or oophorectomy). Similarly, surgeons perform procedures to reconstruct male or female external genitalia for individuals who have certain medical conditions (*e.g.*, cancer) or who have suffered traumatic injuries to or disabling infections of their genitalia. For the male genitalia, this would include procedures to correct conditions such as hypospadias, epispadias, exstrophy, fournier's gangrene, penile webbing, or buried penis (which can occur as a result of obesity, diabetes, or recurrent infections). For the female genitalia, this would include procedures to correct conditions such as congenital absence of the vagina or reconstruction of the vagina/vulva following oncologic resection, traumatic injury, or infection.

When billing insurers for reimbursement, health care providers use Current Procedural Terminology (CPT) codes, which are developed and maintained by the American Medical Association. The same code or codes may apply to a particular procedure regardless of whether the procedure is performed on a transgender patient or a cisgender patient. For example, a subcutaneous mastectomy may be performed for a cisgender woman to reduce her risk of breast cancer or for a transgender man with gender dysphoria. The same CPT code may be used for both procedures. In general, the charge per CPT code would be the same, whether the procedure

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were used for treatment of gender dysphoria or treatment of another condition—for example, the charge for a subcutaneous mastectomy (19304).

The research, as well as my own clinical expertise, show that surgical procedures for gender dysphoria are safe and effective, and that many of these procedures are analogous to surgical procedures used to treat other medical conditions such as those listed above. The fact that the medical community deems these procedures sufficiently safe to treat conditions other than gender dysphoria is by itself more than sufficient to support the safety of those surgeries to treat gender dysphoria.

A number of additional studies provide support for the well-established position that surgery and hormone therapy are safe and effective treatments for gender dysphoria. For example, a recent study of 7905 persons with gender dysphoria, of whom 1047 underwent surgery between 2009-2015, revealed an overall complication rates for all surgical procedures on persons with gender dysphoria of only 5.8%.<sup>14</sup> Looking specifically at the complication rates for chest surgeries (subcutaneous mastectomy and chest wall contouring), two recent study reveal a complication rate among transgender men of between 11% -12%,<sup>15</sup> in comparison to the complication rate of 43% for cisgender women undergoing breast reduction shown in a 2005 study.<sup>16</sup> Likewise, in a systematic review of cis-gender women undergoing nipple-sparing mastectomy and immediate breast reconstruction using breast implants and acellular dermal

<sup>&</sup>lt;sup>14</sup> Trends in gender-affirming surgery in insured patients in the United States, PRS Global open, 2018; 6: e1738.
<sup>15</sup> Female-to-male transgender chest reconstruction: A large consecutive, single-surgeon experience, Journal of Plastic, Reconstructive, and Aesthetic Surgery (2012) 65, 711-719; Quality of lime improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test, Journal of Plastic, Reconstructive, and Aesthetic Surgery (2012) 65, 711-719; Constructive, 2018) 71, 651-657.

<sup>&</sup>lt;sup>16</sup> Analysis of breast reduction complications derived from the BRAVO study PRS 115 (6) 1597-604.

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matrix the complication rates include: 11% skin necrosis, 5% nipple necrosis, 12% infection, 1% hematoma, 5% seroma, 4% explanation, and 9% unplanned return to the operating room.<sup>17</sup>

Complication rates for vaginoplasties in transgender women are similar to rates of complications for cis-gender women undergoing vaginal or vulvar reconstruction for medical conditions (*e.g.*, cancer.) For example, a 2018 study looking at complications and patient-reported outcomes in 3716 cases of male-to-female vaginoplasty found complications rates of 2% (1%-6%) fistula, 14% (10%-18%) stenosis and strictures, 1% (0%-6%) tissue necrosis, and 4% (2%-10%) prolapse with patient-reported satisfaction of 93% (overall results).<sup>18</sup> An additional 2018 study published in the Journal of Urology evaluated 330 patients presenting for primary vaginoplasty. The overall complication rate in this study was 28.7%.<sup>19</sup> In comparison, studies examining complication rates in cis-gender women undergoing vaginal and vulvar reconstruction demonstrate complication rates ranging as high as 61% total complication rate<sup>20</sup> with additional studies demonstrating complication rates of 22.3%-26.7% for flap-related complications.<sup>22</sup> Additional studies reviewing reconstruction of congenital deformities found complications rates ranging from 0-57%.<sup>23</sup>

<sup>&</sup>lt;sup>17</sup> Complications following nipple-sparing mastectomy and immediate acellular dermal matrix implant-based breast reconstruction-A systematic review and meta-analysis PRS global open 2018; 6:e1625

<sup>&</sup>lt;sup>18</sup> Complications and Patient-Reported Outcomes in Male-to-female Vaginoplasty-Where We Are Today Annals of Plastic Surgery, 2018

<sup>&</sup>lt;sup>19</sup> Postoperative Complications Following Primary Penile Inversion Vaginoplasty Among 330 Male-to-Female Transgender Patients Journal of Urology vol 199, 760-765, March 2018

<sup>&</sup>lt;sup>20</sup> Outcomes of Partial Vaginal Reconstruction with Pedicled Flaps following Oncologic Resection PRS 127: 663, 2011

<sup>&</sup>lt;sup>21</sup> Vulvovagional reconstruction after radical excision from treatment of vulvar cancer: evaluation of feasibility and morbidity of different surgical techniques Surgical Oncology, 26 (2017) 511-521

<sup>&</sup>lt;sup>22</sup> Vaginal reconstruction following radical surgery for colorectal malignancies: a systematic review of the literature Annals of Surgical Oncology (2012) 19:3933-3942

<sup>&</sup>lt;sup>23</sup> Postoperative complications after reconstructive surgery for cloacal malformations: a systematic review Tech Coloproctol (2015) 19: 201-207

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Mayer is simply wrong to claim that "[m]edical and surgical treatments have not been demonstrated to be safe and effective for gender dysphoria." (Mayer Report, p. 3 ¶6.) In addition to the studies cited above, there is a substantial additional body of evidence showing that the standard medical and surgical treatments for gender dysphoria are both safe and effective.<sup>24</sup>

Recent studies have shown that transgender adults who receive cross-sex hormones have no significant increased risk of major thromboembolic events once oral estrogens, (especially oral synthetic estrogens) are substituted with parenteral estrogens, such as patches or injectable estrogens.<sup>25</sup> Additionally, two recent studies show that transgender adults who receive cross-sex hormones do not have an increased risk of breast cancers when compared with transgender adults how do not receive such hormones.<sup>26</sup> It is a basic principle in medicine that every medication and/or intervention has potential side effects. However, denying or minimizing effective treatment may cause harm and risks future harm.

As support for Mayer's claim that there is "minimal" support for the safety, efficacy, and optimality of surgical treatments, Mayer cites a 2016 decision of the U.S. Department of Health & Human Services Center for Medicare and Medicaid Services ("CMS"), called a Decision

<sup>&</sup>lt;sup>24</sup> See e.g., Hadj-Moussa, M., Ohl, D.A., & Kuzon, W.M., (2017): Feminizing Genital Gender-Confirmation Surgery, Sexual Med. Rev. 2018 1-14, a literature review concluding that gender confirmation surgery is effective at improving quality of life, overall happiness, and sexual functioning in gender dysmorphic MTF patients appropriately selected with WPATH SOC criteria; Van de Grift, et al., (2016): Body Image in Transmen: Multidimensional Measurement and the Effects of Mastectomy, J. Sexual Med. 13, 1778-1786, a pre-operative and six-month post-operative survey of FTM patients finding strong increases in positive body image, as well as decreases in gender dysmorphia and feelings of low self-worth; Papadopulos, N.A., et al., (2017): Male-to-Female Sex Reassignment Surgery Using the Combined Technique Leads to Increase Quality of Life in a Prospective Study, a post-operative and six-month follow-up survey of MTF patients finding improvements in quality of life in a significant majority of patients.

<sup>&</sup>lt;sup>25</sup> Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ (2011): A long-term follow up study of mortality in transsexuals receiving treatment with cross-sex hormones, Eur J Endoccrinol 164:635-642; *see also* Van Kesteren PJ, Asscheman H, Megens JA, Gooren LJ (1997): Mortality and morbidity in transsexual subjects treated with cross-sex hormones. Clin Endocrinol (Oxf) 47, 337-342.

<sup>&</sup>lt;sup>26</sup> Brown GR, Jones KT (2015 online, print forthcoming): Incidence of breast cancer in a cohort of 5,135 transgender veterans. Breast Cancer Research and Treatment, 149(1),191-198, DOI: 10.1007/s10549-014-3213-2, 2014; Gooren LJ, van Trotsenburg MA, Giltay EJ, vanDiest PJ (2013): Breast cancer development in transsexual subjects receiving cross-sex hormone treatment. J Sex Med 12:3129–3134. doi:10.1111/jsm.12319.

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Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) ("2016 CMS Decision Memo"), claiming that it found "'inconclusive' clinical evidence regarding gender reassignment surgery." What Mayer fails to point out is that in 2014 an impartial adjudicative board in the Department of Health & Human Services concluded, based on decades of studies, that surgical care to treat gender dysphoria is safe, effective, and not experimental. *See* Exhibit B. The decision specifically noted that, regardless of whether the studies were randomized doubleblind trials, there was sufficient evidence to prove "a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for [gender dysphoria]." *Id.* at 20. Ever since the adjudicative board's decision, Medicare has provided coverage for transition-related surgery based on patients' individual needs.

In the 2016 CMS Decision Memo, CMS decided to continue cover surgical treatment of gender dysphoria based on patients' individual needs and refrain from issuing national standards regarding how do determine medical necessity in individualized cases.<sup>27</sup> The decision specifically clarified that "GRS [gender reassignment surgery] may be a reasonable and necessary service for certain beneficiaries with gender dysphoria," but "[t]he current scientific information is not complete for CMS to make a [national coverage determination] that identifies *the precise patient population* for whom the service would be reasonable and necessary."<sup>28</sup> In particular, CMS expressed concern that the Medicare population includes "older adults [who] may respond to health care treatments differently than younger adults."<sup>29</sup> "These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for

<sup>&</sup>lt;sup>27</sup> See Exhibit C.

<sup>&</sup>lt;sup>28</sup> Id. at 54 (emphasis added).

<sup>&</sup>lt;sup>29</sup> *Id.* at 57.

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healing, metabolic variances, and impact of reduced mobility."<sup>30</sup> Indeed, most studies on outcomes of patients with gender dysphoria include only a minority of individuals over the age of 65, which is not uncommon in medical studies that are not focused on geriatric issues. The CMS memorandum concluded that the appropriateness of surgical care for this population should be determined on an individualized basis. Indeed, most medical and surgical care provided to patients should be individualized, taking into account each patient's unique clinical circumstances. In contrast, the exclusion found in the Wisconsin Uniform Benefits plan does not evaluate the medical necessity of care for gender dysphoria on an individualized basis. It categorically excludes all coverage regardless of an individualized showing of medical necessity.

Mayer also cites to pages 106-13 of his article "Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences" in *The New Atlantis* and his amicus brief filed in *Glucester County School Board v. G.G. ex rel. Grimm*, No. 16-272 (U.S.). *The New Atlantis* is not a peer-reviewed medical journal, but rather a quarterly publication from a socially conservative advocacy group known as the Ethics and Public Policy Center. Moreover, the article's critiques of the studies supporting the efficacy of treatment fail to undermine the conclusion reached by the mainstream medical community that surgery and hormone therapy are safe and effective treatments for gender dysphoria.<sup>31</sup>

<sup>&</sup>lt;sup>30</sup> Id.

<sup>&</sup>lt;sup>31</sup> Additionally, some of the studies Mayer cites as evidence of the lack of effectiveness of surgery and hormone therapy for gender dysmorphia do not provide any such evidence. *See e.g.*, Dhejne, C., et al., (2011): Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden, 6 PLOS ONE 1, is a study comparing morality and other measures of 324 individuals who had gender confirmation surgeries between 1973 and 2003, with members of the *general* population, finding that post-operative gender dysmorphia patients had higher suicide rates than the general population. The study however does not compare the transgender individuals who had gender confirmation surgeries with transgender individuals who did not have and wanted or did not have and did not want gender confirmation surgeries. As both Mayer and the study's authors concede, the study cannot address "the effectiveness of sex reassignment as a treatment for transsexualism" and "things might have been even worse without sex reassignment" (Lawrence S. Mayer and Paul R. McHugh, *Sexuality and Gender: Findings from the Biological, Psychological, and Social Sciences*, 50 The New Atlantis 4, 111 (2016) (Mayer quoting Dhejne))

Mayer's reliance on a study<sup>32</sup> of fifteen patients who underwent surgery published in 1979 by Jon Meyer and his secretary, Donna Reter, shows how far he has to search to find anything to support his opinions. The report is extremely outdated by current standards but was even criticized at the time of publication because of serious methodological flaws. In 1980, Fleming, Steinman, and Bockman published a paper<sup>33</sup> challenging the report's findings, citing to methodological problems, as well conceptual flaws in research design, score reporting, interpretation of data, and conclusions. One striking example of the flaws includes the authors' assignment of a negative value of minus one to persons who cohabited with a person of "the nongender appropriate sex." It is unclear what such cohabitation was intended to imply and why it was given a negative value. This is just one example of the value judgments and researcher bias that contaminate the findings of this 1979 study. Mayer recognizes at least some of the methodological flaws, but continues to rely on it to support his overall assertion that the evidence supporting surgical treatment is weak. It is also worth pointing out that while Johns Hopkins ceased performing transition-related surgeries in 1979, it currently provides them.<sup>34</sup>

Mayer also cites studies and papers by Kenneth J. Zucker, claiming that "traditional psychosocial treatments for gender dysphoria, such as those employed by Dr. Zucker, are therefore prudent and natural."<sup>35</sup> However, Zucker's advocacy of non-surgical and hormonal methods is limited entirely to treatment of gender dysphoric children.<sup>36</sup> Further, Zucker refutes

<sup>&</sup>lt;sup>32</sup> Jon K. Meyer and Donna J. Reter, "Sex Reassignment: Follow-up," *Archives of General Psychiatry* 36, no. 9 (1979): 1010 – 1015, http://dx.doi.org/10.1001/archpsyc.1979.01780090096010.

<sup>&</sup>lt;sup>33</sup> Fleming, M., Steinman, C., Bocknek, G., (1980): Methodological problems in assessing sex-reassignment surgery: A reply to Meyer and Reter, 9 Achieves of Sexual Behavior 451.

<sup>&</sup>lt;sup>34</sup> Johns Hopkins Medicine, Center for Transgender Health, Gender Affirmation Surgical Services, *available at* https://www.hopkinsmedicine.org/center\_transgender\_health/services/surgical-services.html

<sup>&</sup>lt;sup>35</sup> Brief of Dr. Paul R. McHugh, Dr. Paul Hruz, and Dr. Lawrence S. Mayer, as Amicus Curiae in Support of Petitioner, p. 13, *Gloucester County School Board v. G.G. ex rel Grimm*, 137 S.Ct. 1239 (2017)

<sup>&</sup>lt;sup>36</sup> In "Gender Dysphoria in Adults," Zucker states "recent investigations have largely confirmed the opinion that hormone therapy is an effective and reasonably safe treatment in adults with GD" and that "a great majority of

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Mayer's assertions in the same paper Mayer cites, stating that "empirical evidence from adulthood suggests that gender dysphoria is best treated through hormonal and surgical interventions, particularly in carefully evaluated patients."<sup>37</sup>

Mayer's amicus brief offers no better scientific basis for his opinions than does his New Atlantis piece. The major medical associations addressed those opinions as follows: "While there are those like McHugh et al. who oppose the medical consensus regarding gender dysphoria—as there are outliers in every area of medicine—the protocols [involving affirming a person's gender identity] are well-established in the fields of medicine and psychology." Br. of Amici Curiae American Academy of Pediatrics, et al. at 21–24, G.G. v. Gloucester County School Board, No. 16-273, 2017 WL 1057281 (U.S. Mar. 2, 2017). Some of the documents he cites in the brief to support his position represent fringe positions far outside the mainstream medical community. For example, he cites a position statement of the American College of Pediatricians, a small, recently founded, socially conservative group with about 500 members, as well as an article by its president, Michelle Cretella.<sup>38</sup> This group represents out a position well outside the evidence-based position of the medical community represented by the mainstream American Academy of Pediatrics (with over 65,000 members founded over 85 years ago), which supports transition-related care, including puberty suppressants and cross-sex hormones for transgender youth (David A. Levine & Comm. On Adolescence, Am. Acad. of Pediatrics Technical Report, Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth, 132 Pediatrics e297, 298 (2013)).

adults with GD [who have undergone sex-reassignment surgery] report improved subjective satisfaction" Zucker, K.J., et al., (2016): Gender Dysphoria in Adults, 12 Annu. Rev. Clin. Psychol. 217, 239.

<sup>&</sup>lt;sup>37</sup> Zucker, K.J., (2008): Children with gender identity disorder: Is there a best practice?, 56 Neuropsychiatrie de l'Enfance et de l'Adolescence 358.

<sup>&</sup>lt;sup>38</sup> Michelle A. Cretella, *Gender Dysphoria in Children and Suppression of Debate*, 21 J. of Am. Physicians & Surgeons (2016).

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Mayer fails to provide current, mainstream, peer-reviewed evidence to support his challenges to the safety and efficacy of medical treatments for gender dysphoria. The evidence regarding the efficacy and safety of these treatments is at least as good, if not better, than the evidence supporting other commonly provided medical and surgical treatments. If Mayer is suggesting that surgery to treat gender dysphoria is distinguishable from surgeries to treat other conditions because the former alters biological development, he is wrong. Many forms of surgical treatments change an individuals' biological development, including prophylactic mastectomy (removal of non-cancerous breasts in cis-gender women), prophylactic oophorectomy (removal of non-cancerous ovaries in cis-gender women).

There is no controversy amongst mainstream medical professionals regarding the appropriateness and necessity of medical and surgical care for gender dysphoria.

#### IV. Conclusions

It is my professional opinion, consistent with the prevailing standards of care, that gender confirming surgery is safe, effective, and medically necessary for many individuals with gender dysphoria. Moreover, Mayer fails to identify any way in which surgeries and hormones to treat gender dysphoria are distinguishable from surgeries and medications to treat other medical conditions. In my professional opinion, surgeries and hormone therapies are analogous to treatment for other medical conditions, aside from the treatment of gender dysphoria.

Based on my 18 years of clinical experience performing gender confirming procedures, and my knowledge of the standards of care and relevant peer-reviewed literature, it is my professional opinion that gender confirming surgeries are a safe and effective treatment for gender dysphoria, and that these surgeries are medically necessary treatments for gender dysphoria for many transgender individuals. In my experience, the overwhelming number of

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individuals who undergo gender confirming procedures describe improvement in their quality of life and overall functioning.

Based on my experience and review of the literature, it is my professional opinion that the denial of necessary medical care is likely to perpetuate gender dysphoria and create or exacerbate other medical issues, such as depression and anxiety, leading to an increased possibility of self-harm, negative health outcomes, and even suicide.

In my professional opinion, the exclusion of coverage for gender confirming surgery and hormone therapy found in the Uniform Benefits plan for state employee health care coverage is not consistent with the prevailing standards of care for treating transgender individuals diagnosed with gender dysphoria, nor is it consistent with the peer-reviewed scientific and medical research demonstrating that gender confirming surgeries and hormone therapy are safe and effective treatments for gender dysphoria. To the extent the Uniform Benefits exclusion is premised on the assumption that gender confirming hormonal and surgical care is never medically necessary, that assumption is wrong. The standards of care confirm, based on clinical evidence, that gender confirmation surgeries and hormone therapy are medically necessary to help people alleviate the serious and often life-threatening symptoms.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 31st day of May, 2018.

Loren S. Schechter, M.D.

# Exhibit A

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## Curriculum Vitae

NAME :	LOREN SLONE SCHECHTER, MD, FACS	
OFFICE:	9000 Waukegan Rd. Suite 210 Morton Grove, Il 60053 Tel: 847.967.5122 Fax: 847.967.5125	
<u>E-MAIL:</u> WEB SITE:	<pre>lss@univplastics.com www.univplastics.com www.plasticsurgery.org/md/DRLOREN.htm</pre>	
BIRTHDATE: BIRTHPLACE: MARITAL STATUS: SPOUSE: CHILDREN:	August 14, 1968 Galveston, Texas Married Rebecca Brown Schechter, MD Owen Slone Schechter Miles Slone Schechter	
CERTIFICATION:	The American Board of Plastic Surgery Certificate Number 6271 Date Issued: September 2001 Maintenance of Certification:	2001 2011
EDUCATION: 1986-1990 1990-1994	The University of Michigan The University of Chicago Pritzker School of Medicine	BS, 1990 MD, 1994
POSTGRADUATE TRAINING:		
Residency:	The University of Chicago Hospitals Coordinated Training Program in Plastic and Reconstructive Surgery	1994-1999
Chief Resident:	The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1998-1999
Fellowship:	Reconstructive Microsurgery The University of Chicago Hospitals Section of Plastic and Reconstructive Surgery	1999-2000
TEACHING APPOINTMENT:		

Visiting clinical professor, The University of Illinois at Chicago

Associate Professor, Physician Assistant Program, College of Health Professionals, Rosalind Franklin University

- LICENSURE: Illinois Illinois Controlled Substance DEA
- **STAFF APPOINTMENTS:** University of Illinois at Chicago Hospital Advocate Lutheran General Hospital Louis A. Weiss Memorial Hospital Illinois Sports Medicine and Orthopedic Surgery Cente

## HONORS AND AWARDS:

2015	University of Minnesota Program in Human
	Sexuality Leadership Council
2014	National Center for Lesbian Rights honored guest
2013	Illinois State Bar Association Award for
	Community Leadership
2010	Advocate Lutheran General 2009 Physicians
	Philanthropy Leadership Committee-Outstanding
	Leadership
2009	Advocate Lutheran General Hospital Value Leader
1994	Doctor of Medicine with Honors
1994	University of Chicago Department of
	Surgery Award for Outstanding
	Performance in the Field of Surgery
1994	Catherine Dobson Prize for the Best Oral
	Presentation Given at the $48^{th}$
	Annual Senior Scientific Session in
	The Area of Clinical Investigation
1993	Alpha Omega Alpha
1991	University of Chicago National Institutes
	Of Health Summer Research Award
1990	Bachelor of Science with High Distinction
	And Honors in Economics
1990	James B. Angell Award for Academic Distinction
1989	Omicron Delta Epsilon-National Economic Honor
	Society
1988	College Honors Program Sophomore Honors Award
	For Academic Distinction
1988	Class Honors (Dean's List)

#### MEMBERSHIPS:

2016-	The American Society for Gender Surgeons
	(founding member and president-elect)
2010-	World Society for Reconstructive Microsurgery
2005-	The University of Chicago Plastic Surgery Alumni
	Association
2005-	The Chicago Surgical Society

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2004-	The American Society for Reconstructive Microsurgery
2003-	The American College of Surgeons
2002-	The American Society of Plastic Surgeons
2001-	Illinois Society of Plastic Surgeons (formerly,
	Chicago Society of Plastic Surgeons)
2001-	The American Society of Maxillofacial Surgeons
2001-	American Burn Association
2001-	Midwest Association of Plastic Surgeons
2001-	WPATH
1994-	The University of Chicago Surgical Society
1994-	The University of Chicago Alumni Association
1992-	American Medical Association
1992-	Illinois State Medical Society
1992-	Chicago Medical Society
1990-	The University of Michigan Alumni Association

#### CURRENT HOSPITAL COMMITTEES:

Director, Center for Gender Confirmation Surgery, Louis A. Weiss Memorial Hospital

#### PROFESSIONAL SOCIETY COMMITTEES:

Board of Directors, at-large, The World Professional Association for Transgender Health

PlastyPac, Chair, Board of Governors

American Society of Plastic Surgeons, Coding and Payment Policy Committee

American Society of Plastic Surgeons, Practice Management Education Committee

Medicare Carrier Advisory Committee

Chair of the Metro Chicago District #2 Committee on Applicants, American College of Surgeons

American Society of Plastic Surgery, Health Policy Committee

American Society of Plastic Surgery, Patient Safety Committee

#### OTHER:

Guest Book Reviewer, Plastic and Reconstructive Surgery

Editorial Board, Transgender Health

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Editorial Board (Associate Editor), International Journal of Transgenderism

Fellow of the Maliniac Circle

Guest Reviewer, Journal of Reconstructive Microsurgery

Guest Reviewer, Journal of Plastic and Reconstructive Surgery

Guest Reviewer, Journal of Sexual Medicine

Guest Editor, Clinics in Plastic Surgery, Transgender Surgery (Elsevier Publishing)

Guest Reviewer, The Journal of Plastic and Reconstructive Surgery

#### PREVIOUS EDITORIAL ROLE:

Guest Reviewer, EPlasty, online Journal

Module Editor for Patient Safety, Plastic Surgery Hyperguide

Editorial Advisory Board, Plastic Surgery Practice

Guest Reviewer, International Journal of Transgenderism

Guest Reviewer, Pediatrics

#### PREVIOUS ACADEMIC APPOINTMENT:

Chief, Division of Plastic and Reconstructive Surgery, Chicago Medical School, Rosalind Franklin University of Medicine and Science

Associate Professor of Surgery, The College of Health Professionals, Rosalind Franklin University

Clinical Associate in Surgery, The University of Chicago

#### PREVIOUS HOSPITAL COMMITTEES:

Division Director, Plastic Surgery, Lutheran General Hospital

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Division Director, Plastic Surgery, St. Francis Hospital

Medical Staff Executive Committee, Secretary, Advocate Lutheran General Hospital

Credentials Committee, Lutheran General Hospital

Pharmacy and Therapeutics Committee Lutheran General Hospital

Operating Room Committee, St. Francis Hospital

Cancer Committee, Lutheran General Hospital -Director of Quality Control

Risk and Safety Assessment Committee, Lutheran General Hospital

Nominating Committee, Rush North Shore Medical Center

Surgical Advisory Committee, Rush North Shore Medical Center

Section Director, Plastic Surgery, Rush North Shore Medical Center

#### PREVIOUS SOCIETY COMMITTEES:

Board of Governors, Governor-at-large, The American College of Surgeons

American College of Surgeons, International Relations Committee

Chair, Government Affairs Committee, American Society of Plastic Surgeons

President, The Metropolitan Chicago Chapter of The American College of Surgeons

2012 Nominating Committee, American Society of Plastic Surgeons

Program Committee, The World Society for Reconstructive Microsurgery, 2013 Bi-Annual Meeting

President, Illinois Society of Plastic Surgeons

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Vice-President, The Illinois Society of Plastic Surgeons (formerly the Chicago Society of Plastic Surgery)

Vice-President, The Metropolitan Chapter of the American College of Surgeons

American Society of Plastic Surgery, Chairman, Patient Safety Committee

2006-2007 Pathways to Leadership, The American Society of Plastic Surgery

2005 & 2006 President, The University of Chicago Plastic Surgery Alumni Association

2003 Leadership Tomorrow Program, The American Society of Plastic Surgery

Senior Residents Mentoring Program, The American Society of Plastic Surgery

American Society of Maxillofacial Surgery, Education Committee

Alternate Councilor, Chicago Medical Society

American Society of Aesthetic Plastic Surgery, Electronic Communications Committee

American Society of Aesthetic Plastic Surgery, Intranet Steering Committee

American Society of Aesthetic Plastic Surgery, International Committee

Membership Coordinator, The Chicago Society of Plastic Surgeons The Illinois State Medical Society, Governmental Affairs Council

The Illinois State Medical Society, Council on Economics

Chicago Medical Society, Physician Review Committee -Subcomittee on Fee Mediation

Chairman, Chicago Medical Society, Healthcare Economics Committee

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Secretary/Treasurer, The Metropolitan Chicago Chapter of the American College of Surgeons

Scientific Committee, 2007 XX Biennial Symposium WPATH

Local Organizing Committee 2007 WPATH

Secretary, The Chicago Society of Plastic Surgeons

Treasurer, The Chicago Society of Plastic Surgeons

Council Member, The Metropolitan Chicago Chapter of the American College of Surgeons

#### INTERNATIONAL MEDICAL SERVICE:

Northwest Medical Teams Manos de Ayuda (Oaxaca, Mexico)

Hospital de Los Ninos (San Juan, Puerto Rico)

#### COMMUNITY SERVICE:

Board of Directors, Committee on Jewish Genetic Diseases, Jewish United Fund, Chicago, Illinois

Board of Directors, Chicago Plastic Surgery Research Foundation

## PREVIOUS COMMUNITY SERVICE:

Governing Council, Lutheran General Hospital, Park Ridge, Il

Lutheran General Hospital Development Council, Park Ridge, Il

Lutheran General Hospital Men's Association, Park Ridge, Il

Advisory Board, Committee on Jewish Genetic Diseases, Cancer Genetics Subcommittee, Jewish United Fund, Chicago, Illinois

Health Care Advisory Board, Congressman Mark Kirk, 10<sup>th</sup> Congressional District, Illinois

Major Gifts Committee, Saint Francis Hospital Development Council, Evanston, Il Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 29 of 242

## Visiting Professor:

- 1. University of Utah, Division of Plastic Surgery, November 6-8, 2014.
- Northwestern University, Division of Plastic Surgery, April 21-22, 2016.
- 3. The University of North Carolina, Division of Plastic Surgery, March 28-29, 2017
- 4. Georgetown University, Department of Plastic Surgery, May 17-18, 2017

## Research Interests:

1. Role of Omental Stem Cells in Wound Healing (Grant: Tawani Foundation)

2. Robotic-Assisted Bilateral Prophylatic Nipple Sparing Mastectomy with Immediate Tissue Expander/Implant Reconstruction (Pending submission to the FDA for Investigational Device Exemption in association with Intuitive Surgical)

3. Transgender Health and Medicine Research Conference, National Institutes of Health, Bethesda, MD May 7-8, 2015

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2. David C. Cronin, II, **Loren Schechter**, Somchi Limrichramren, Charles G. Winans, Robert Lohman, and J. Michael Millis, Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow with an Implantable Doppler Probe. *Transplantation 74(6):887-889, 2002*.

3. Robert F. Lohman, Loren S. Schechter, Lawrence S. Zachary, Solomon Aronson: Evaluation of Changes in Skeletal Muscle Blood Flow in the Dog with Contrast Ultrasonography Revisited: Has the Technique Been Useful, and Where are We Headed Now? *The Journal of Plastic and Reconstructive Surgery* 111(4):1477-1480, 2003.

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6. Iris A. Seitz, MD, David Tojo, MD, **Loren S. Schechter**, MD Anatomy of a Medication Error: Inadvertent Intranasal Injection of Neosynephrine During Nasal Surgery - A Case Report and Review of The Literature (accepted for publication, *Journal of Plastic and Reconstructive Surgery*, *March 2010*)

7. Iris Seitz, MD Craig Williams, MD, Thomas Weidrich, MD, John Seiler, MD, Ginard Henry, MD, and **Loren S. Schechter, MD**: Omental Free Tissue Transfer for Coverage of Complex Upper Extremity Defects: The Forgotten Flap (published online March 25, 2009, *Hand*)*Hand*, *Vol. 4. Issue 4 (2009)*p.397

8. Michael Salvino and **Loren S. Schechter**: Microvascular Reconstruction of Iatrogenic Femoral Artery Thrombus in an Infant: A Case Report and Review of the Literature ePlasty Volume 9 ISSN: 19357-5719, E-location ID: e20

9. Phillip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Ronald E. Iverson, MD., Loren S. Schechter, MD, Robert Singer, MD, Bob Basu, MD, MPH, Lynn A. Damitz, MD, Scott Bradley Bradley Glasberg, MD, Lawrence S. Glasman, MD, Michael F. McGuire, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

10. Philip C. Haeck, MD, Jennifer A. Swanson, BS, Med, Loren S. Schechter, MD, Elizabeth J. Hall-Findlay, MD, Noel B. McDevitt, MD, Gary Smotrich, MD, Neal R. Reisman, MD, JD, Scot Bradley Glasberg, MD, and the ASPS Patient Safety Committee: Evidence-Based Patient Safety Advisory: Blood Dyscrasias, Patient Selection and Procedures in Ambulatory Surgery, Supplement to Plastic and Reconstructive Surgery, Volume 124, Number 4s, October Supplement 2009.

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12. Iris A Seitz, MD, PhD, Craig Williams, MD, Loren S. Schechter, MD, Facilitating Harvest of the Serratus Fascial Flap With Ultrasonic Dissection, *Eplasty 2010 Feb 23;10:e18* 

13. Seitz, I, Friedewald SM, Rimler, J, **Schechter**, **LS**, Breast MRI helps define the blood supply to the nipple-areolar complex,

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14. Iris A. Seitz, Sally Friedwald, MD; Jonathon Rimler, Loren S. Schechter, Breast MRI to Define The Blood Supply to The Nipple-Areolar Complex. *Plast Recon Surg Suppl 126 (26) p. 27 Oct 2010* 

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4. Loren S. Schechter, MD: A Helping Hand. *Plastic Surgery Products*, November 2005.

5. Loren S. Schechter, MD: On Guard for DVT. *Plastic Surgery Products*, June 2007.

6. Loren S. Schechter, MD and Iris Seitz, MD, PhD: Mission: Possible Achieving a Successful Microsurgical Reconstruction of the Head and Neck, *Plastic Surgery Practice*, May 2009.

7. Loren S. Schechter, MD and Iris A. Seitz, MD, PhD: Soft-tissue Reconstruction of Arms and Hands, *Plastic Surgery Practice*, February, 2010.

8. Lucio A. Pavone, MD, Iris A. Seitz, MD, PhD, Loren S. Schechter, MD: Current Options in Autologous Breast Reconstruction, *Plastic Surgery Practice*, November, 2010. Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 33 of 242

9. Lucio A. Pavone, MD, Iris A. Seitz, MD, Michelle C. Roughton, MD, Daniel Z. Liu, Loren S. Schechter, MD: Options in Breast Reconstruction, *Chicago Medicine*, June 2013.

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2. Loren S. Schechter, Surgery for Gender Identity Disorder, *Plastic Surgery*, Fourth Edition, ed. Neligan, 2013, Elsevier, Vol. Four, Volume Editor (Submitted for publication): David H. Song

3. Nicholas Kim and **Loren S. Schechter**, Plastic Surgery Board Review: Pearls of Wisdom, 3<sup>rd</sup> Edition, Gender Confirmation Surgery McGraw Hill, 2016

4. Loren S. Schechter, Surgical Management of the Transgender Patient (Elsevier, 2016)

5. Loren S. Schechter and Rebecca B. Schechter, Pursuing Gender Transition Surgeries, Adult Transgender Care An Interdisciplinary Approach for Training Mental Health Professionals, First Edition, published 2018, Taylor and Francis, edited by Michael Kauth and Jillian Shipherd

6. Loren S. Schechter, Breast and Chest Surgery in Transgender Patients, Comprehensive Care of the Transgender Patient (Elsevier, submitted for publication)

7. Loren S. Schechter, Gender Confirmation Surgery-Principles and Techniques for an Emerging Field, (Springer-Verlag, in preparation, delivery date November 2017)

8. Loren S. Schechter, Gender Confirmation Surgery, Clinics in Plastic Surgery (Elsevier, in preparation)

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14. Joseph Talarico, MD, Wayne Lee, MD, Loren Schechter, MD: When Component Separation Isn't Enough, American Hernia Society, Inc, Hernia Repair 2005, P. 194

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16. Jacob M.P. Bloom, MS, Alvin B. Cohn, MD, Benjamin Schlechter, MD, Nancy Davis, MA, Loren S. Schechter, MD, Abdominoplasty and Intra-Abdominal Surgery: Safety First, Plastic Surgery Abstract Supplement vol. 120, no 4, p. 99

17. I.A. Seitz, C.S. Williams, T.A. Wiedrich, **L.S. Schechter**, Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap, Plastic Surgery At The Red Sea International Symposium Book Of Abstracts, March 24-28, 2009, p. 25

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23. Michelle Roughton, MD, Loren Schechter, MD, FACS, Patient Safety: Abdominoplasty and Intra-Abdominal Procedures, Advocate Research Forum, Research and Case Report Presentation Abstracts, Advocate Lutheran General Hospital, May 5, 2010, p. 20

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### PRESENTATIONS:

1. Student Summer Research Poster Forum-The University of Chicago, Jan. 21, 1992: "A Comparison of Dynamic Energy Expenditure Versus Resting Energy Expenditure in Burn Patients Using The Doubly Labeled Water Method"

2. American Association for the Surgery of Trauma, Sept. 17-19, 1992, Louisville, KY: "Routine HIV Testing in A Burn Center: A Five Year Experience"

3. American Burn Association Poster Session, April 20-23, 1994, Orlando, Fl: "Calculated Versus Measured Energy Requirements in Adult Burn Patients"

4. 48<sup>th</sup> Annual Senior Scientific Session: The University of Chicago, May 19, 1994: "Calculated Versus Measured Energy Requirements in Adult Burn Patients"

5. Plastic Surgery Senior Residents Conference, April 20-25, 1999, Galveston, TX: "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

6. The Chicago Society of Plastic Surgery, May 6, 1999, "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

7. The American Society for Aesthetic Plastic Surgery, May 14-19, 1999, Dallas, TX: "Plication of the Orbital Septum in Lower Eyelid Blepharoplasty"

8. XIII Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, June 27-July 2, 1999, San Francisco, CA: "Craniofacial Osseo-Distraction: A Bridge to Eucephaly"

9. XIII Congress of the International Confederation for Plastic, Reconstructive, and Aesthetic Surgery, June 27-July 2, 1999 San Francisco, CA: "Ethnic Aesthetic Analysis and Surgery"

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11. American Society for Reconstructive Microsurgery, January 12-15, 2002, Cancun, Mexico: "The Role to Free Tissue Transfer and Sural Neurocutaneous flaps for Reconstruction of Leg Wounds"

12. American Society of Plastic Surgery, 71st Annual Scientific Meeting, November 2-6, 2002, San Antonio, Texas: "Defining the Role for Negative Pressure Therapy in the Treatment Algorithm of Extremity Wounds"

13. American Society of Reconstructive Microsurgery, Annual Scientific Meeting, January 11-15, 2003, Kauai, Hawaii: "Advances in Pediatric Liver Transplantation: Continuous Monitoring of Portal Venous and Hepatic Artery Flow With an Implantable Doppler Probe"

14. The 5<sup>th</sup> Annual Chicago Trauma Symposium, August 8-10, 2003, Chicago, Illinois: "Soft Tissue Salvage: Where Are We in 2003?"

15. The Midwestern Association of Plastic Surgeons, 42<sup>nd</sup> Annual Meeting, Chicago, Il May 1-2, 2004: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

16. The 6<sup>th</sup> Annual Chicago Trauma Sympsoium, August 12-15, 2004, Chicago, Il "Complex Wound Management"

17. The American Society of Plastic Surgery, October 9-13, 2004, Philadelphia, Pennsylvania: "The Gastrocnemius-Achilles Tendon Myocutaneous Flap (GAT Flap) for Single Stage Reconstruction of Combined Soft Tissue and Extensor Mechanism Defects of the Knee: An Eighteen Year Experience"

18. The American Society for Reconstructive Microsurgery, January 15-18, 2005, Fajardo, Puerto Rico: "Surviving as a Plastic Surgeon"

19. American Hernia Society, Poster Presentation, February 9-12, 2005, San Diego, California: "When Component Separation Isn't Enough"

20. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Hereditary Gingival Fibromatosis in Monozygotic Twins: First Reported Case" Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 38 of 242

21. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Modified Components Separation Technique for Two Massive Ventral Hernias"

22. The Midwestern Association of Plastic Surgeons, April 23-24, Chicago, Il: "Mucormycosis of the Head and Neck: A Fatal Disease?"

23. The 7<sup>th</sup> Annual Chicago Trauma Symposium, August 11-14, 2005, Chicago, Il "Management of Complex Injuries"

24. Current Concepts in Advanced Wound Healing: A Practical Overview, Rush North Shore Medical Center, Skokie, Il September 18, 2005 "From Flaps to Grafts"

25. Taizoon Baxamusa, M and Loren S.Schechter, MD, Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity, The American Association For Hand Surgery Annual Scientific Meeting, January 11-14, 2006, Tucson, Arizona.

26. The American Academy of Orthopedic Surgeons 2006 Annual Meeting, March 22-26, 2006, Chicago, Il "Methods of Patella-Femoral and Extensor Mechanism Reconstruction for Fracture and Disruption After Total Knee Arthroplasty"

27. Midwestern Association of Plastic Surgeons 44<sup>th</sup> Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Elective Abdominal Plastic Surgery Procedures Combined with Concomitant Intra-abdominal Operations: A Single Surgeon's Four Year Experience"

28. Midwestern Association of Plastic Surgeons 44<sup>th</sup> Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Hereditary Gingival Fibromatosis: Aggressive Two-Stage Surgical Resection Versus Traditional Therapy"

29. Midwestern Association of Plastic Surgeons 44<sup>th</sup> Annual Meeting, April 29-30, 2006, Oak Brook, Illinois "Abdominoplasty Graft & VAC Therapy: Two Useful Adjuncts in Full-Thickness Grafting of the Mangled Upper Extremity"

30. The American Association of Plastic Surgeons 85<sup>th</sup> Annual Meeting, May 6-9, 2006 Hilton Head, South Carolina "Excision of Giant Neurofibromas"

31. The 8<sup>th</sup> Annual Chicago Trauma Symposium, July 27-30, 2006, Chicago, Il "Management of Complex Injuries"

32. The American Society of Plastic Surgeons Annual Meeting, October 6-12, 2006, San Francisco, California "Excision of Giant Neurofibromas"

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33. The American College of Surgeons Poster Presentation, October, 2006, Chicago, Il "Abdominoplasty: Use in Reconstruction of the Mangled Upper Extremity"

34. American Medical Association-RFS 3<sup>rd</sup> Annual Poster Symposium, November 10, Las Vegas, NV, 2006 "Abdominal Wall Reconstruction With Alloderm"

35. Advocate Injury Institute: "Trauma 2006: The Spectrum of Care), November 30-December 2, 2006, Lisle, Il, "Pit Bull Mauling: A Case Study"

36. The 9<sup>th</sup> Annual Chicago Trauma Symposium, August 10-12, 2007, Chicago, Il "Management of Complex Injuries"

37. The World Professional Association for Transgender Health (WPATH) 2007 XX Biennial Symposium, September 5-8. 2007, Chicago, Il Revision Vaginoplasty With Sigmoid Interposition: "A Reliable Solution for a Difficult Problem"

38. Metropolitan Chicago Chapter of the American College of Surgeons, 2008 Annual Meeting, March 15, 2008 "ER Call: Who's Job is it Anyway"

39. The 10<sup>th</sup> Annual Chicago Trauma Symposium, August 7-10, 2008, Chicago, Il "Management of Complex Injuries"

40. 23nd Annual Clinical Symposium on Advances in Skin & Wound Care: The Conference for Prevention and Healing October 26-30, 2008, Las Vegas, Nevada, poster presentation "Use of Dual Therapies Consisting of Negative Pressure Wound Therapy (NPWT) and Small Intestine Mucosa (SIS) on a Complex Degloving Injury With an Expose Achilles Tendon: A Case Report."

41. The American Society of Plastic Surgeons Annual Meeting, October 31-November 3, 2008, Chicago, Il "Panel: Fresh Faces, Real Cases"

42. The American Association for Hand Surgery Annual Meeting, January 7-13, 2009, Maui, Hawaii, poster session: "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

43. Plastic Surgery At The Red Sea Symposium, March 24-28, 2009 Eilat, Israel, "Omental Free Tissue Transfer for Coverage of Complex Upper Extremity and Hand Defects-The Forgotten Flap."

44. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Advertising in Plastic Surgery?" Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 40 of 242

45. ASPS/IQUAM Transatlantic Innovations Meeting, April 4-7, 2009 Miason de la Chimie, Paris, France, "Cost-Effectiveness of Physician Extenders in Plastic Surgery"

46. Midwestern Association of Plastic Surgeons, 47<sup>th</sup> Annual Meeting, April 18-19, 2009, Chicago, Il, "Microvascular Reconstruction of Iatrogenic Femoral Artery Injury in a Neonate"

47. Midwestern Association of Plastic Surgeons, 47<sup>th</sup> Annual Meeting, April 18-19, 2009, Chicago, Il,"Two Birds, One Stone: Combining Abdominoplasty with Intra-Abdominal Procedures"

48. The 11<sup>th</sup> Annual Chicago Trauma Symposium, August 1, 2009, Chicago, Il "Management of Complex Injuries"

49. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Omental Free Tissue Transfer for Coverage of Complex Extremity Defects: The Forgotten Flap."

50. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Challenging Cases."

51. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, "President's Panel: The Future of the Solo Practice-Can We, Should We Survive?"

52. The 12<sup>th</sup> Annual Chicago Trauma Symposium, August 5-8, 2010, Chicago, Il "Management of Complex Injuries"

53. Breast MRI to Define The Blood Supply to the Nipple-Areolar Complex. German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPRAEC), Dresden, Germany, September 2010

54. Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA

55. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The American Society of Plastic Surgeons Annual Meeting, October 3, 2010, Toronto, CA.

56. ASPS/ASPSN Joint Patient Safety Panel: Patient Selection and Managing Patient Expectations, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 41 of 242

57. Lunch and Learn: Prevention of VTE in Plastic Surgery Patients, The American Society of Plastic Surgeons Annual Meeting, October 5, 2010, Toronto, CA

58. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, 16<sup>th</sup> Congress of The International Confederation for Plastic Reconstructive and Aesthetic Surgery, May 22-27, 2011, Vancouver, Canada

59. Breast MRI Helps Define the Blood Supply to the Nipple-Areolar Complex, The 6<sup>th</sup> Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

60. Applications of the Omentum for Limb Salvage: The Largest Reported Series, The 6<sup>th</sup> Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

61. Successful Tongue Replantation Following Auto-Amputation Using Supermicrosurgical Technique, Poster Session, The 6<sup>th</sup> Congress of The World Society for Reconstructive Microsurgery, WSRM 2011, 29 June-2 July, 2011, Helsinki, Finland

62. The 13<sup>th</sup> Annual Chicago Trauma Symposium, August 25-28, 2011, Chicago, Il "Soft Tissue Defects-Getting Coverage"

63. WPATH: Pre-conference Symposium, September 24, 2011, Atlanta, GA "Surgical Options and Decision-Making"

64. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part I: Patient Selection and Preventing Adverse Events in the Ambulatory Surgical Setting

65. American Society of Plastic Surgeons Annual Meeting, September 27, 2011, Denver, CO Closing Session Lunch and Learn: Pathways to Prevention-Avoiding Adverse Events, Part III: Preventing VTE

66. XXIV Congresso Nazionale della Societa Italiana di Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: 3 Step Approach to Lower Extremity Trauma

67. XXIV Congresso Nazionale della Societa Italiana Microchirugia congiunto con la American Society for Reconstructive Microsurgery, October 20-22, 2011, Palermo, Sicily: Applications of the Omentum for Limb Salvage: The Largest Reported Series

68. American Society for Reconstructive Microsurgery, Poster Presentation, January 14-17, 2012, Las Vegas, NV: Neonatal Limb Salvage: When Conservative Management is Surgical Intervention Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 42 of 242

69. The 14<sup>th</sup> Annual Chicago Trauma Symposium, August 2-5, 2012, Chicago, Il "Soft Tissue Defects-Getting Coverage"

70. The Annual Meeting of The American Society of Plastic Surgeons, October 25<sup>th</sup>-30, 2012, New Orleans, LA "Reimbursement in Breast Reconstruction"

71. The Annual Meeting of The American Society of Plastic Surgeons, October 25<sup>th</sup>-30, 2012, New Orleans, LA "Thriving in a New Economic Reality: Business Relationships and Integration in the Marketplace"

72. The 15<sup>th</sup> Annual Chicago Trauma Symposium, August 2-5, 2013, Chicago, Il "Soft Tissue Defects-Getting Coverage"

73. 2014 WPATH Symposium, Tansgender Health from Global Perspectives, February 14-18, 201, "Short Scar Chest Surgery."

74. 2014 WPATH Symposium, Transgender Health from Global Perspectives, February 14-18, 2014, "Intestinal Vaginoplasty with Right and Left Colon."

75. 24<sup>th</sup> Annual Southern Comfort Conference, September 3-7, 2014, Atlanta, Georgia, "Gender Confirmation Surgery: State of the Art."

76. The 15<sup>th</sup> Annual Chicago Trauma Symposium, September 4-7, 2014, Chicago, Il "Soft Tissue Defects-Getting Coverage"

77. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il "Gender Confirmation Surgery: A Single-Surgeon's Experience"

78. The Midwest Association of Plastic Surgeons, May 30, 2015, Chicago, Il, Moderator, Gender Reassignment.

79. the American Society of Plastic Surgeons 2015 Professional Liability Insurance and Patient Safety Committee Meeting, July 17, 2015, "Gender Confirmation Surgery."

80. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. From Fee-for-Service to Bundled Payments

81. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Moderator, Transgender Surgery

82. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Efficient Use of Physician Assistants in Plastic Surgery.

83. The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA. Patient Safety: Prevention of VTE

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84. The World Professional Association for Transgender Health, Objective Quality Parameters for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

85. The World Professional Association for Transgender Health, Resident Education Curriculum for Gender Confirmation Surgery, June 18-22, 2016, Amsterdam, Netherlands

86. The World Professional Association for Transgender Health, Urologic Management of a Reconstructed Urethra(Poster session #195), June 18-22, 2016, Amsterdam, Netherlands

87. The World Professional Association for Transgender Health, Construction of a neovagina for male-to-female gender reassignment surgery using a modified intestinal vaginoplasty technique, poster session (Poster session #198), June 18-22, 2016, Amsterdam, Netherlands

88. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Genital Aesthetics: What are we trying to achieve?, Washington, DC June 23-25, 2016

89. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Female to Male Gender Reassignment, Washington, DC June 23-25, 2016

90. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The journal of retractions, what I no longer do, Washington, DC June 23-25, 2016

91. Aesthetica Super Symposium, The American Society of Plastic Surgeons, The three minute drill, tips and tricks, Washington, DC June 23-25, 2016

92. Aesthetica Super Symposium, The American Society of Plastic Surgeons, Moderator, Mini master class: Male genital plastic surgery, Washington, DC June 23-25, 2016

93. The 16<sup>th</sup> Annual Chicago Trauma Symposium, August 18-21, 2016, Chicago, Il "Soft Tissue Defects-Getting Coverage"

94. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Partial Flap Failure Five Weeks Following Radial Forearm Phalloplasty: Case Report and Review of the Literature

95. USPATH Poster Session, Feb 2-5, 2017, Los Angeles, CA, Urethroplasty for Stricture after Phalloplasty in Transmen Surgery for Urethral Stricture Disease after Radial Forearm Flap Phalloplasty-Management Options in Gender Confirmation Surgery Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 44 of 242

96. USPATH, Feb 2-5, 2017, Los Angeles, CA, Patient Evaluation and Chest Surgery in Transmen: A Pre-operative Classification

97. USPATH, Feb 2-5, 2017, Los Angeles, CA Single Stage Urethral Reconstruction in Flap Phalloplasty: Modification of Technique for Construction of Proximal Urethra

98. USPATH, Feb 2-5, 2017, Los Angeles, CA, Use of Bilayer Wound Matrix on Forearm Donor Site Following Phalloplasty

99. USPATH, Feb 2-5, 2017, Los Angeles, CA, Vaginoplasty: Surgical Techniques

100. USPATH, Feb 2-5, 2017, Los Angeles, CA, Positioning of a Penile Prosthesis with an Acellular Dermal Matrix Wrap following Radial Forearm Phalloplasty

101. USPATH, Feb 2-5, 2017, Los Angeles, CA, Principles for a Gender Surgery Program

102. USPATH, Feb 2-5, 2017, Los Angeles, CA, Construction of a Neovagina Using a Modified Intestinal Vaginoplasty Technique

103. The 18<sup>th</sup> Annual Chicago Orthopedic Symposium, July 6-9, 2017, Chicago, Il "Soft Tissue Defects-Getting Coverage"

104. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Moderator: Genital Surgery Trends for Women

105. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Adding Transgender Surgery to Your Practice, Moderator and Speaker

106. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, Transbottom Surgery

#### INSTRUCTIONAL COURSES:

 Emory University and WPATH: Contemporary Management of Transgender Patients: Surgical Options and Decision-Making, September 5, 2007 Chicago, Il

2. Craniomaxillofacial Trauma Surgery: An Interdisciplinary Approach, February 16-17, 2008, Burr Ridge, Il

3. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, Moderator: Free Papers, Lower Extremity 4. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Moderator: ASPS/ASPSN Patient Panel: Effective Communication-A Key to Patient Safety and Prevention of Malpractice Claims

5. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Instructional Course: Strategies to Identify and Prevent Errors and Near Misses in Your Practice

6. American Society of Plastic Surgeons Annual Meeting, October 23-27, 2009, Seattle, WA, Roundtable Discussion: Electronic Health Records-Implications for Plastic Surgeons

7. 10<sup>th</sup> Congress of The European Federation of Societies for Microsurgery, May 2-22, 2010, Genoa, Italy, "The Mangled Lower Extremities: An Algorithm for Soft Tissue Reconstruction."

8. Mulitspecialty Course for Operating Room Personnel-Craniomaxillofacial, Orthopaedics, and Spine, A Team Approach, AO North American, June 26-27, 2010, The Westin Lombard Yorktown Center.

9. Management of Emergency Cases in the Operating Room, The American Society of Plastic Surgeons Annual Meeting, October 4, 2010, Toronto, CA.

10. Surgical Approaches and Techniques in Craniomaxillofacial Trauma, November 6, 2010, Burr Ridge, Il.

11. The Business of Reconstructive Microsurgery: Maximizing Economic value (Chair) The American Society for Reconstructive Microsurgery, January 14-17, 2012, Las Vegas, Nevada.

12. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 25<sup>th</sup>-30<sup>th</sup>, 2012, New Orleans, LA

13. Strategies to Identify and Prevent Errors and Near Misses in Your Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11<sup>th</sup>-15th, 2013, San Diego, CA

14. Mythbusters: Microsurgical Breast Reconstruction in Private Practice, The Annual Meeting of The American Society of Plastic Surgeons, October 11<sup>th</sup>-15th, 2013, San Diego, CA

15. Minimizing Complications in Perioperative Care, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

16. Genitourinary and Perineal Reconstruction, The American Society for Reconstructive Microsurgery, January 11-14, 2014, Kauai, Hawaii

17. Transgender Breast Surgery, The American Society of Plastic Surgeons, October 16-20, 2015, Boston, MA

18. Gender Confirmation Surgery, The School of the Art Institute (recipient of American College Health Fund's Gallagher Koster Innovative Practices in College Health Award), October 27, 2015, Chicago, Il

19. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Overview of Surgical Treatment Options

20. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015 Chicago, Il Surgical Procedures

21. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Surgical Complications

22. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Post-operative Care

23. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, November 5-7, 2015, Chicago, Il Case Discussions: The Multidisciplinary Team

24. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23,2016, Atlanta, GA Overview of Surgical Treatment Options

25. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, January 20-23, 2016, Atlanta, GA Surgical Treatment Options

26. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Surgical Treatment Options.

27. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Certified Training Course, March 30-April 1, 2016, Springfield, MO, Multi-disciplinary Case Discussion.

28. Introduction to Transgender Surgery, ASPS Breast Surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

29. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, September 28, 2016, Ft. Lauderdale, FL. Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 47 of 242

30. Cirugias de Confirmacion de Sexo Paso a Paso, XXXV Congreso Confederacion Americana de Urologia (CAU), Panama City, Panama, October 4-8, 2016.

31. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course, December 3, 2016, Arlington, VA.

32. PSEN (sponsored by ASPS and endorsed by WPATH), Transgender 101 for Surgeons, January 2017-March 2017

33. Surgical Anatomy and Surgical Approaches to M-to-F Genital Gender Affirming Surgery and the Management of the Patient Before, During and After Surgery: A Human Cadaver Based Course, Orange County, CA, Feb. 1, 2017

34. Gender Confirmation Surgery, ALAPP, 2 Congreso Internacional de la Asociacion Latinoamericana de Piso Pelvico, Sao Paulo, Brasil, 9-11 de marzo de 2017

35. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, Overview of Surgical Treatment, March 31-April 2, 2017, Minneapolois Minnesota.

36. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course, The Multi-Disciplinary Team Case Discussions, March 31-April 2, 2017, Minneapolois Minnesota.

37. Transfeminine Cadaver Course, WPATH, May 19-20, 2017, Chicago, Il

38. Transgender/Penile Reconstruction-Penile Reconstruction: Radial Forearm Flap Vs. Anterolateral Thigh Flap, Moderator and Presenter, The World Society for Reconstructive Microsurgery, June 14-17, 2017, Seoul, Korea

39. Primer of Transgender Breast Surgery, ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

40. Confirmation Surgery in Gender Dysphoria: current state and future developments, International Continence Society, Florence, Italy, September 12-15, 2017

41. The American Society of Plastic Surgeons Annual meeting, October 6-10, 2017, Orlando, FL, ASPS/WPATH Joint Session, Session Planner and Moderator

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42.Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Foundations Training Course: Overview of Surgical Treatment, Columbus, OH, October 20-21, 2017

43. Transgender Health: Best Practices in Medical and Mental Health Care. A WPATH Global Education Initiative Advanced Training Course: Medical Care in the Perioperative Period, Aftercare: Identifying Potential Complications, Columbus, OH, October 20-21, 2017

44. Webinar: Gender Affirming Surgeries 101: Explore The Latest Topics in Gender Affirmation Surgery, PSEN, April 18, 2018

45. Course Director: MT. Sinai/WPATH Live Surgery Training Course for Gender Affirmation Procedures, April 26-28, 2018, New York, NY

## SYMPOSIA:

1. Program Director, 2011 Chicago Breast Symposium, October 15, 2011, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, IL,

2. Fundamentals of Evidence-Based Medicine & How to Incorporate it Into Your Practice, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

3. Understanding Outcome Measures in Breast & Body Contouring Surgery, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

4. Benchmarking Complications: What We Know About Body Contouring Complication Rates from Established Databases, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

5. Special Lecture: VTE Prophylaxis for Plastic Surgery in 2011, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

6. Nipple Sparing Mastectomy: Unexpected Outcomes, Challenging Complications in Plastic Surgery: Successful Management Strategies, The American Society of Plastic Surgeons, July 13-14, 2012 Washington, DC

7. Program Director, 2011 Chicago Breast Symposium, October 13-14, 2012, The Chicago Plastic Surgery Research Foundation and The Chicago Medical School at Rosalind Franklin University, North Chicago, Il

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8. Practice Strategies in a Changing Healthcare Environment, Moderator, Midwestern Association of Plastic Surgeons, April 27-28, 2013, Chicago, Il

9. Moderator: Breast Scientific Paper Session, The Annual Meeting of The American Society of Plastic Surgery, October 12, 2014, Chicago, Il.

10. Moderator: The World Professional Association for Transgender Health, Tuesday, June 21, Surgical Session (0945-1045), June 18-22, 2016, Amsterdam, Netherlands

11. Course Director: Transmale Genital Surgery: WPATH Gender Education Initiative, October 21-22Chicago, Il

12. Co-Chair and Moderator: Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

13. Vascular Anastomosis: Options for Lengthening Vascular Pedicle, Surgeon's Only Session, USPATH, Los Angeles, CA, Feb. 2, 2017

14. Transgender Healthcare Mini-Symposium, Chicago Medical School of Rosalind Franklin University, North Chicago, Il March 10, 2017.

15. Moderator: Penile Transplant: Genito-urinary trauma/penile cancer, The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

## FACULTY SPONSORED RESEARCH:

1. Societa Italiana Di Microchirurgia, XXIII Congresso Nazionale della Societa Italiana di Microchirurgia, First Atlanto-Pacific Microsurgery Conference, Modena, Italy, October 1-3, 2009, "Free Tissue Transfer in the Treatment of Zygomycosis." Presented by Michelle Roughton, MD

2. Hines/North Chicago VA Research Day, Edward Hines, Jr., VA Hospital, Maywood, Il, April 29, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

3. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Breast MRI Helps to Define the Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

4. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Achieving Soft Tissue Coverage of Complex Upper and Lower

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Extremity Defects with Omental Free Tissue Transfer." Presented by Iris A. Seitz, MD, PhD.

5. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010, "Facilitating Harvest of the Serratus Fascial Flap with Ultrasonic Dissection." Presented by Iris A. Seitz, MD, PhD.

6. Advocate Research Forum, Advocate Lutheran General Hospital, May 5, 2010,"Patient Safety: Abdominoplasty and Intra-Abdominal Procedures." Presented by Michelle Roughton, MD

7. The Midwestern Association of Plastic Surgeons, 49<sup>th</sup> Annual Scientific Meeting, May 15<sup>th</sup>, 2010, "Breast MRI Helps Define The Blood Supply to the Nipple-Areolar Complex." Presented by Iris A. Seitz, MD, PhD.

8. Jonathan M. Hagedorn, BA, **Loren S. Schechter**, MD, FACS, Dr. Manoj R. Shah, MD, FACS, Matthew L. Jimenez, MD, Justine Lee, MD, PhD, Varun Shah. Re-examining the Indications for Limb Salvage, 2011 All School Research Consortium at Rosalind Franklin University. Chicago Medical School of Rosalind Franklin University, 3/16/11.

9. Jonathan Bank, MD, Lucio A. Pavone, MD, Iris A. Seitz, Michelle C. Roughton, MD, Loren S. Schechter, MD Deep Inferior Epigastric Perforator Flap for Breast Reconstruction after Abdominoplasty The Midwestern Association of Plastic Surgeons, 51st Annual Educational Meeting, April 21-22, 2012, Northwestern Memorial Hospital, Chicago, Illinois

10. Samuel Lake, Iris A. Seitz, MD, Phd, Loren S. Schechter, MD, Daniel Peterson, Phd Omentum and Subcutaneous Fat Derived Cell Populations Contain hMSCs Comparable to Bone Marrow-Derived hMSCsFirst Place, Rosalind Franklin University Summer Research Poster Session

11. J. Siwinski, MS II, Iris A. Seitz, MD PhD, Dana Rioux Forker, MD, Lucio A. Pavone, MD, Loren S Schechter, MD FACS. Upper and Lower Limb Salvage With Omental Free Flaps: A Long-Term Functional Outcome Analysis. Annual Dr. Kenneth A. Suarez Research Day, Midwestern University, Downers Grove, IL, May 2014

12. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter** LS. A Case Report: Penile Prosthesis With an Alloderm Wrap Positioned After Radial Forearm Phalloplasty. Poster session presented at: American Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

13. Whitehead DM, Kocjancic E, Iacovelli V, Morgantini LA, **Schechter** LS. An Innovative Technique: Single Stage Urethral Reconstruction in Female-to-Male Patients. Poster session presented at: American Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 51 of 242

Society for Reconstructive Microsurgery Annual Meeting, 2018 Jan 13-16; Phoenix, AZ.

14. Whitehead, DM Inflatable Penile Prosthesis Implantation Post Phalloplasty: Surgical Technique, Challenges, and Outcomes, MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

15. Whitehead, DM, Inverted Penile Skin With Scrotal Graft And Omission of Sacrospinal Fixation: Our Novel Vaginoplasty Technique MAPS 2018 Annual Scientific Meeting, April 14, 2018, Chicago, Il

#### Keynote Address:

1. University of Utah, Gender Confirmation Surgery, Transgender Provider Summit, November 8, 2014

#### **INVITED LECTURES:**

1. Management of Soft Tissue Injuries of the Face, Grand Rounds, Emergency Medicine, The University of Chicago, August, 1999

2. Case Report: Excision of a Giant Neurofibroma, Operating Room Staff Lecture Series, Continuing Education Series, St. Francis Hospital, Evanston, Il March 2000

3. Wounds, Lincolnwood Family Practice, Lincolnwood, Il April 2000

4. The Junior Attending, Grand Rounds, Plastic and Reconstructive Surgery, The University of Chicago, June 2000

5. Case Report: Excision of a Giant Neurofibroma, Department of Medicine Grand Rounds, St. Francis Hospital, Evanston, Il June 2000

6. Facial Trauma, Resurrection Medical Center Emergency Medicine Residency, September 2000

7. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Evanston Hospital, September, 2000

8. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Rush North Shore Medical Center, October, 2000

9. Reconstructive Surgery of the Breast, Professional Lecture Series on Breast Cancer, St. Francis Hospital, October, 2000

10. Plastic Surgery of the Breast and Abdomen, Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, December, 2000

11. Change of Face; Is Cosmetic Surgery for You?, Adult Education Series, Lutheran General Hospital and The Arlington Heights Public Library, December, 2000

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12. Updates in Breast Reconstruction, The Breast Center, Lutheran General Hospital, January 2001

13. Abdominal Wall Reconstruction, Trauma Conference, Lutheran General Hospital, February 2001

14. Wound Care, Rush North Shore Medical Center, March 2001

15. Breast Reconstruction, Diagnosis and Treatment Updates on Breast Cancer, Lutheran General Hospital, April 2001

16. Wound Care and V.A.C. Therapy, Double Tree Hotel, Skokie, Il October 2001

17. The Role of the V.A.C. in Reconstructive Surgery, LaCrosse, WI November 2001

18. Dressing for Success: The Role of the V.A.C. in Reconstructive Surgery, Grand Rounds, The University of Minnesota Section of Plastic and Reconstructive, Minneapolis, MN January, 2002

19. The Vacuum Assisted Closure Device in the Management of Complex Soft Tissue Defects, Eau Claire, WI February, 2002

20. The Vacuum Assisted Closure Device in Acute & Traumatic Soft Tissue Injuries, Orland Park, Il March, 2002

21. Body Contouring After Weight Loss, The Gurnee Weight Loss Support Group, Gurnee, Il April, 2002

22. An Algorithm to Complex Soft Tissue Reconstruction With Negative Pressure Therapy, Owensboro Mercy Medical Center, Owensboro, Ky, April, 2002

23. Breast and Body Contouring, St. Francis Hospital Weight Loss Support Group, Evanston, Il April, 2002

24. The Wound Closure Ladder vs. The Reconstructive Elevator, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il, May, 2002.

25. An Algorithm for Complex Soft Tissue Reconstruction with the Vacuum Assisted Closure Device, The Field Museum, Chicago, Il, May, 2002

26. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Kinetic Concepts, Inc. San Antonio, Texas, July 31, 2002

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27. Management of Complex Soft Tissue Injuries of the Lower Extremity, Chicago Trauma Symposium, August 2-5, 2002, Chicago, Illinois:

28. Wound Bed Preparation, Smith Nephew, Oak Brook, Il, August 6, 2002

29. Getting Under Your Skin...Is Cosmetic Surgery for You?, Rush North Shore Adult Continuing Education Series, Skokie, Il August 28, 2002.

30. The Role of Negative Pressure Therapy in Complex Soft Tissue Wounds, Columbia/St. Mary's Wound, Ostomy, and Continence Nurse Program, Milwaukee, Wi, September 17, 2002

31. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy and Rehabilitation Medicine, Lutheran General Hospital, September 19, 2002

32. The Role of Negative Pressure Wound Therapy in Reconstructive Surgery, Ann Arbor, Mi September 26, 2002

33. Dressing for Success: The Role of the Vaccuum Assisted Closure Device in Plastic Surgery, Indianopolis, In November 11, 2002

34. The Wound Closure Ladder Versus the Reconstructive Elevator, Crystal Lake, Il November 21, 2002

35. A Systematic Approach to Functional Restoration, Grand Rounds, Dept. of Physical Therapy, Evanston Northwestern Healthcare, Evanston, Il February 13, 2003

36. Case Studies in Traumatic Wound Reconstruction, American Association of Critical Care Nurses, Northwest Chicago Area Chapter, Park Ridge, Il February 19, 2003

37. Reconstruction of Complex Soft Tissue Injuries of the Lower Extremity, Podiatry Lecture Series, Rush North Shore Medical Center, Skokie, Il March 5, 2003

38. The Use of Negative Pressure Wound Therapy in Reconstructive Surgery, Kalamazoo, Mi March 19, 2003

39. Updates in Breast Reconstruction, The Midwest Clinical Conference, The Chicago Medical Society, Chicago, Il March 21, 2003

40. Updates of Vacuum Assisted Closure, Grand Rounds, The Medical College of Wisconsin, Department of Plastic Surgery, Milwaukee, Wi March 26, 2003 Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 54 of 242

41. Breast Reconstruction, Surgical Grand Rounds, Lutheran General Hospital, Park Ridge, Il March 27, 2003

42. Decision-Making in Breast Reconstruction: Plastic Surgeons as Members of a Multi-Disciplinary Team, 1st Annual Advocate Lutheran General Hospital Breast Cancer Symposium, Rosemont, Il, April 11, 2003

43. The Wound Closure Ladder Versus The Reconstructive Elevator, Duluth, Mn, April 24, 2003

44. Dressing For Successs: The Role of The Wound VAC in Reconstructive Surgery, Detroit, Mi, May 9, 2003

45. Plastic Surgery Pearls, Grand Rounds Orthopedic Surgery Physician Assistants Lutheran General Hospital and Finch University of Health Sciences, Park Ridge, Il, June 5, 2003

46. A Systematic Approach to Complex Reconstruction, 12<sup>th</sup> Annual Vendor Fair "Surgical Innovations," October 18, 2003, Lutheran General Hospital, Park Ridge, Il 2003

47. Dressing For Success: The Role of the Wound VAC in Reconstructive Surgery, American Society of Plastic Surgery, October 26, 2003, San Diego, CA

48. Beautiful You: From Botox to Weekend Surgeries, 21<sup>st</sup> Century Cosmetic Considerations, March 21, 2004 Hadassah Women's Health Symposium, Skokie, Il

49. Updates in Breast Reconstruction, The 2<sup>nd</sup> Annual Breast Cancer Symposium, Advocate Lutheran General, Hyatt Rosemont, April 2, 2004

50. Head and Neck Reconstruction, Grand Rounds, The University of Illinois Metropolitan Group Hospitals Residency in General Surgery, Advocate Lutheran General Hospital, May 6, 2004

51. Abdominal Wall Reconstruction, Surgeons Forum, LifeCell Corporation, May 15, 2004, Chicago, Il

52. 4<sup>th</sup> Annual Chicagoland Day of Sharing for Breast Cancer Awareness, Saturday, October 2, 2004, Hoffman Estates, Il

53. Abdominal Wall Reconstruction, University of Illinois Metropolitan Group Hospitals Residency in General Surgery, November 19, 2004, Skokie, Il

54. Advances in Wound Care, Wound and Skin Care Survival Skills, Advocate Good Samaritan Hospital, Tuesday, February 8, 2005, Downer's Grove, Il Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 55 of 242

55. Plastic Surgery: A Five Year Perspective in Practice, Grand Rounds, The University of Chicago, May 18, 2005, Chicago, Il

56. New Techniques in Breast Reconstruction, The Cancer Wellness Center, October 11, 2005 Northbrook, Il

57. Principles of Plastic Surgery; Soft Tissue Reconstruction of the Hand, Rehab Connections, Inc., Hand, Wrist, and Elbow Forum, October 28, 2005, Homer Glen, Il

58. Principles of Plastic Surgery, Lutheran General Hospital Quarterly Trauma Conference, November 9, 2005, Park Ridge, Il

59. Principles of Plastic Surgery, Continuing Medical Education, St. Francis Hospital, November 15, 2005, Evanston, Il

60. Dressing for Success: A Seven Year Experience with Negative Pressure Wound Therapy, Kinetic Concepts Inc, November 30, 2005, Glenview, Il.

61. Breast Reconstruction: The Next Generation, Breast Tumor Conference, Lutheran General Hospital, May 9, 2006.

62. Complex Wound Care: Skin Grafts, Flaps, and Reconstruction, The Elizabeth D. Wick Symposium on Wound Care, *Current Concepts in Advanced Healing: An Update*, Rush North Shore Medical Center, November 4, 2006.

63. An Approach to Maxillofacial Trauma: Grand Rounds, Lutheran General Hospital/Univ. of Illinois Metropolitan Group Hospital Residency in General Surgery, November 9, 2006.

64. "From Paris to Park Ridge", Northern Trust and Advocate Lutheran General Hospital, Northern Trust Bank, June 7, 2007.

65. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, The University of Chicago, Section of Plastic Surgery.

66. "Meet the Experts on Breast Cancer," 7<sup>th</sup> Annual Chicagoland Day of Sharing, Sunday, April 13<sup>th</sup>, 2008

67. Gender Confirmation Surgey: Surgical Options and Decision-Making, The University of Minnesota, Division of Human Sexuality, May 10, 2008, Minneapolis, Minnesota.

68. "Private Practice Plastic Surgery: A Seven Year Perspective," Grand Rounds, Loyola University, 2008 Section of Plastic Surgery.

69. "Management of Lower Extremity Trauma," Grand Rounds, The University of Chicago, Section of Plastic Surgery, October, 8, 2008.

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70. "Concepts in Plastic Surgery: A Multi-Disciplinary Approach," Frontline Surgical Advancements, Lutheran General Hospital, November 1, 2008

71. "Surgical Techniques-New Surgical Techniques/Plastic Surgery/Prosthetics," Caldwell Breast Center CME Series, Advocate Lutheran General Hospital, November 12, 2008

72. "Genetics: A Family Affair" Panel Discussion: Predictive Genetic Testing, 23<sup>rd</sup> Annual Illinois Department of Public Health Conference, Oak Brook Hills Marriott Resort, Oak Brook, Il, March 18, 2009

73. "Gender Confirmation Surgery" Minnesota TransHealth and Wellness Conference, May 15, 2009, Metropolitan State University, Saint Paul, MN.

74. "The Role of Plastic Surgery in Wound Care, " Practical Wound Care A Multidisciplinary Approach, Advocate Lutheran General Hospital, October 9-10, 2009, Park Ridge, Il.

75. "In The Family," Panel, General Session III, 2009 Illinois Women's Health Conference, Illinois Dept. of Health, Office of Women's Health October 28-29, 2009, Oak Brook, Il.

76. "Patient Safety in Plastic Surgery," The University of Chicago, Section of Plastic Surgery, Grand Rounds, November 18, 2009.

77. "Compartment Syndrome," 6<sup>th</sup> Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

78. "Maxillofacial Trauma," 6<sup>th</sup> Annual Advocate Injury Institute Symposium, Trauma 2009: Yes We Can!, November 19-20, 2009.

79. "Management of Complex Lower Extremity Injuries," Grand Rounds, The Section of Plastic Surgery, The University of Chicago, December 16, 2009, Chicago, Il.

80. "Gender-Confirming MTF Surgery: Indications and Techniques," Working Group on Gender, New York State Psychiatric Institute, March 12, 2010

81. "Gender-Confirmation Surgery," Minnesota Trans Health and Wellness Conference, Metropolitan State University, St. Paul Campus, May 14<sup>th</sup>, 2010

82. "Physical Injuries and Impairments," Heroes Welcome Home The Chicago Association of Realtors, Rosemont, Illinois, May 25<sup>th</sup>, 2010.

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83. "Genetics and Your Health," Hadassah Heals: Healing Mind, Body, & Soul, Wellness Fair, 2010, August 29, 2010, Wilmette, Illinois.

84. "GCS," Southern Comfort Conference 2010, September 6-11, 2010, Atlanta, GA.

85. "Gender Confirming Surgery," The Center, The LGBT Community Center, October 22, 2010 New York, NY.

86. "Gender Confirming Surgery," the Center, The LGBT Community Center, May 20, 2011, New York, NY.

87. "Gender Confirming Surgery," Roosevelt-St. Lukes Hospital, May 20, 2011, New York, NY

88. "Principles of Plastic Surgery," Learn about Ortho, Lutheran General Hospital, May 25, 2011, Park Ridge, Il.

89. "Forging Multidisciplinary Relationships in Private Practice," Chicago Breast Reconstruction Symposium 2011, September 9, 2011, Chicago, Il

90. "Gender Confirming Surgery," Minnesota TransHealth and Wellness Conference, Diverse Families: Health Through Community, September 10, 2011, Minneapolis, Minnesota

91. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 16, 2011, Chicago, Il

92. "Facial Trauma," 8<sup>th</sup> Annual Advocate Injury Institute Symposium, Trauma 2011: 40 years in the Making, Wyndham Lisle-Chicago, November 9-10, 2011

93. "Establishing a Community-Based Microsurgical Practice," QMP Reconstructive Symposium, November 18-20, 2011, Chicago, Il

94. "Surgery for Gender Identity Disorder," Grand Rounds, Dept. of Obstetrics and Gynecology, Northshore University Health System, December 7, 2011

95. "Managing Facial Fractures," Trauma Grand Rounds, Lutheran General Hospital, Park Ridge, Il July 17, 2012

96. "Principles of Transgender Medicine," The University of Chicago Pritzker School of Medicine, Chicago, Il, September 7, 2012

97. "State of the art breast reconstruction," Advocate Health Care, 11<sup>th</sup> Breast Imaging Symposium, January 26, 2013, Park Ridge, Il.

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98. "State of the art breast reconstruction," Grand Rounds, Dept. of Surgery, Mount Sinai Hospital, April 25, 2013, Chicago, Il.

99. "Getting under your skin: is cosmetic surgery right for you?" Lutheran General Hospital community lecture series, May 7, 2013, Park Ridge, Il.

100. "Gender Confirming Surgery," University of Chicago, Pritzker School of Medicine, Anatomy Class, September 27, 2013, Chicago, Il

101. "State of the Art Breast Reconstruction," Edward Cancer Center, Edward Hospital, October 22, 2013, Naperville, Il

102. "Transgender Medicine and Ministry," Pastoral Voice, Advocate Lutheran General Hospital, October 23, 2013, Park Ridge, Il

103. "Principles of Transgender Medicine and Surgery," The University of Illinois at Chicago College of Medicine, January 28, 2014, Chicago, Il

104. "Principles of Transgender Medicine and Surgery," Latest Surgical Innovations and Considerations, 22<sup>nd</sup> Annual Educational Workshop, Advocate Lutheran General Hospital, March 1, 2014, Park Ridge, Il.

105. "Principles of Transgender Medicine: Gender Confirming Surgery," Loyola University Medical Center, March 12, 2014.

106. "Principles of Plastic Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, Lutheran General Hospital, September 12, 2014.

107. "Gender Confirmation Surgery," The University of Chicago, Pritzker School of Medicine, October 3, 2014

108. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgical Administrators/The American Society of Plastic Surgery Assistants, Chicago, Il, October 11, 2014.

109. "Private Practice: Is There a Future?" The Annual Meeting of The American Society of Plastic Surgery Nurses, Chicago, Il, October 12, 2014.

110. "Gender Confirmation Surgery" Grand Rounds, The University of Minnesota, Dept. of Plastic Surgery, Minneapolis, MN, October 29, 2014.

111. "Body Contour After Massive Weight Loss," The Bariatric Support Group, Advocate Lutheran General Hospital, February 5, 2015, Lutheran General Hospital, Park Ridge, Il. Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 59 of 242

112. "Gender Confirmation Surgery," The School of the Art Institute of Chicago, February 1, 2015, Chicago, Il.

113. "Gender Confirmation Surgery," The Community Kinship Life/Bronx Lebanon Department of Family Medicine, Bronx, NY, March 6, 2015

114. "Gender Confirmation Surgery," Educational Inservice, Lutheran General Hospital, Park Ridge, Il, April 20, 2015

115. "Principles of Plastic Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

116. "Updates on Gender Confirmation Surgery, " Surgical Trends, Lutheran General Hospital, Park Ridge, Il, May 16, 2015

117. "Gender Confirmation Surgery," Lurie Childrens' Hospital, Chicago, Il, May 18, 2015, Chicago, Il 2015.

118. "Gender Confirmation Surgery," TransClinical Care and Management Track Philadelphia Trans-Health Conference, June 5, 2015, Philadelphia, Pa.

119. "Gender Confirmation Surgery: A Fifteen Year Experience," Grand Rounds, The University of Minnesota, Plastic and Reconstructive Surgery and the Program in Human Sexuality, July 30, 2015, Minneapolis, Mn

120. "Gender Confirmation Surgery," Grand Rounds, Tel Aviv Medical Center, Tel Aviv, Israel, August 13, 2015

121. "Gender Confirmation Surgery," Grand Rounds, University of Illinois, Dept of Family Medicine, September 2, 2015

122. "Principles of Plastic Surgery," Grand Rounds, St. Francis Hospital, Evanston, Il September 18, 2015

123. "Gender Confirmation Surgery," Midwest LGBTQ Health Symposium, Chicago, Il, October 2, 2015

124. "Gender Confirmation Surgery," Southern Comfort Conference, Weston, Fl, October 3, 2015

125. "Surgical Transitions for Transgender Patients," Transgender Health Training Institute, Rush University Medical Center, Chicago,Il, October 8, 2015

126. "Gender Confirmation Surgery," The Transgender Health Education Peach State Conference, Atlanta, GA, October 30, 2015

127. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 4, 2015, Chicago, Il Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 60 of 242

128. "Gender Confirmation Surgery," University of Illinois at Chicago, Operating Room Staff Inservice, November 18, 2015, Chicago, Il

129. "Gender Confirmation Surgery," University of Illinois at Chicago, Plastic Surgery and Urology Inservice, November 18, 2015, Chicago, Il

130. "Gender Confirmation Surgery," Weiss Memorial Medical Center, November 19, 2015, Chicago, Il

131. "Gender Confirmation Surgery," Section of Plastic Surgery, The University of Illinois at Chicago, January 13, 2016, Chicago, Il

132. "Gender Confirmation Surgery," Dept. of Medicine, Louis A. Weiss Memorial Hospital, February 18, 2016, Chicago, Il

133. "Gender Confirmation Surgery," BCBSIL Managed Care Roundtable March 2, 2016 Chicago, Il

134. "Gender Confirmation Surgery-MtF," Keystone Conference, March 10, 2016, Harrisburg, PA

135. "Gender Confirmation Surgery-FtM," Keystone Conference, March 10, 2016, Harrisburg, PA

136. "Gender Confirmation Surgery," Grand Rounds, Dept. of Ob-Gyn, March 25, 2016, Lutheran General Hospital, Park Ridge, Il 60068

137. "Surgical Management of the Transgender Patient," Spring Meeting, The New York Regional Society of Plastic Surgeons, April 16, 2016, New York, NY

138. "A Three Step Approach to Complex Lower Extremity Trauma," University of Illinois at Chicago, April 27, 2016, Chicago, Il.

139. "Gender Confirmation Surgery," Howard Brown Health Center, July 12, 2016, Chicago, Il

140. "Creating the Transgender Breast M-F; F-M", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

141. "Overview of Transgender Breast Surgery," ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016

142. "VTE Chemoprophylaxis in Cosmetic Breast and Body Surgery: Science or Myth", ASPS Breast surgery and Body Contouring Symposium, Santa Fe, NM, August 25-27, 2016 Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 61 of 242

143. "Gender Confirmation Surgery," Gender Program, Lurie Childrens', Parent Group, September 20, 201, 467 W. Deming, Chicago, Il

144. "Gender Confirmation Surgery," The American Society of Plastic Surgeons Expo, September 24, 2016, Los Angeles, CA

145. Transgender Surgery, Management of the Transgender Patient, Female to Male Surgery, Overview and Phalloplasty, The American College of Surgeons, Clinical Congress 2016 October 16-20,2016 Washington, DC

146. "Gender Confirmation Surgery," The Department of Anesthesia, The University of Illinois at Chicago, November 9, 2016

147. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 14, 2016

148. "Gender Confirmation Surgery," Nursing Education, The University of Illinois at Chicago, January 10, 2017

149. "F2M-Radial Forearm Total Phalloplasty: Plastic Surgeon's Point of View," The European Association of Urologists, Meeting of the EAU Section of Genito-Urinary Reconstructive Surgeons (ESGURS), London, United Kingdom, March 23-26, 2017

150. "Gender Confirmation Surgery," Grand Rounds, The Department of Surgery, The University of North Carolina, March 29, 2017.

151. "Transgender Facial Surgery," The Aesthetic Meeting 2017 - 50 Years of Aesthetics - in San Diego, California April 27- May 2, 2017.

152. "Gender Confirmation Surgery: A New Surgical Frontier," 15<sup>th</sup> Annual Morristown Surgical Symposium Gender and Surgery, Morristown, NJ, May 5, 2017.

153. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, The Medical College of Wisconsin, May 24, 2017

154. "Gender Confirmation Surgery: A New Surgical Frontier," Dept. of Obstetrics and Gynecology, Howard Brown Health Center, August 8, 2017

155. "Current State of the Art: Gynecomastia," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017

156. "Gender Confirmation Surgery-An Overview," ASPS Breast Surgery and Body Contouring Symposium, San Diego, CA, August 10-12, 2017 Case: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 62 of 242

157. "Gender Confirmation Surgery," Grand Rounds, Dept. of Obstetrics and Gynecology, The University of Chicago, August 25, 2017

158. "Gender Confirmation Surgery," Wake Forest School of Medicine, Transgender Health Conference, Winston-Salem, NC, September 28-29, 2017

159. "Phalloplasty," Brazilian Professional Association for Transgender Health, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

160. "Gender Confirmation Surgery," Brazlian Professional Association for Transgender Health/WPATH Session, Teatro Marcos Lindenberg, Universidade Federal de São Paulo (Unifesp), November 1-4, 2017

161. "Gender Confirmation Surgery," The Division of Plastic Surgery, The University of Illinois at Chicago, December 13, 2017, Chicago, Il

162. "Gender Confirmation Surgery," Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, December 18, 2017, Chicago, Il

163. "Transgender Breast Augmentation," 34<sup>th</sup> Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

164. "Top Surgery: Transmasculine Chest Contouring," 34<sup>th</sup> Annual Atlanta Breast Surgery Symposium, January 19-21, 2018, Atlanta, GA

165. "Gender Confirmation Surgery," The 17<sup>th</sup> International Congress of Plastic and Reconstructive Surgery in Shanghai, March 18-25, 2018, Shanghai, China

166. "Gender Confirmation Surgery: Facial Feminization and Metoidioplasty," 97<sup>th</sup> Meeting of the American Association of Plastic Surgeons, Reconstructive Symposium, April 7-10, 2018, Seattle, WA

167. Moderator: "Gender Confirmation Surgery: Top Surgery", The Annual Meeting of The American Society of Aesthetic Plastic Surgery, April 26-May 1, 2018, New York, NY

# Exhibit B

#### Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

NCD 140.3, Transsexual Surgery Docket No. A-13-87 Decision No. 2576 May 30, 2014

#### DECISION

The Board has determined that the National Coverage Determination (NCD) denying Medicare coverage of all transsexual surgery as a treatment for transsexualism is not valid under the "reasonableness standard" the Board applies. The NCD was based on information compiled in 1981. The record developed before the Board in response to a complaint filed by the aggrieved party (AP), a Medicare beneficiary denied coverage, shows that even assuming the NCD's exclusion of coverage at the time the NCD was adopted was reasonable, that coverage exclusion is no longer reasonable. This record includes expert medical testimony and studies published in the years after publication of the NCD. The Centers for Medicare & Medicaid Services (CMS), which is responsible for issuing and revising NCDs, did not defend the NCD or the NCD record in this proceeding and did not challenge any of the new evidence submitted to the Board.

#### Effect of this decision

Since the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery, and local coverage determinations (LCDs) used to adjudicate such claims may not rely on the provisions of the NCD. The decision does not bar CMS or its contractors from denying individual claims for payment for transsexual surgery for other reasons permitted by law. Nor does the decision address treatments for transsexualism other than transsexual surgery. The decision does not require CMS to revise the NCD or issue a new NCD, although CMS, of course, may choose to do so. CMS may not reinstate the invalidated NCD unless it has a different basis than that evaluated by the Board. 42 C.F.R. § 426.563.

CMS must implement this Board decision within 30 days and apply any resulting policy changes to claims or service requests made by Medicare beneficiaries other than the AP for any dates of service after that implementation. With respect to the AP's claim in

particular, CMS and its contractors must "adjudicate the claim without using the provision(s) of the NCD that the Board found invalid." 42 C.F.R. § 426.560(b)(1).<sup>1</sup>

#### Legal background

With exceptions not relevant here, section 1862(a)(l)(A) of the Social Security Act (Act) (42 U.S.C. § 1395y(a)(l)(A)) bars Medicare payment for items or services "not reasonable and necessary for the diagnosis or treatment of illness or injury[.]"<sup>2</sup> CMS refers to this requirement as the "medical necessity provision." 67 Fed. Reg. 54,534, 54,536 (Aug. 22, 2002). An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Act §§ 1862(1)(6)(A),1869(f)(1)(B); *see also* 42 C.F.R. § 400.202 (NCD "means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act."). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. at 54,535. When CMS issues NCDs, they apply nationally and are binding at all levels of administrative review of Medicare claims. 42 C.F.R. § 405.1060. CMS and its contractors use applicable NCDs in determining whether a beneficiary may receive Medicare reimbursement for a particular item or service. 42 C.F.R. §§ 405.920, 405.921.

A Medicare beneficiary "in need of coverage for a service that is denied based on ... an NCD" is an "aggrieved party" who may challenge the NCD by filing a "complaint" with the Board. <sup>3</sup> Act § 1869(f)(1); 42 C.F.R. §§ 426.110, 426.320. The complaint must comply with the requirements for a valid complaint in 42 C.F.R. § 426.500 in order to be accepted by the Board. 42 C.F.R. §§ 426.510(b)(2), 426.505(c)(2). After the Board notifies CMS of the receipt of a complaint that is acceptable under the regulations, CMS produces the "NCD record," which "consists of any document or material that CMS

<sup>&</sup>lt;sup>1</sup> See generally 42 C.F.R. § 426.560(b) (setting out the effects of a Board NCD decision); 42 C.F.R. § 426.555 (specifying what the Board's decision "may not do"). This decision has no effects beyond those set out in 42 C.F.R.§ 426.560(b) and does not impose on CMS or its contractors any orders or requirements prohibited by 42 C.F.R. § 426.555.

<sup>&</sup>lt;sup>2</sup> The table of contents to the current version of the Social Security Act, with references to the corresponding United States Code chapter and sections, can be found at <u>http://www.socialsecurity.gov/OP\_Home/ssact/ssact-toc.htm</u>.

<sup>&</sup>lt;sup>3</sup> The regulations also provide that a person other than the aggrieved party with an interest in the issues may petition to participate in the review process as an amicus curiae. 42 C.F.R. §§ 426.510(f), 426.513. The Board posts on its website notice of the NCD complaint specifying a time period for requests to participate in the review. 42 C.F.R. § 426.510(f).

considered during the development of the NCD" including "medical evidence considered on or before the date the NCD was issued ...." 42 C.F.R. §§ 426.510(d)(3), 426.515, 426.518(a). The aggrieved party submits a statement "explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard," and CMS may submit a response "in order to defend the NCD." 42 C.F.R. § 426.525(a), (b). If the Board determines that the NCD record "is complete and adequate to support the validity of the NCD," the review process ends with the Board's "[i]ssuance of a decision finding the record complete and adequate to support the validity of the NCD ....." 42 C.F.R. § 426.525(c)(1), (2). If the Board determines that the record is *not* complete and adequate to support the validity of the NCD, the Board "permits discovery and the taking of evidence ... and evaluates the NCD" in accordance with the requirements of Part 426, including conducting a hearing, unless the matter can be decided on the written record. 42 C.F.R. §§ 426.525(c)(3), 426.531(a)(2).

Prior to issuing a decision, the Board must review any "new evidence" admitted to the record before the Board and determine whether it "has the potential to significantly affect" the Board's evaluation. 42 C.F.R. §§ 426.340(a), (b), 426.505(d)(3). "New evidence" is defined as "clinical or scientific evidence that was not previously considered by ... CMS before the ... NCD was issued." 42 C.F.R. § 426.110. If the Board so concludes, the Board stays proceedings for CMS "to examine the new evidence, and to decide whether [to] initiate[] ... a reconsideration" of the NCD. 42 C.F.R. § 426.340(d). If CMS does not reconsider the NCD, or reconsiders it but does not change the challenged provision, the Board lifts the stay and the NCD challenge process continues. 42 C.F.R. § 426.340(f). At the end of that process, the Board closes the record and issues a decision that the challenged "provision of the NCD is valid" or "is not valid under the reasonableness standard."<sup>4</sup> 42 C.F.R. § 426.550. The Board's decision "constitutes a final agency action and is subject to judicial review" on appeal by an aggrieved party. 42 C.F.R. § 426.566.

<sup>&</sup>lt;sup>4</sup> Section 426.547(b) states that the Board must make the decision available at the HHS Medicare Internet site and that "the posted decision does not include any information that identifies any individual, provider of service, or supplier." CMS has indicated in the preamble to the Part 426 regulations that this provision was meant to protect the privacy of Medicare beneficiaries such as the AP. *See, e.g.*, 68 Fed. Reg. 63,692, 63,708 (Nov. 7, 2003) ("Board decisions regarding NCDs will be made available on the Medicare Internet site, without beneficiary identifying information").

#### Case background

#### The NCD and the NCD record

The challenged NCD, titled "140.3, Transsexual Surgery," states:<sup>5</sup>

#### **Item/Service Description**

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingooophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses.

#### **Indications and Limitations of Coverage**

Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

NCD Record at 93. CMS's predecessor, the Health Care Financing Administration (HCFA), published the NCD in the Federal Register on August 21, 1989.<sup>6</sup> 54 Fed. Reg. 34,555, 34,572 (Aug. 21, 1989); NCD Record at 76, 78, 93, 128. The NCD quotes or paraphrases portions of an 11-page report that the former National Center for Health Care Technology (NCHCT) of the HHS Public Health Service (PHS) issued in 1981, titled

<sup>&</sup>lt;sup>5</sup> NCDs are available at <u>http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list\_type=ncd</u>.

<sup>&</sup>lt;sup>6</sup> The Federal Register notice stated, "This notice lists those current Medicare national coverage decisions which have been issued in the Medicare Coverage Issues Manual (HCFA Pub. 6)." 54 Fed. Reg. at 34,555.

"Evaluation of Transsexual Surgery" (1981 report).<sup>7</sup> NCD Record at 13-23. The NCHCT forwarded the 1981 report to HCFA with a May 6, 1981 memorandum stating that the 1981 report "concludes that transsexual surgery should be considered experimental because of the lack of proven safety and efficacy of the procedures for the treatment of transsexualism" and recommending "that transsexual surgery not be covered by Medicare at this time." *Id.* at 12.

The NCD record includes three April 1982 letters from the American Civil Liberties Union (ACLU) of Southern California disagreeing with HCFA's noncoverage determination. *Id.* at 24-25, 26, 41-42. The ACLU submitted letters and affidavits from physicians and therapists supporting the medical necessity of transsexual surgery and taking issue with the non-coverage determination. *Id.* at 27-75. On May 11, 1982, the HCFA physicians panel, by a vote of five to two, recommended against referring the ACLU's submissions to PHS, "on the basis that it does not contain information about new clinical studies or other medical and scientific evidence sufficiently substantive to justify reopening the previous PHS assessment." *Id.* at 7, 9. Thus, although the NCD was issued in 1989, it was based on the analysis of medical and scientific publications in the 1981 report.

#### The NCD complaint

The AP in this case, a Medicare beneficiary whose insurer denied a physician's order for sex reassignment surgery (transsexual surgery), filed an acceptable NCD complaint and supporting materials. CMS submitted the NCD record on May 15, 2013, and the AP submitted a statement of why the NCD record is not complete or adequate to support the validity of the NCD under the reasonableness standard (AP Statement) on June 14, 2013. The Board granted unopposed requests by six advocacy organizations to participate as amici curiae in the NCD review by filing written briefs arguing that the NCD was invalid. (Four of the amici submitted a joint brief.)<sup>8</sup>

NCD Record at 19.

<sup>8</sup> The six amici are the Human Rights Campaign (HRC) and the World Professional Association for Transgender Health (WPATH), which each submitted briefs, and the FORGE Transgender Aging Network, the National Center for Transgender Equality, the Sylvia Rivera Law Project, and the Transgender Law Center, which submitted a joint brief.

<sup>&</sup>lt;sup>7</sup> The concluding summary of the 1981 NCHTC report stated in relevant part:

Transsexual surgery for sex reassignment of transsexuals is controversial. There is a lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism. There is evidence of a high rate of serious complications of these surgical procedures. The safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned. Therefore, transsexual surgery must be considered still experimental.

On June 26, 2013, CMS notified the Board that it "declines to submit a response" to the AP's statement. On December 2, 2013, the Board ruled that the NCD record "is not complete and adequate to support the validity of the NCD[.]" *NCD 140.3, Transsexual Surgery*, NCD Ruling No. 2 (Dec. 2, 2013) (NCD Ruling).<sup>9</sup> The parties then jointly reported that they did not intend to submit additional evidence (except for curricula vitae (CVs) of the AP's witnesses) or cross-examine any witness and asked the Board to close the NCD review record to the taking of evidence and decide the case based on the written record.

The Board determined that the new evidence in the record had the potential to significantly affect its review of the NCD and, as required, stayed proceedings for 10 days for CMS to examine the new evidence and decide whether to reconsider the NCD.<sup>10</sup> *Order Closing Record & Staying Proceedings for CMS to Determine Whether to Reconsider NCD* (Feb. 25, 2014) (Order); 42 C.F.R. §§ 426.340(d), 426.505(d)(3). Two days later, CMS informed the Board by email that it "does not wish to reconsider the NCD." On February 28, 2014, the Board lifted the stay and informed the parties that it would proceed to decision.

#### The record developed before the Board

The record before the Board consists of the NCD record, the briefs submitted by the AP and the amici and evidence submitted by the AP and one of the amici, the Human Rights Campaign. Since neither party submitted argument or evidence (except for the CVs) after the Board's Ruling, the Board treats the AP statement as the AP's brief in this appeal.<sup>11</sup> The AP submitted written declarations made under penalty of perjury from a clinical psychologist and a physician, and two notarized physician letters submitted to an Administrative Law Judge in the Department of Health and Human Services Office of Medicare Hearings and Appeals in another matter. The AP described the witnesses, who are active in the field of treating transgender persons, as experts and submitted their resumes or CVs. AP Statement at 9; AP complaint; AP/CMS e-mail (Jan. 7, 2014).

<sup>&</sup>lt;sup>9</sup> The NCD Ruling is at <u>http://www.hhs.gov/dab/decisions/dabdecisions/ncd1403.pdf</u>.

<sup>&</sup>lt;sup>10</sup> The Board also published on its website notice providing an additional time period for interested parties to submit participation requests; none were received.

<sup>&</sup>lt;sup>11</sup> Most of the AP's evidence other than witness statements is an appendix of sources the clinical psychologist cited in her declaration. We refer to these materials as the AP's exhibits (AP Exs.) and cite to the page numbers used in the publications in which they appeared. In addition, the physician's declaration includes an appendix of 20 unnumbered pages of insurance regulations from four states and the District of Columbia barring exclusion of sex reassignment surgery as medically necessary treatment for severe gender dysphoria. One of the amici, the Human Rights Campaign, submitted 62 exhibits with its brief ("HRC Exs.").

CMS did not challenge the witnesses' qualifications as experts or seek to cross-examine them. We summarize their qualifications when we address their testimony below. In this decision we use the term "new evidence" to refer to the evidence submitted to us by the AP and amici to distinguish it from the evidence used to support the NCD which, as noted, consists principally of the 1981 report. Under the regulatory definition in 42 C.F.R. § 426.110, "new evidence" would also include any evidence submitted by CMS in response to an NCD complaint that was not considered by CMS before the NCD was issued. In this case, however, as we discuss below, CMS submitted no "new evidence."

#### **Standard of review**

The Board "evaluate[s] the reasonableness" of an NCD by determining whether it "is valid [or] is not valid under the reasonableness standard," which requires us to uphold the NCD "if the findings of fact, interpretations of law, and applications of fact to law by ... CMS are reasonable" based on the NCD record and the relevant record developed before us. Act § 1869(f)(1)(A)(iii); 42 C.F.R. §§ 426.110, 426.531(a), 426.550(a). The Board "defer[s] only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(1)(A)(iii); 42 C.F.R. § 426.505(b).

During the review, the aggrieved party bears the burden of proof and the burden of persuasion for the issues raised in an NCD complaint; the burden of persuasion is judged by a preponderance of the evidence. 42 C.F.R. § 426.330. CMS has explained that "[s]o long as the outcome [in the NCD] is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld," and that if CMS "has a logical reason as to why some evidence is given more weight than other evidence," the Board "may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage." 68 Fed. Reg. at 63,703.

#### <u>Analysis</u>

#### The NCD is invalid because a preponderance of the evidence in the record as a whole supports a conclusion that the NCD's stated bases for its blanket denial of coverage for transsexual surgery are not reasonable.

As previously stated, the NCD was based principally on the 1981 report findings that the safety and effectiveness of transsexual surgery had not been proven. The AP argues that these findings are not "supportable by the current state of medical science" and "not reasonable in light of the current state of scientific and clinical evidence and current medical standards of care" and are contradicted by studies conducted in the 32 years since the 1981 report. AP Statement at 6-7, 14. The amici made similar arguments. *See, e.g.*, WPATH Br. at 13 ("since [the NCD] was issued, it has been repeatedly

demonstrated that SRS [sex reassignment surgery] is safe, effective, and indisputably necessary treatment for certain individuals with severe GID [gender identity disorder]"). As we discuss below, the new evidence, which is unchallenged, indicates that the bases stated in the NCD and the NCD record for denying coverage, even assuming they were reasonable when the NCD was issued, are no longer reasonable.

#### A. The fact that the new evidence is unchallenged and the NCD record undefended is significant.

As we stated earlier, the AP has the burden of proof by a preponderance of the evidence that an NCD is invalid under a reasonableness standard. In deciding whether the AP has met this burden, we must weigh the evidence in the record before us. Thus, we consider it important to note at the outset that the only evidence before us, other than the record for the NCD, which consists principally of the 1981 report, is the new evidence submitted by the AP and the amicus HRC. CMS submitted the NCD record, as it was required to do, but has not argued that that record or any other evidence supports the NCD. CMS also did not elect to cross-examine the AP's witnesses, has not challenged their testimony or professional qualifications and joined the AP in asking the Board to decide the appeal based on the written record. See AP/CMS e-mail (Jan. 7, 2014). The preamble to the regulations that implement the NCD statute states that the "reasonableness standard . . . recognizes the expertise of ... CMS in the Medicare program-specifically, in the area of coverage requiring the exercise of clinical or scientific judgment." 68 Fed. Reg. at 63,703 (emphasis added). Accordingly, in determining whether the NCD is valid under the reasonableness standard, we must accord some deference to CMS's position, and its decision not to defend the NCD or challenge the new evidence in this case has some significance for our decision-making.

Apart from the absence of any challenge to the new evidence or defense of the NCD record, we find the new evidence credible and persuasive on its face.<sup>12</sup> We have no difficulty concluding that the new evidence, which includes medical studies published in the more than 32 years since issuance of the 1981 report underlying the NCD, outweighs the NCD record and demonstrates that transsexual surgery is safe and effective and not experimental. Thus, as we discuss below, the grounds for the NCD's exclusion of coverage are not reasonable, and the NCD is invalid.

<sup>&</sup>lt;sup>12</sup> For this reason, we found it unnecessary to exercise our independent authority to "consult with appropriate scientific or clinical experts concerning clinical and scientific evidence." *See* 42 C.F.R. § 426.531(b).

## B. The new evidence indicates acceptance of criteria for diagnosing transsexualism.

Transsexual surgery is a treatment option for the medical condition of transsexualism. The NCD recognized that transsexualism is a diagnosed medical condition. The 1981 report stated that transsexualism "is defined as an overwhelming desire to change anatomic sex stemming from the fixed conviction that one is a member of the opposite sex." NCD Record at 13, citing Dorland's Illustrated Medical Dictionary, 25<sup>th</sup> ed. The 1981 report recognized that the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders issued in 1980 (DSM III) had "included for the first time the diagnostic category of 'Transsexualism.'" NCD Record at 13. Nonetheless, the 1981 report expressed concern that diagnosing transsexualism was "problematic" because, the report contended, the criteria for establishing the diagnosis "vary from center to center and have changed over time." NCD Record at 14.

One of the AP's expert witnesses, Randi Ettner, Ph.D., a clinical psychologist, testified that the expressed basis for this concern is "completely untrue now." Ettner Supp. Decl. at  $\P$  5. Dr. Ettner stated that "Gender Identity Disorder is a serious medical condition codified in the International Classification of Diseases (10<sup>th</sup> revision; World Health Organization) and the [DSM]."<sup>13</sup> Ettner Decl. at  $\P$  10; *see also* Ettner Supp. Decl. at  $\P$  6 (similar testimony). She described the condition as follows:

The disorder is characterized by intense and persistent discomfort with one's primary and secondary sex characteristics—one's birth sex. The suffering that arises is often described as "being trapped in the wrong body." The psychiatric term for this severe and unremitting emotional pain is "gender dysphoria."

Ettner Decl. at ¶ 10. Dr. Ettner's declaration and CV state that she has a doctorate in psychology, has evaluated or treated between 2,500 and 3,000 individuals with GID and mental health issues related to gender variance, has published three books, including *Principles of Transgender Medicine and Surgery*, has authored articles in peer-reviewed journals, and is a member of the board of directors of the World Professional Association for Transgender Health (WPATH) and an author of the WPATH Standards of Care for

<sup>&</sup>lt;sup>13</sup> The record indicates that the term "transsexualism" that was used in the NCD and the DSM-III was succeeded in the DSM-IV and DSM-V by the terms "Gender Identity Disorder" (GID) and "gender dysphoria." AP Statement at 1 n.1; Ettner Supp. Decl. at  $\P$  6; Hsiao Decl. at  $\P$  11; AP Ex. 7, at 208; WPATH Br. at 2 n.3. In this decision, we use the term "transsexualism" because it is used in the NCD, but our decision should be read as encompassing the successor terminology as well.

the Health of Transsexual, Transgender, and Gender-Nonconforming People. *Id.* at ¶¶ 3-6; *see also Sundstrom v. Frank*, 630 F. Supp. 2d 974, 986-87 (E.D.Wis. 2007) ("Dr. Ettner's experience speaks for itself ... the doctor has conducted research and has been an instructor specializing in the etiology, diagnosis and treatment of GID [and] is the editor of a medical textbook in which she wrote the chapter of that book on the etiology of GID. The court finds that Dr. Ettner is sufficiently qualified to provide expert testimony.").

We find nothing in the new evidence that would undercut Dr. Ettner's statement. The DSM-IV-TR (text revision), published in 2000, continues to recognize "transsexualism" as a diagnosed medical condition, although it refers to the same disorder as GID and identifies criteria for diagnosing GID in adolescents and adults that are consistent with Dr. Ettner's description, albeit more detailed. The criteria include "strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex)" that is "manifested by symptoms such as a stated desire to be the other sex, frequent passing as the other sex, desire to live or be treated as the other sex, or the conviction that he or she has the typical feelings and reactions of the other sex;" "[p]ersistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex" that is "manifested by symptoms such as preoccupation with getting rid of primary and secondary sex characteristics (e.g., request for hormones, surgery, or other procedures to physically alter sexual characteristics to simulate the other sex) or belief that he or she was born the wrong sex;" and "[t]he disturbance is not concurrent with a physical intersex condition." AP Ex. 4, at 581. The DSM-IV-TR states that if GID is present in adults, "[t]he disturbance can be so pervasive that the mental lives of some individuals revolve only around those activities that lessen gender distress." Id. at 576, 78. The WPATH brief indicates that transsexualism or GID remains a diagnostic category in the fifth edition of the DSM issued in 2013 (DSM-V), which uses the term "Gender Dysphoria." WPATH Br. at 2, n.3.

The DSM has been recognized as a primary diagnostic tool of American psychiatry. *See O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, at 60 (2010) (stating "all three experts agree [that the DSM-IV-TR] is the primary diagnostic tool of American psychiatry"); *see also* AP Ex. 3, at 1<sup>14</sup> (resolution of American Medical Association House of Delegates noting the DSM description of GID as "a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering" that "if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death").

<sup>&</sup>lt;sup>14</sup> American Medical Association House of Delegates, *Resolution 122 (A-08), Removing Financial Barriers to Care for Transgender Patients* (2008).

We conclude that to the extent the NCD was based on concerns expressed in the NCD record about problems diagnosing transsexualism, that concern is unreasonable based on the new evidence.

#### C. The new evidence indicates that transsexual surgery is safe.<sup>15</sup>

The 1981 report stated that transsexual surgery "cannot be considered safe because of the high complication rates." NCD Record at 18. The 1981 report identified surgical complications including "rectovaginal fistulas, perineal abscesses, introital and deep vaginal stenosis, and vaginal shortening" in male-to-female (MF) patients, and "rejection of the testicular implants, scrotal fusion, and phalloplasty infections" in female-to-male (FM) patients, and states that "[m]ultiple complications for individual patients and secondary surgeries to correct complications or to improve on undesirable results are not uncommon." *Id.* at 15 (citations omitted). The AP argues that "advancements in surgical techniques have dramatically reduced the risk of complications from sex reassignment surgery and the rates of serious complications from such surgeries are low" and that the studies cited in the 1981 report "evaluated outdated surgical techniques that have been replaced with improved, safer procedures." AP Statement at 7, 10. The new evidence supports the AP.

Expert witness Katherine Hsiao, M.D., testified that hysterectomies and mastectomies are common procedures used to treat gender GID in transgender men (FM) and "are routinely performed in other contexts, such as in cases of breast cancer, ovarian cancer, uterine cancer and/or cervical cancer . . . ." Hsiao Decl. at ¶ 11. These procedures, she stated, "have low rates of complications" and are "generally identical whether performed on transgender men to treat gender dysphoria or to treat women for these other conditions."<sup>16</sup> *Id.* Dr. Hsiao also stated that "insurance companies routinely cover the costs associated" with hysterectomies. *Id.* Dr. Hsiao testified that based on her own practice of providing surgery to transgender men, "gender affirming surgeries for transgender men are extremely safe and have very low rates of serious complications,"

Hsiao Decl. at ¶ 9.

<sup>&</sup>lt;sup>15</sup> We are unable to discuss in the space of this decision all of the new evidence and see no need to do so since it is all unchallenged. However, we find nothing in the new evidence not discussed that would alter our conclusion that the NCD is invalid, at least absent argument or counter-evidence from CMS. We have attached to this decision an Overview of the Scientific Literature in the New Evidence.

<sup>&</sup>lt;sup>16</sup> Dr. Hsiao testified without contradiction that a "serious complication" of surgery-

is generally understood among surgeons to include death, conditions requiring an unplanned admission to the Intensive Care Unit or unplanned readmission to the hospital within 30 days, severe hemorrhage requiring transfusion of several units of blood product, permanent disability, an intraoperative injury requiring an unplanned intervention during the surgical procedure, permanent brain damage, or cardiac arrest.

that she has performed hysterectomies for transgender men for the past ten years and that those procedures "are generally identical to the ones I perform on women to treat early cancer or other conditions." *Id.* at  $\P$  20. Dr. Hsiao reports having "typically performed multiple obstetrical, gynecologic, or other pelvic surgeries every week, including but not limited to hysterectomies and other advanced pelvic surgeries targeting the reproductive system and adjacent organs . . . ." *Id.* at  $\P$  6. Dr. Hsiao's declaration and CV indicate that she is certified by the American Board of Obstetrics and Gynecology, is the chief of the division of gynecology and the director of Ob/Gyn resident education at a California medical center and an assistant clinical professor in the department of obstetrics, gynecology and reproductive medicine at the University of California at San Francisco. *Id.* at  $\P$  3-6; CV.

Dr. Hsiao further stated, regarding MF transsexual surgery, that she has been part of a surgical team that performed surgery to create a neovagina in women born with a congenital "complete or partial absence of a vagina, cervix, and uterus," a condition called Mayer-Rokitansky-Kuster-Hauser syndrome, or MRKH. Hsiao Decl. at ¶ 12. She stated that this procedure has "a low rate of complications," and that the associated surgical costs are, in her experience, "routinely cover[ed]" by insurance companies for women born with MRKH. She stated that while women with MRKH "can never have biological children … the role of surgery is essential to affirm their gender identity and to align their anatomy with that identity." *Id*.

Dr. Ettner stated that "[t]here is no scientific or medical basis" for the NCD's statement that sex reassignment surgery has not been proven safe and has a high rate of serious complications; that the "[r]ates of complications during and after sex reassignment surgery are relatively low, and most complications are minor;" and that the risk of complications "has, moreover, been dramatically reduced since 1985." Ettner Decl. at ¶¶ 32, 34. Dr. Ettner testified that during eight years at the Chicago Gender Clinic she "regularly consulted with our surgeon" and is "aware of only two major surgical complications, both of which were immediately repaired." Id. at  $\P$  36. She stated that the clinic "as a whole has a 12 percent complication rate for genital surgery" and that "the vast majority of those complications [were] minor, all were easily corrected, and none involved surgical site infection or readmission." Id. Dr. Ettner stated the 1981 report's discussion of surgical complication rates was "outdated and irrelevant based on current medical practices and procedures." Ettner Supp. Decl. at ¶ 9. In particular, she stated that one of the studies cited in the 1981 report's discussion of complications (Laub & Fisk 1974) reflected the use of a MF surgical technique that "led to unacceptably high rates of fistulae and other complications" and was later abandoned by the study's authors. *Id.* at ¶ 10.

Another of the AP's expert witnesses, Marci L. Bowers, M.D., stated in her notarized letter that in her experience of performing gender-related surgeries, transsexual surgery "does not have a higher rate of complication than any other surgery, and in fact has very

few complications, which are mainly minor in nature." Bowers Letter at 1 (Mar. 5, 2013), Att. to AP Statement. Dr. Bowers stated that she performs approximately 220 gender-related surgeries annually and has performed over 1000 "Male to Female Gender Corrective Surgeries." *Id.* Her CV indicates that she has served as the Chair of the Department of Obstetrics and Gynecology at the Swedish (Providence) Medical Center in Seattle.

The fourth expert witness, Sherman N. Leis, M.D., stated that he personally "perform[s] several gender reassignment procedures each week" and has "seen only relatively minor complications which are easily treated" and has "thus far seen no life threatening complications from any of the transgender surgeries" he has performed. Leis Letter at 2 (Feb. 28, 2013), Att. to AP Statement. Dr. Leis's letter and CV indicate that he is Board-certified in plastic and reconstructive surgery and in general surgery. *Id.* at 1.

The testimony of Drs. Ettner and Hsiao is based on studies as well as personal experience. Dr. Hsiao testified that she reviewed five studies in the AP exhibits "that include complication rate data and information for gender affirming surgeries performed in recent years" and that "[n]one of these five studies reported high rates of serious complications." Hsiao Decl. at ¶¶ 13-14, citing studies at AP Exs. 2, 9, 14, 21, 28. She stated that "almost all of the complications listed in these studies, such as urinary incontinence or retention, stenosis or stricture, bleeding, recto-vaginal fistula, and partial necrosis, are not specific to sex reassignment surgeries, but rather are known potential side effects of any type of urogenital surgery which are covered by Medicare." Id. at ¶ 15. She further testified that "every complication tracked in [Jarolim, et al. (2009)] for instance, falls into this category and none of them are serious;" that "[t]he Spehr (2007) study includes similar types of complications at very low rates;" and that "none of the complications listed in Lawrence (2006) are serious and many of them are consistent with what would be potential, expected outcomes for any urogenital surgery." Id. at 15-17, citing studies at AP Exs. 14,<sup>17</sup> 21,<sup>18</sup> 28.<sup>19</sup> She also stated that of the four "potentially serious" complications noted in the Amend (2013) study of 24 MF patients, none "were serious as that term is generally understood." *Id.* at  $\P$  14, citing study at AP Ex. 2.<sup>20</sup>

<sup>20</sup> Bastian Amend, et al., *Surgical Reconstruction for Male-to-Female Sex Reassignment*, 64 Eur. Urol. 1-9 (2013).

<sup>&</sup>lt;sup>17</sup> Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009).

<sup>&</sup>lt;sup>18</sup> Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006).

<sup>&</sup>lt;sup>19</sup> Christiane Spehr, *Male-to-Female Sex Reassignment Surgery in Transsexuals*, 10 Int'l J. Transgenderism 25-37 (2007).

Dr. Hsiao further stated that Eldh et al. (1997) compared complication rates for surgeries

performed before and after 1986 and showed that "[n]early all of the surgical complication rates decreased significantly over time." Hsiao Decl. at ¶ 18, citing study at AP Ex. 9.<sup>21</sup> Dr. Hsiao stated that "fistulas, in particular, which are a risk of many urogenital surgeries, decreased from 18 percent in surgeries before 1986 to only 1 percent between 1986 and 1995," and that "the only fistula that occurred after 1985 'closed spontaneously,' meaning without the need for any medical intervention." *Id.* Eldh, Dr. Hsiao stated, showed that "[t]here is not a high rate of serious complications in any of the surgeries performed after 1986" and she noted that "there have been nearly 20 years of additional surgical progress since the last surgery tracked." *Id.* 

Dr. Ettner cited the same five studies as showing that surgical outcomes were "far superior" after 1985 due to "improvements in technique, shortened hospital stays and improvements in postoperative care;" that significant surgical complications were uncommon; that only a low percentage of patients experienced complications, which were successfully resolved; and that "the complication rate is low and most complications can be overcome by adequate correctional interventions." Ettner Decl. at ¶¶ 34-35.

We find no reason to discount the opinions of these experts or their representations regarding the findings in the studies they cite. We have conducted our own review of the studies cited by Dr. Hsiao and Dr. Ettner and find them consistent with these opinions and representations. We note, for example, that Eldh, which divided the study group into those operated on before 1986 and those operated on from 1986–1995, made findings tending to support these expert opinions. The Eldh study states:

After 1985 the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment. Total time spent in hospital decreased dramatically after 1985 because the number of procedures was less and the rate of early and late postoperative complications dropped. Haemorrhage and haematoma were common in both groups, predominantly originating from the spongious tissue of the urethra. Infections occurred less often in the late group perhaps as a result of peroperative antibiotic prophylaxis. Serious complications like fistula formation and partial flap necrosis were rare after 1985, though they were common before then. The reason for the lower fistula rate in the later group may be ascribed to better anatomical knowledge of this region and a more precise surgical technique. There was only one rectovaginal fistula after 1985 and this fistula closed spontaneously.

<sup>&</sup>lt;sup>21</sup> Jan Eldh, *et al., Long-Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997).

AP Ex. 9, at 44. Dr. Hsiao stated that those findings are "consistent with what I would expect to find when comparing surgeries, and surgical techniques, over a long period of time." Hsiao Decl. at ¶ 18; *see also* WPATH Br. at 9-10 (citing Eldh and stating that "while early sex reassignment surgeries were sometimes accompanied by serious complications like fistulas or necrotic tissue, the rate of such complications has dropped dramatically with the advent of more sophisticated surgical techniques, among other reasons").

We conclude that the AP has shown that the NCD's statement that transsexual surgery is unsafe and has a high rate of complications is not reasonable in light of the evolution of surgical techniques and the studies of outcomes discussed in the unchallenged new evidence presented here.

## D. The new evidence indicates that transsexual surgery is an effective treatment option in appropriate cases.<sup>22</sup>

1. The expert testimony and studies on which the experts rely support the surgery's effectiveness.

The AP argues that studies conducted after the 1981 report was issued confirm that transsexual surgery is an effective treatment for persons with severe gender dysphoria, and the expert testimony and studies support that argument. AP Statement at 7-8.

Dr. Ettner testified that "[b]ased on decades of extensive scientific and clinical research, the medical community has reached the consensus that altering a transsexual individual's primary and secondary sex characteristics is a safe and effective treatment for persons with severe Gender Identity Disorder." Ettner Decl. at ¶ 13.<sup>23</sup> With regard to effectiveness in particular, Dr. Ettner testified that "more than three decades of research confirms that sex reassignment surgery is therapeutic and therefore an effective treatment for Gender Identity Disorder" and that "for many patients with severe Gender Identity

<sup>&</sup>lt;sup>22</sup> We use the term "appropriate cases" because we do not read the new evidence as necessarily stating that transsexual surgery is appropriate in all cases of transsexualism, and our conclusion that the NCD's blanket preclusion of Medicare coverage for transsexual surgery is invalid does not require a finding to that effect. However, it is worth noting that WPATH has developed, in its standards of care, criteria for the use of different transsexual surgical procedures. *See, e.g.*, WPATH "[c]riteria for hysterectomy and salpingooophorectomy in [FM] patients and for orchiectomy in [MF] patients." AP Ex. 7, at 202 (E. Coleman, et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7, 13 Int'l J. Transgenderism 165–232 (2011)).

 $<sup>^{23}</sup>$  Dr. Ettner in her declaration focuses on genital surgery for the male-to-female (MF) transsexual. *See* Ettner Decl. at ¶ 8. Dr. Hsiao's testimony addressed procedures performed on FM patients. Hsiao Decl. at ¶¶ 7, 11, 20-21.

Disorder, sex reassignment surgery is the only effective treatment." *Id.* at ¶ 19. She concluded that "[t]he NCD's determination regarding efficacy is not reasonably supported by scientific or clinical evidence, or standards of professional practice, and fails to take into account the robust body of research establishing that surgery relieves, and very often completely eliminates, gender dysphoria." *Id.* at ¶ 31.

Dr. Bowers stated that "[m]any patients report a dramatic improvement in mental health following surgery, and patients have been able to become productive members of society, no longer disabled with severe depression and gender dysphoria." Bowers Letter at 1. She concluded that "Gender Corrective Surgery has been shown to be a life-saving procedure, and is unequivocally medically necessary." *Id.* Dr. Leis stated that "[m]edical literature reports a dramatic drop in the incidence of depression and suicide attempt[s] by individuals who have undergone gender reassignment, indicating that many lives have been saved because of this surgery," that "there is a very low incidence of 'regret'" of "only about 1% of patients who have had gender reassignment surgery" and that "I personally have never had a single patient who has regretted having this surgery."

Dr. Ettner cited 20 studies published between 1987 and 2010 as showing the effectiveness of transsexual surgery. Ettner Decl. at ¶¶ 20-26, 28-30. She emphasized three studies, two of which were published in 1998 and 2007 and analyze other studies of the treatment of transsexuals published during the years 1961 to 1991 and 1990 to 2007, respectively. Id. at ¶¶ 20-22, citing studies at AP Exs. 10, 25, 27; see also WPATH Br. at 7-8 (discussing the same three studies). The 1998 study (Pfafflin & Junge) reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery" including more than 70 individual studies and eight published reviews from four continents. AP Ex. 25 at unnumbered page 1.<sup>24</sup> As "general results," the researchers in the 1998 study stated that the studies they reviewed concluded "that gender reassigning treatments are effective," that positive, desired results outweigh the negative or non-desired effects, and that "[p]robably the most important change that is found in most research is the increase of subjective satisfaction [which] contrasts markedly to the subjectively unsatisfactory start position of the patients." Id. at 45, 49. The study's summary, which it qualified as a "simplification," stated that the studies reviewed show that "[i]n over 80 qualitatively different case studies and reviews from 12 countries, it has been demonstrated during the last 30 years that the treatment that includes the whole process of gender reassignment is effective." Id. at 66. The summary stated that all "follow-up studies mostly found the desired effects" the most important of

<sup>&</sup>lt;sup>24</sup> Friedemann Pfafflin & Astrid Junge, *Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991* (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992) (<u>http://web.archive.org/web/20061218132346/http://www.symposion.com/ijt/pfaefflin/1000.htm</u>, accessed May 29, 2014).

which the patients felt were "the lessening of suffering" and "desired changes in the areas of partnership and sexual experience, mental stability and socio-economic functioning level." *Id.* at 66-67.

The 2007 study, Gijs & Brewaeys, which examined the results of 18 studies published between 1990 and 2006, states that sex reassignment "is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals" and that "96% of the persons who underwent [surgery] were satisfied and regret was rare." AP Ex. 10, at 215, cited in Ettner Decl. at ¶ 22, WPATH Br. at 7.<sup>25</sup> Two of the reviewed studies showed that "[s]uicidality was significantly reduced postoperatively" and that in MF patients there were no suicide attempts after surgery as opposed to three attempts before surgery. AP Ex. 10, at 188, 192.

Dr. Ettner and WPATH also cited what Dr. Ettner described as "a large-scale prospective study" finding "that after surgery there was 'a virtual absence of gender dysphoria' in the cohort and that the 'results substantiate previous conclusions that sex reassignment is effective." Ettner Decl. at ¶ 21, citing Smith et al. (2005), AP Ex. 27;<sup>26</sup> WPATH Br. at 8. Dr. Ettner concluded that Smith et al. and other studies have, variously, "shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, sex reassignment surgery improves virtually every facet of a patient's life," including "satisfaction with interpersonal relationships and improved social functioning," "improvement in self-image and satisfaction with body and physical appearance," and "greater acceptance and integration into the family[.]" Ettner Decl. at ¶ 24, citing studies at AP Exs. 1, 12, 15, 19, 22, 26, 27, 30. She also cited nine studies as having "shown that surgery improves patients' abilities to initiate and maintain intimate relationships." *Id.* at ¶ 25, citing studies at AP Exs. 8, 13, 14, 16, 20-22, 26, 27.

Based on our own review of the cited studies, we find no reason to question the expert testimony about them. In general, the studies included interviewing post-operative patients with a variety of surveys or questionnaires to assess changes in different aspects of their lives and psychological symptoms following surgery. The studies also generally used statistical techniques to assess the results. The studies were conducted in countries including the United States, Canada, Sweden, the Czech Republic, Israel, Brazil, The Netherlands, and Belgium.

<sup>&</sup>lt;sup>25</sup> Luk Gijs & Anne Brewaeys, Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges, 18 Ann. Rev. Sex Res. 178-224 (2007).

<sup>&</sup>lt;sup>26</sup> Yolanda L.S. Smith et al., Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals, 35 Psychol. Med. 89-99 (2005).

We note that these studies are scientific writings and do not make sweeping pronouncements or claim discoveries beyond possible doubt. Indeed, the authors sometimes qualify the results and caution against drawing overly broad and simplistic conclusions. *See, e.g.*, AP Ex. 25, at 66 (Pfafflin & Junge, qualifying the study's summary of its conclusion as a simplification). This, in our view, enhances their facial credibility. Nonetheless, even keeping in mind the possible limitations of these studies, they support the AP's position that transsexual surgery has gained broad acceptance in the medical community.

## 2. The 1981 report's expressed concern about an alleged lack of controlled, long-term studies is not reasonable in light of the new evidence.

The 1981 report summarized the findings of nine studies on "[t]he result or outcome of" transsexual surgery. NCD record at 15-18. With respect to those studies, the report stated that "surgical complications are frequent, and a very small number of post-surgical suicides and psychotic breakdowns are reported." Id. at 17-18. However, the report also acknowledged that eight of those nine studies "report that most transsexuals show improved adjustment on a variety of criteria after sex reassignment surgery, and that "[i]n all of these studies the large majority of those who received surgery report that they are personally satisfied with the change[.]" NCD Record at 17. Notwithstanding its discussion of these studies, the 1981 report (and the NCD) cited an alleged "lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism" as a ground for finding the procedures "experimental." Id. at 19. The 1981 report did not define "long term" for the purpose of assigning weight to study results and the NCD record provided no clarification of that phrase. The 1981 report noted "post-operative followup" and "followup" times for eight of the nine studies on the outcomes of surgery, with "average," "mean" or "median" periods ranging from 25 months to over eight years, and individual periods from three months to 13 years. NCD Record at 15-17. If these studies do not qualify as acceptable long-term studies, the basis for such a conclusion is not adequately explained in the NCD record.

Even assuming the studies cited in the 1981 report could be viewed as not sufficiently "long-term," Dr. Ettner stated that "there are numerous long-term follow-up studies on surgical treatment demonstrating that surgeries are effective and have low complication rates" and, as discussed above, her testimony cited some of those studies. Ettner Decl. at ¶ 26. CMS does not challenge this statement, and we find no reason to question it. We note that the participants in one study Dr. Ettner cited had a mean interval since

vaginoplasty of 75.46 months. AP Ex. 30, at 754.<sup>27</sup> We also note that the 18 studies published between 1990 and 2006 and encompassing 807 MF and FM patients analyzed in Gijs & Brewaeys (2007) had mean follow-up durations ranging from six months to as long as (in one study) 168 months. AP Ex. 10, at 186-87.<sup>28</sup> Additionally, two studies Dr. Ettner cited appear to be long term in that they studied patients who had undergone surgery during periods of 14 and 20 years, respectively. AP Exs. 13,<sup>29</sup> 29.<sup>30</sup> Those studies reported favorable overall results.

Dr. Ettner also testified that two studies from 1987 and 1990 used control groups and found improved psychosocial outcomes in surgery patients. Ettner Decl. at ¶¶ 28-30. In the 1990 study, she stated, MF patients were "matched for family and psychiatric histories and severity of the [GID] diagnosis" and "randomly assigned either to immediately undergo surgery, or be placed on a waiting list for two years." Id. at ¶ 29, citing study at AP Ex. 23.<sup>31</sup> The study found that patients who underwent surgery "demonstrated dramatically improved psychosocial outcomes, compared to the stillwaiting controls" and "were more active socially and had significantly fewer psychiatric symptoms." Id.; see also WPATH Br. at 8 (study found "comparative improvements in neurotic symptoms and social activity for the group receiving surgery"). Dr. Ettner described the 1990 study as the "best example of a well-controlled investigation." Ettner Decl. at ¶ 29. Dr. Ettner also described a 1987 study comparing transsexuals who had undergone surgery with "those who had not, but were otherwise matched (control group)" as finding that "the patients who underwent surgery were better adjusted psychosocially, had improved financial circumstances, and reported increased satisfaction with sexual experiences, as compared to the unoperated group." Id. at  $\P$  30, citing study at AP Ex. 17.<sup>32</sup>

<sup>29</sup> Ciro Imbimbo, M.D. Ph.D., et al., A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals, 6 J. Sex. Med. 2736-45 (2009).

<sup>30</sup> Svetlana Vujovic, M.D. Ph.D., et al., Transsexualism in Serbia: A Twenty-Year Follow-Up Study, 6 J. Sex. Med. 1018-23 (2009).

<sup>31</sup> Charles Mate-Kole, et al., A Controlled Study of Psychological and Social Change After Surgical Gender Reassignment in Selected Male Transsexuals, 157 Brit. J. Psychiatry 261-64 (1990).

<sup>32</sup> G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study*, 16 Archives of Sexual Behavior 511-22 (1987).

<sup>&</sup>lt;sup>27</sup> Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009).

<sup>&</sup>lt;sup>28</sup> Luk Gijs & Anne Brewaeys, Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges, 18 Ann. Rev. Sex Res. 178-224 (2007).

Nothing in the record puts into question the authoritativeness of the studies cited in the new evidence based on methodology (or any other ground). Even if questions about methodology had been raised, we would be hard pressed to find that this alone would justify our not crediting the new evidence that transsexual surgery is effective and safe. This is particularly true since the 1981 report itself suggested it might be impossible to find the kind of adequate control groups needed to assuage this criticism. See NCD Record at 18 (stating the need for adequate control groups and stating "perhaps this is impossible."). We note that in the local coverage determination (LCD) context, CMS guidance for contractors states that the determinations "shall be based on the strongest evidence available." CMS Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.7.1.<sup>33</sup> While the guidance states a "preference" for "[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies . . .," it also includes as evidence meeting that standard, "[g]eneral acceptance by the medical community (standard of practice), as supported by sound medical evidence ....."<sup>34</sup> Id. In LCD Complaint: Homeopathic Med. & Transfer Factor, DAB No. 2315 (2010), the Board relied on that guidance when rejecting the argument that a certain type of controlled study was the sole basis on which a determination of medical necessity could be supported. The Board stated, "[a]s the [CMS guidance] explains, general acceptance in the medical community may be sufficient if it has scientific support." DAB No. 2315, at 34. While the guidance applies to contractors, who develop LCDs but not NCDs, it is instructive here as representing CMS's determination of the type of evidence that may support Medicare coverage. Regardless of whether the new evidence here meets the first option for meeting the evidentiary standard set forth in the guidance (and CMS does not assert that it does not), it clearly meets the second option because it indicates a consensus among researchers and mainstream medical organizations that transsexual surgery is an effective, safe and medically necessary treatment for transsexualism.

Based on the record as a whole, including the new evidence discussed above, we conclude that the AP has shown that transsexual surgery is an effective treatment option for transsexualism in appropriate cases.

<sup>&</sup>lt;sup>33</sup> CMS Manuals are available at <u>http://www.cms.gov/Regulations-and-</u> <u>Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html</u>, accessed May 14, 2014.

<sup>&</sup>lt;sup>34</sup> The guidance further provides that the "sound medical evidence" supporting this "general acceptance" should be based on "[s]cientific data or research studies published in peer-reviewed medical journals; ... [c]onsensus of expert medical opinion (i.e., recognized authorities in the field); or ... [m]edical opinion derived from consultations with medical associations or other health care experts." MPIM § 13.7.1.

### E. The new evidence indicates that the NCD's rationale for considering the surgery experimental is not valid.

The NCD asserted that transsexual surgery was considered experimental because it had not been shown to be safe and effective.<sup>35</sup> The 1981 report stated that transsexual surgery "must be considered still experimental" because "[t]he safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned." NCD Record at 19. As discussed above, the unchallenged new evidence indicates that transsexual surgery is a safe and effective treatment option for transsexualism in appropriate cases. Accordingly, the NCD's reasons for asserting that transsexual surgery was experimental are no longer valid.

In addition, the new evidence independently indicates that transsexual surgery is not considered experimental in a broader sense relating to its acceptance as a treatment for transsexualism. Dr. Bowers stated that "[m]any thousands of gender corrective surgeries have been performed worldwide for decades, and this treatment is in no way experimental." Bowers Letter at 1. Dr. Hsiao testified that there is "no scientific or medical basis for [the NCD's] description of gender affirming surgeries as 'experimental." Hsiao Decl. at ¶ 22. Dr. Hsiao, as noted, stated that some of the procedures involved in transsexual surgery are routinely performed in other contexts, and that surgery to create a neovagina is performed on women born MRKH. Hsiao Decl. at ¶¶ 11, 12; *see* Ettner Supp. Decl. at ¶ 15 ("mastectomies, hysterectomies and salpingo-oophorectomies, which are ... excluded from coverage under [the NCD] are performed frequently... when indicated for medical conditions other than gender dysphoria").

Dr. Hsiao cited the "increasing coverage of sex affirming surgeries by private and public medical plans" and the inclusion of those surgeries "in prominent surgical text books" as showing that "gender affirming surgeries ... are the standard of care and are not experimental." *Id.* at ¶¶ 23, 24. Dr. Hsiao cited California managed care guidance "clarifying that any attempt 'to exclude insurance coverage of [] transsexual surgery" would violate California law, and she stated that Vermont, Colorado, Oregon, and Washington, D.C. "have issued similar insurance directives prohibiting discrimination based on gender identity with respect to healthcare policies." *Id.* at ¶ 25, citing Letter No. 12-K: Gender Nondiscrimination Requirements, Calif. Dep't of Managed Health Care

<sup>&</sup>lt;sup>35</sup> "Because of the lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental." NCD Record at 93.

(Apr. 9, 2013), Ex. A to Hsiao Decl.<sup>36</sup> "These events in the private and public sector," Dr. Hsiao stated, "solidify what the medical community has known for years—that gender affirming surgeries to treat gender dysphoria are evidence-based, medically necessary, and the standard of care for these patients." *Id.* at ¶ 26.

Dr. Leis stated that gender reassignment surgery "is not experimental and has been performed thousands of times with surgeons around the world and has been proven to be a medically necessary and successful treatment, saving many lives and significantly improving the lives of those who undergo this surgery." Leis Letter at 2. Dr. Leis also stated that "[m]edical and mental health professionals who are knowledgeable and experienced in this field recognize that counseling or psychotherapy, hormone therapy and genital reassignment surgery are medically necessary treatment modalities for many individuals with [GID]" and that those therapies "are widely accepted treatments for individuals with significant [GID] in the United States and in many other countries." *Id.* at 1. Dr. Leis also pointed to the acceptance of transsexual surgery procedures "as standard therapy by leading medical and mental health organizations" including the American Medical Association, the National Association of Social Workers, the American Psychological Association, the American Psychiatric Association, "and experts in the field belonging to" WPATH. *Id.* at 2.

HRC stated that its "Corporate Equality Index" annually surveys the "LGBT [lesbian, gay, bisexual and transgender] workplace policies" of "the Fortune 1000 list of the largest publicly traded companies along with American Lawyer Magazine's top 200 revenue-grossing law firms" and considers "whether these organizations afford transgender-inclusive health care options through at least one firm-wide plan that covers surgical procedures." HRC Br. at 1, 11-12. HRC stated that in 2002, "zero percent of the rated companies had such plans" but "by 2008, nineteen percent met this criterion, and by 2013, forty-two percent of companies expressly covered" care related to gender reassignment. *Id.* citing HRC Ex. 30, at 28.<sup>37</sup>

Dr. Bowers, Dr. Hsiao and Dr. Ettner cited acceptance of the WPATH standards of care, which were first published in 1979 and last revised in 2011, as evidence that transsexual surgery is not experimental. Bowers Letter at 1; Hsiao Decl. at ¶ 22; Ettner Decl. at ¶¶ 38, 39; AP Ex. 7, at 165; *see also* AP Ex. 3 (AMA resolution stating that "[h]ealth experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition"). The new evidence indicates that

<sup>&</sup>lt;sup>36</sup> <u>http://www.dmhc.ca.gov/library/reports/news/dl12k.pdf</u>, accessed May 14, 2014.

<sup>&</sup>lt;sup>37</sup> HRC Corporate Quality Index (2013), available at <u>http://www.hrc.org/corporate-equality-index</u>, accessed April 25, 2014.

the WPATH standards of care have attained widespread acceptance.<sup>38</sup> See Hsiao Decl. at ¶ 22 ("the WPATH established standards of care for patients with gender dysphoria ... have been endorsed by the American Medical Association, the Endocrine Society, the American Psychological Association, and the American College of Obstetricians and Gynecologists"); AP Ex. 3 (AMA resolution stating that WPATH is "the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders" and that its "internationally accepted Standards of Care for providing medical treatment for people with GID ... are recognized within the medical community to be the standard of care for treating people with GID"). Federal courts have recognized the acceptance of the WPATH standards of care. See, e.g., De'lonta v. Johnson, 708 F.3d 520, at 522-23 (4th Cir. 2013) (WPATH standards of care "are the generally accepted protocols for the treatment of GID"); Glenn v. Brumby, 724 F. Supp. 2d 1284, at 1289 n.4 (N.D. Ga. 2010) ("there is sufficient evidence that statements of WPATH are accepted in the medical community")."<sup>39</sup> The acceptance of the WPATH standards of care also suggests that transsexual surgery is no longer considered experimental.

In its amicus brief, WPATH cited a 2007 study that examined the results of 18 studies published between 1990 and 2006 as showing "that [sex reassignment surgery] can no longer be considered an experimental treatment" and that "it [has] bec[o]me the dominant treatment for transsexuality and the *only* treatment that has been evaluated empirically." WPATH Br. at 7-8, citing AP Ex. 10, at 214-15.<sup>40</sup>

We note that in addition to stating that transsexual surgery was experimental, the NCD and the 1981 report stated that transsexual surgery was "controversial." NCD Record at 18 (1981 report stating that "[o]ver and above the medical and scientific issues, it would also appear that transsexual surgery is controversial in our society"). The AP and the new evidence dispute the relevance of this statement. The AP objected that this point relies on two "polemics" that are "are either completely unscientific or fall far outside the scientific mainstream," and Dr. Ettner stated that the views expressed therein "fall far outside the mainstream psychological, psychiatric, and medical professional consensus,

<sup>40</sup> Luk Gijs & Anne Brewaeys, Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges, 18 Ann. Rev. Sex Res. 178-224 (2007).

<sup>&</sup>lt;sup>38</sup> WPATH was "formerly the Harry Benjamin International Gender Dysphoria Association." Ettner Decl. at ¶ 6. Harry Benjamin, M.D. "was an endocrinologist who in conjunction with mental health professionals in New York did pioneering work in the study of transsexualism." *O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, 37 n.8 (2010). The 1981 report cites a 1966 study by Dr. Benjamin finding a positive outcome from MF transsexual surgery as "perhaps the first report" on transsexual surgery "in the literature." NCD Record at 15, 21.

<sup>&</sup>lt;sup>39</sup> The general acceptance of a set of standards of care for the treatment of transsexuals appears to render invalid one of the 1981 report criticisms of the studies it discussed, that "therapeutic techniques are not standardized." NCD Record at 18.

and call into question the objective reasonableness of the NCD." AP Statement at 15-16; Ettner Supp. Decl. at ¶¶ 17-18. CMS has not asserted that the Board's decision may be based on factors "over and above the medical and scientific issues" involved. Considerations of social acceptability (or nonacceptability) of medical procedures appear on their face to be antithetical to Medicare's "medical necessity" inquiry, which is based in science, and such considerations do not enter into our decision that the NCD is not valid.

For the reasons stated above, we conclude that citing the alleged "experimental" nature of transsexual surgery as a basis for noncoverage of all transsexual surgery is not reasonable in light of the unchallenged new evidence and contributes to our conclusion that the NCD is not valid.

#### **Conclusion**

For the reasons explained above, we conclude that the AP has shown that NCD 140.3 is not valid under the reasonableness standard.

Leslie A. Sussan

Constance B. Tobias

/s/

/s/

/s/

Sheila Ann Hegy Presiding Board Member

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#### **ATTACHMENT TO DECISION NO. 2576**

#### Overview of the Scientific Literature in the New Evidence

We provide below brief summaries of key findings in some of the studies submitted and reviewed by the Board as new evidence. The key findings in the remaining studies reviewed by the Board (also as new evidence) do not differ in any way material to our decision.

Jan Eldh, et al., *Long Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plast. Reconstr. Surg. Hand Surg. 39-45 (1997), AP Ex. 9. This study was a "long-term follow up of 136 patients operated on for sex reassignment ... to evaluate the surgical outcome" that divided MF and FM patients into "two groups according to the surgical technique: those operated on before 1986 and those operated on from 1986–1995." The study found that after 1985 "the outcome of surgery became much better not only because of changes in management but also because of improvements in surgical technique, preoperative planning, and postoperative treatment," that "[m]odern surgical techniques can give good aesthetic and functional results" and that "[p]ersonal and social instability before operation correlated with an unsatisfactory outcome of sex reassignment." *Id.* at 39, 44, 45.

Luk Gijs & Anne Brewaeys, Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges, 18 Ann. Rev. Sex Res. 178-224 (2007), AP Ex. 10. This study examined results of 18 international studies published between 1990 and 2006 that reported follow-up data of at least one year from 807 persons who had undergone sex reassignment surgery (193 FM, 614 MF). The purpose of this study was to update and assess the current validity of a conclusion in a 1990 article (based itself on review of 11 studies following post-operation) that transsexual surgery is an effective treatment for the alleviation of gender disorder in adults. This study concluded that "[d]espite methodological shortcomings of many of the studies ... SRS is an effective treatment for transsexualism and the only treatment that has been evaluated empirically with large clinical case series" and that the "conclusion that SR [sex reassignment] is the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals still stands: 96% of the persons who underwent SRS were satisfied and regret was rare." The authors noted that the methodologies and designs of later studies were improved but that true randomized control studies are not feasible, and might be unethical for SRS. Id. at 178, 185, 215-16.

Ciro Imbimbo, M.D. Ph.D., et al., *A Report from a Single Institute's 14-Year Experience in Treatment of Male-to-Female Transsexuals*, 6 J. Sex. Med. 2736-45 (2009), AP Ex. 13. This study's aim was "to arrive at a clinical and psychosocial profile of male-to-female transsexuals in Italy through analysis of their personal and clinical experience and evaluation of their postsurgical satisfaction levels SRS." From January 1992 to September 2006, 163 MF patients who had undergone SRS were asked to complete

patient satisfaction questionnaires. The study concluded that the "relatively high satisfaction level" was the result of a combination of "competent surgical skills, a well-conducted preoperative preparation program, and adequate postoperative counseling . . . ." Although postoperative pain and required revision surgeries were reported, the study found that 94% were satisfied with their post-surgical status and did not report regret. *Id.* at 2736, 2740, 2743.

Ladislav Jarolim, et al., *Gender Reassignment Surgery in Male-to-Female Transsexualism: A Retrospective 3-Month Follow-up Study with Anatomical Remarks*, 6 J. Sex. Med. 1635-44 (2009), AP Ex. 14. This study aimed "[t]o evaluate the results of surgical reassignment of genitalia in male-to-female transsexuals" by measuring "[s]exual functions and complications 3 months after surgery." The study followed 134 patients who had undergone surgical procedures between 1992 and 2008 and described the evolution in surgical techniques since the 1950s. Although the study noted potential complications and risks specific to SRS ("such as impairment of urinary continence, fecal continence, intestinal fistula, urinary fistula, and necrosis of the skin graft"), it concluded that "[s]urgical conversion of the genitalia is a safe and important phase of the treatment of male-to-female transsexuals." It also concluded that "[a]n increasing number of patients undergo this treatment because of the extensive progress in surgery involving the genitals and urethra" and that "[f]or male transsexuals, surgery can provide a cosmetically acceptable imitation of female genitals that enables coitus with orgasm." *Id*. at 1635-36,1642-43.

Annika Johansson, et al., *A Five-Year Follow-Up Study of Swedish Adults with Gender Identity Disorder*, 39 Arch. Sex. Behav. 1429-37 (2010), AP Ex. 15. This study evaluated from the perspective of both clinicians and patients the outcome of sex reassignment of "42 [MF and FM] transsexuals [who] completed a follow-up assessment after 5 or more years in the process or 2 or more years after completed sex reassignment surgery." It found that "the outcome was very encouraging from both perspectives ... with almost 90% enjoying a stable or improved life situation at follow-up and only six out of 42 (according to the clinician) with a less favorable outcome." *Id.* at 1429, 1436.

G. Kockott, M.D. & E. M. Fahrner, Ph.D., *Transsexuals Who Have Not Undergone Surgery: A Follow-Up Study*, 16 Archives of Sexual Behavior 511-22 (1987), AP Ex. 17. This single-clinic study compared 26 transsexuals who sought but did not undergo surgery with 32 who did; psychosocial adjustment of those who delayed surgery did not improve from the time of diagnosis to follow-up while statistically significant positive changes in gender role, sexual, and socioeconomic adjustment were seen in transsexuals who had had surgery. *Id.* at 511, 517-19, 521.

Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Maleto-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006), AP Ex. 21. This study "examined preoperative preparations, complications, and physical and

functional outcomes of [MF SRS] based on reports by 232 patients, all of whom underwent penile-inversion vaginoplasty and sensate clitoroplasty, performed by one surgeon using a consistent technique," who were surveyed a mean of three years after surgery. The study found that "[r]eports of significant surgical complications were uncommon," although one third had urinary stream problems, and that "[o[n average, participants expressed high levels of satisfaction with nearly all of the specific physical and functional outcomes of SRS." *Id.* at 717, 719, 724.

Maria Inês Lobato, et al., *Follow-Up of Sex Reassignment Surgery in Transsexuals: A Brazilian Cohort,* 35 Arch. Sex. Behav. 711-15 (2006), AP Ex. 22. This small study examined the "impact of sex reassignment surgery on satisfaction with sexual experience, partnerships, and relationship with family members in ... 19 patients who received sex reassignment between 2000 and 2004." The results "indicate[d] that SRS had a positive effect on different dimensions of the patients' lives in all three aspects analyzed: sexual relationships, partnerships, and family relationships." *Id.* at 711-12, 714.

Charles Mate-Kole, et al., A Controlled Study of Psychological and Social Change after Surgical Gender Reassignment in Selected Male Transsexuals, 157 Brit. J. Psychiatry 261-64 (1990), AP Ex. 23. This study reviewed 40 patients accepted for gender reassignment surgery, randomly assigned to have surgery early or later such that only half had had surgery by the time of a follow-up two years later. The study found that "[a]lthough the groups were similar initially, significant differences between them emerged at follow-up . . . ." Patients who received surgery were "seen to improve significantly as far as neurotic symptoms are concerned and to become more socially active" in comparison with the patients who had not yet received surgery. *Id.* at 261, 264.

Friedemann Pfafflin & Astrid Junge, Sex Reassignment: Thirty Years of International Follow-Up Studies After Sex Reassignment Surgery: A Comprehensive Review 1961-1991 (Roberta B. Jacobson & Alf B. Meier trans., 1998) (1992), AP Ex. 25. This overview was completed in 1992 and published in English in 1998. It reviewed "30 years of international follow-up studies of approximately two thousand persons who had undergone sex reassignment surgery," including "more than 70 individual studies and eight published reviews from four continents." In general, more frequent and severe complications were found in the earlier years covered than in later reports. The overview concluded that "[s]ex reassignment, properly indicated and performed, has proven to be a valuable tool in the treatment of individuals with transgenderism," that "gender reassigning treatments are effective" and that "the treatment that includes the whole process of gender reassignment is effective." *Id.* at unnumbered pages 1, 45, 66-67.

Yolanda L.S. Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adolescent and Adult Transsexuals*, 35 Psychol. Med. 89-99 (2005), AP Ex. 27. This study evaluated "outcomes of sex reassignment, potential differences between subgroups

of transsexuals, and predictors of treatment course and outcome" in 162 adults (104 MF, 58 FM). The study found that "[a]fter treatment the group was no longer gender dysphoric," had "improved in important areas of function, that 1-4 years after surgery, SR appeared therapeutic and beneficial . . . [and that] the vast majority expressed no regrets about their SR." The study further concluded "that sex reassignment is effective" but that "clinicians need to be alert for non-homosexual male-to-females with unfavourable psychological functioning and physical appearance and inconsistent gender dysphoria reports, as these are risk factors for dropping out and poor post-operative results." *Id.* at 89, 91, 96.

Svetlana Vujovic, M.D., Ph.D., et al., *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009), AP Ex. 29. This study [a]imed to "describe a transsexual population seeking sex reassignment treatment in Serbia" by analyzing "data collated over a period of 20 years" from 147 transsexuals "applying for sex reassignment" of whom SRS was performed in 83% of MF and in 77% of MF patients. The study concluded that "in our population, there were no cases who regretted sex reassignment treatment," which was attributed to diagnostic procedures used and the "young [adult] age at which our subjects embarked on treatment." *Id.* at 1018-20, 1022.

Steven Weyers, M.D., et al., *Long-term Assessment of the Physical, Mental, and Sexual Health Among Transsexual Women*, J. Sex. Med. 752-60 (2009), AP Ex. 30. This study [a]imed "[t]o gather information on physical, mental, and sexual well-being, health-promoting behavior and satisfaction with gender-related body features of [49] transsexual women [MF] who had undergone SRS" with mean interval since vaginoplasty of 75.46 months. The study found that "sample ... functions well after surgery on a physical, emotional, psychological and social level" and that "[o]nly with respect to sexuality do transsexual women appear to suffer from specific difficulties, especially concerning arousal, lubrication and pain." *Id.* at 752, 754, 759.

# Exhibit C

# Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

# **■**Decision Summary

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

In the absence of a NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local MACs on a case-by-case basis. To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination of whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary after considering the individual's specific circumstances. For Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, the initial determination of whether or not surgery is reasonable and necessary will be made by the MA plans.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination related to counseling, hormone therapy treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

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#### To: Administrative File: CAG #00446N

From: Tamara Syrek Jensen, JD Director, Coverage and Analysis Group

> Joseph Chin, MD, MS Deputy Director, Coverage and Analysis Group

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Subject: Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria

Date: August 30, 2016

# I. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

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# II. Background

Below is a list of acronyms used throughout this document.

AHRQ - Agency for Healthcare Research and Quality AIDS - Acquired Immune Deficiency Syndrome ANOVA - Analysis of Variance APA - American Psychiatric Association APGAR - Adaptability, Partnership Growth, Affection, and Resolve test **BIQ - Body Image Questionnaire** BSRI - Bem Sex Role Inventory CCEI - Crown Crips Experimental Index CDC – Centers for Disease Control CHIS - California Health Interview Survey CI - Confidence Interval CMS - Centers for Medicare & Medicaid Services DAB - Departmental Appeals Board DSM - Diagnostic and Statistical Manual of Mental Disorders EMBASE - Exerpta Medica dataBASE FBeK - Fragebogen zur Beurteilung des eigenen Korpers FDA - Food and Drug Administration FPI-R - Freiburg Personality Inventory FSFI - Female Sexual Function Index GAF - Global Assessment of Functioning GID - Gender Identity Disorder GIS - Gender Identity Trait Scale GRS - Gender Reassignment Surgery GSI - Global Severity Indices HADS - Hospital Anxiety Depression Scale HHS - U.S. Department of Health and Human Services HIV - Human Immunodeficiency Virus IIP - Inventory of Interpersonal Problems IOM - Institute of Medicine KHQ - King's Health Questionnaire LGB - Lesbian, Gay, and Bisexual LGBT - Lesbian, Gay, Bisexual, and Transgender MAC - Medicare Administrative Contractor MMPI - Minnesota Multiphasic Personality Inventory NCA - National Coverage Analysis NCD - National Coverage Determination NICE - National Institute for Health Care Excellence NIH - National Institutes of Health NZHTA - New Zealand Health Technology Assessment PIT - Psychological Integration of Trans-sexuals QOL - Quality of Life S.D. - Standard Deviation SADS - Social Anxiety Depression Scale SCL-90R - Symptom Check List 90-Revised SDPE - Scale for Depersonalization Experiences SES - Self Esteem Scale

SF - Short FormCase: 3:17-cv-00264-wmc Document #: 104 Filed: 06/08/18 Page 96 of 242 SMR - Standardized Mortality Ratio SOC – Standards of Care STAI-X1 - Spielberger State and Trait Anxiety Questionnaire STAI-X2 - Spielberger State and Trait Anxiety Questionnaire TSCS - Tennessee Self-Concept Scale U.S. - United States VAS - Visual Analog Scale WHOQOL-BREF - World Health Organization Quality of Life - Abbreviated version of the WHOQOL-100 WPATH - World Professional Association for Transgender Health

# A. Diagnostic Criteria

The criteria for gender dysphoria or spectrum of related conditions as defined by the American Psychiatric Association (APA) in the Diagnostic and Statistical Manual of Mental Disorders (DSM) has changed over time (See Appendix A).

Gender dysphoria (previously known as gender identity disorder) is a classification used to describe persons who experience significant discontent with their biological sex and/or gender assigned at birth. Although there are other therapeutic options for gender dysphoria, consistent with the NCA request, this decision only focuses on gender reassignment surgery.

# **B.** Prevalence of Transgender Individuals

For estimates of transgender individuals in the U.S., we looked at several studies.

The Massachusetts Behavior Risk Factor Surveillance Survey (via telephone) (2007 and 2009) identified 0.5% individuals as transgender (Conron et al., 2012).

Derivative data obtained from the 2004 California Lesbian Gay Bisexual and Transgender (LGBT) Tobacco Survey (via telephone) and the 2009 California Health Interview Survey (CHIS) (via telephone) suggested the LGB population constitutes 3.2% of the California population and that transgender subjects constitute approximately 2% of the California LGBT population and 0.06% of the overall California population (Bye et al., 2005; CHIS 2009; Gates, 2011).

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Most recently, the Williams Institute published a report that utilized data from the Centers for Disease Control's (CDC) Behavioral Risk Factor Surveillance System (BRFSS). Overall, they found that 0.6% or 1.4 million U.S. adults identify as transgender. The report further estimated 0.7% of adults between the ages of 18-25 identify as transgender, 0.6% of adults between the ages of 25-65 identify as transgender, and 0.5% of adults age 65 or older identify as transgender (Flores et al., 2016).

In a recent review of Medicare claims data, CMS estimated that in calendar year 2013 there were at least 4,098 transgender beneficiaries (less than 1% of the Medicare population) who utilized services paid for by Medicare, of which 90% had confirmatory diagnosis, billing codes, or evidence of a hormone therapy prescription. The Medicare transgender population is racially and ethnically diverse (e.g., 74% White, 15% African American) and spans the entire country. Nearly 80% of transgender beneficiaries are under age 65, including approximately 23% ages 45-54. (CMS Office of Minority Health 2015).

For international comparison purposes, recent estimates of transgender populations in other countries are similar to those in the United States. New Zealand researchers, using passport data, reported a prevalence of 0.0275% for male-to-female adults and 0.0044% female-to-male adults (6:1 ratio) (Veale, 2008). Researchers from a centers of transgender treatment and reassignment surgery in Belgium conducted a survey of regional plastic surgeons and reported a prevalence of 0.008% male-to-female and 0.003% female-to-male (ratio 2.7:1) surgically reassigned transsexuals in Belgium (De Cuypere et al., 2007). Swedish researchers, using national mandatory reporting data on those requesting reassignment surgery, reported secular changes over time in that the number of completed reassignment surgeries per application increased markedly in the 1990s; the male-to-female/female-to-male sex ratio changed from 1:1 to 2:1; the age of male-to-female and female-to-male applicants was initially similar, but increased by eight years for male-to-female applicants; and the proportion of foreign born applicants increased (Olsson and Moller 2003).

# **III. History of Medicare Coverage**

# Date

Action

August CMS published the initial NCD, titled "140.3, Transsexual Surgery" in the Federal Register. (54 Fed. Reg. 34,555, 34,572)

May 30, 2014 The HHS Departmental Appeals Board (DAB) determined that the NCD denying coverage for all transsexual surgery was not valid. As a result, MACs determined coverage on a case-by-case basis.

CMS does not currently have a NCD on gender reassignment surgery.

# A. Current Request

On December 3, 2015, CMS accepted a formal complete request from a beneficiary to initiate a NCA for gender reassignment surgery.

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CMS opened this National Coverage Analysis (NCA) to thoroughly review the evidence to determine whether or not gender reassignment surgery may be covered nationally under the Medicare program.

# **B. Benefit Category**

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories as outlined in the Act. For gender reassignment surgery, the following are statutes are applicable to coverage:

```
Under §1812 (Scope of Part A) Under §1832 (Scope of Part B)
Under §1861(s) (Definition of Medical and Other Health Services)
Under §1861(s)(1) (Physicians' Services)
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This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

# **IV. Timeline of Recent Activities**

#### Timeline of Medicare Coverage Policy Actions for Gender Reassignment Surgery

Date	Action
December 3, 2015	CMS accepts an external request to open a NCD. A tracking sheet was posted on the web site and the initial 30 day public comment period commenced.
January 2, 2016	Initial comment period closed. CMS received 103 comments.
June 2, 2016	Proposed Decision Memorandum posted on the web site and the final 30 day public comment period commenced.
July 2, 2016	Final comment period closed. CMS received 45 comments.

# V. FDA Status

Surgical procedures per se are not subject to the Food and Drug Administration's (FDA) approval.

Inflatable penile posst hetiz devices high menile in pants #tested ulari provide the plants period of east implants have been approved and/or cleared by the FDA.

# VI. General Methodological Principles

In general, when making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. (§ 1862 (a)(1)(A)). The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical question relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve health outcomes for patients.

A detailed account of the methodological principles of study design the agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, blinding of readers of the index test, and reference test results.

# VII. Evidence

# A. Introduction

Below is a summary of the evidence we considered during our review, primarily articles about clinical trials published in peer- reviewed medical journals. We also considered articles cited by the requestor, articles identified in public comments, as well as those found by a CMS literature review. Citations are detailed below.

#### **B. Literature Search Methods**

CMS staff extensively searched for primary studies for gender dysphoria. The emphasis focused less on specific surgical techniques and more on functional outcomes unless specific techniques altered those types of outcomes. Printed on 5/31/2018. Page 7 of 150

The reviewed evidence included articles obtained by searching literature databases and technology review databases from PubMed (1965 to current date), EMBASE, the Agency for Healthcare Research and Quality (AHRQ), the Blue Cross/Blue Shield Technology Evaluation Center, the Cochrane Collection, the Institute of Medicine, and the National Institute for Health and Care Excellence (NICE) as well as the source material for commentary, guidelines, and formal evidence-based documents published by professional societies. Systematic reviews were used to help locate some of the more obscure publications and abstracts.

Keywords used in the search included: Trans-sexual, transgender, gender identity disorder (syndrome), gender dysphoria and/or hormone therapy, gender surgery, genital surgery, gender reassignment (surgery), sex reassignment (surgery) and/or quality of life, satisfaction-regret, psychological function (diagnosis of mood disorders, psychopathology, personality disorders), suicide (attempts), mortality, and adverse eventsreoperations. After the identification of germane publications, CMS also conducted searches on the specific psychometric instruments used by investigators.

Psychometric instruments are scientific tools used to measure individuals' mental capabilities and behavioral style. They are usually in the form of questionnaires that numerically capture responses. These tools are used to create a psychological profile that can address questions about a person's knowledge, abilities, attitudes and personality traits. In the evaluation of patients with gender dysphoria, it is important that both validity and reliability be assured in the construction of the tool (validity refers to how well the tool actually measures what it was designed to measure, or how well it reflects the reality it claims to represent, while reliability refers to how accurately results of the tool would be replicated in a second identical piece of research). Reliability and validity are important because when evaluating patients with gender dysphoria most of the variables of interest (e.g., satisfaction, anxiety, depression) are latent in nature (not directly observed but are rather inferred) and difficult to quantify objectively.

Studies with robust study designs and larger, defined patient populations assessed with objective endpoints or validated test instruments were given greater weight than small, pilot studies. Reduced consideration was given to studies that were underpowered for the assessment of differences or changes known to be clinically important. Studies with fewer than 30 patients were reviewed and delineated, but excluded from the major analytic framework. Oral presentations, unpublished white papers, and case reports were excluded. Publications in languages other than English were excluded. The CMS initial internal search for the proposed decision memorandum was limited to articles published prior to March 21, 2016. The CMS internal search for the final decision memorandum continued through articles published prior to July 22, 2016.

Included studies were limited to those with adult subjects. Review and discussion of the management of children and adolescents with the additional considerations of induced pubertal delay are outside the scope of this NCD. In cases where the same population was studied for multiple reasons or where the patient population was expanded over time, the latest and/or most germane sections of the publications were analyzed. The excluded duplicative publications are delineated.

CMS also searched Clinicaltrials.gov to identify relevant clinical trials. CMS looked at trial status including early

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termination, completed Longoing 2014 አባት አዋውስ አው ባር መንግስት በመንግስት በመንግስት በመንግስት በመንግስት በመንግስት በመንግስት በመንግስት በመንግስት በ Publications on completed trials were sought. For this final decision, CMS also reviewed all evidence submitted via public comment.

# **C. Discussion of Evidence**

The development of an assessment in support of Medicare coverage determinations is based on the same general question for almost all national coverage analyses (NCAs): "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this specific NCA, CMS is interested in answering the following question:

*Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?* 

The evidence reviewed is directed towards answering this question.

# 1. Internal Technology Assessment

CMS conducted an extensive literature search on gender reassignment related surgical procedures and on facets of gender dysphoria that provide context for this analysis. The latter includes medical and environmental conditions.

CMS identified numerous publications related to gender reassignment surgery. A large number of these were case reports, case series with or without descriptive statistics, or studies with population sizes too small to conduct standard parametric statistical analyses. Others addressed issues of surgical technique.

CMS identified and described 36 publications on gender reassignment surgery that included health outcomes. Because the various investigators at a site sometimes conducted serial studies on ever-enlarging cohort populations, studied sub-populations, studied different outcomes, or used different tools to study the same outcomes, not all study populations were unique. To reduce bias from over-lapping populations, only the latest or most germane publication(s) were described. Subsumed publications were delineated.

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Of these 36 publications, two publications used different assessment tools on the same population, and, so for the purposes of evaluation, were classified as one study (Udeze et al., 2008; Megeri and Khoosal, 2007). A total of 33 studies were reviewed (See Figure 1). Appendices C, D, and F include more detail of each study. The publications covered a time span from 1979 to 2015. Over half of the studies were published after 2005.

Figure 1. Studies of Gender Reassignment Surgery (GRS)

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ANOVA=Analysis of Variance Normative=Psychometric Tests with known normative for large populations

Figure 1 Legend: The studies in Figure 1 are categorized into three groups. The first group, depicted by the colored boxes (red, blue, and green), had explicit controls. There was a single randomized study. The remainder in the first group were observational studies. These were subdivided into longitudinal studies and cross-sectional studies. The second group, depicted by black boxes (starting with the surgery only population box) consisted of surgical series. The third group, depicted by black boxes (starting with mixed population), was composed of patients whose treatment could involve a variety of therapeutic interventions, but who were not stratified by that treatment.

When looking at the totality of studies, the 33 studies could be characterized by the following research design groups:

# a. Observational, mixed population of surgical and non-surgical patients without stratification

Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. Eur J Endocrinol. 2011 Apr;164(4):635 -42. Epub 2011 Jan 25.

Asscheman et al. conducted a retrospective, non-blinded, observational study of mortality using a longitudinal design to assess a mixed population treated with hormones, as well as, reassignment surgery in comparison to a population-based cohort. The study was not designed to assess the specific impact of gender reassignment surgery on clinical outcomes.

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The investigators assessed mortality in patients who (a) were from a single-center, unspecified, Dutch university specialty clinic, (b) had initiated cross-sex hormone treatment prior to July 1, 1997, and (c) had been followed (with or without continued hormone treatment) by the clinic for at least one year or had expired during the first year of treatment. The National Civil Record Registry (Gemeentelijke Basis Administratie) was used to identify/confirm deaths of clinic patients. Information on the types or hormones used was extracted from clinic records, and information on the causation of death was extracted from medical records or obtained from family physicians. Mortality data for the general population were obtained through the Central Bureau of Statistics of the Netherlands (Centraal Bureau voor Statistiek). Mortality data from Acquired Immune Deficiency Syndrome (AIDS) and substance abuse were extracted from selected Statistics Netherlands reports. The gender of the general Dutch population comparator group was the natal sex of the respective gender dysphoric patient groups.

A total of 1,331 patients who met the hormone treatment requirements were identified (365 female-to-male [27.4%]; 966 male- to-female [72.6%]; ratio 1:2.6). Of these, 1,177 (88.4%) underwent reassignment surgery (343 [94.0% of female-to-male entrants]; 834 [86.3% of male-to-female entrants]; ratio difference 1:2.4 with a p-value p<0.0001). Later calculations did not distinguish between those with hormone therapy alone versus those with hormone therapy plus reassignment surgery. The mean age at the time of hormone initiation in female -to-male and male-to-female patients was  $26.1\pm7.6$  (range 16-56) years and  $31.4\pm11.4$  (range 16-76) years respectively, although the male-to-female subjects were relatively older (p<0.001). The mean duration of hormone therapy in female-to-male and male-to-female patients was  $18.8\pm6.3$  and  $19.4\pm7.7$  years respectively.

There were a total of 134 deaths in the clinic population using hormone therapy with or without surgical reassignment. Of these patients, 12 (3.3%) of the 365 female-to-male patients and 122 (12.6%) of the 966 male -to-female patients died. All-cause mortality for this mixed population was 51% higher and statistically significant (Standardized Mortality Ratio [SMR] 95% confidence interval [CI]) 1.47-1.55) for males-to-females when compared to males in the general Dutch population. The increase in all-cause mortality (12%) for females-to-males when compared to females in the general Dutch population was not statistically significant (95% CI 0.87-1.42).

Ischemic heart disease was a major disparate contributor to excess mortality in male-to-female patients but only in older patients (n=18, SMR 1.64 [95% CI 1.43-1.87]), mean age [range]: 59.7 [42-79] years. Current use of a particular type of estrogen, ethinyl estradiol, was found to contribute to death from myocardial infarction or stroke (Adjusted Hazard Ratio 3.12 [95% CI 1.28-7.63], p=0.01). There was a small, but statistically significant increase in lung cancer that was thought to possibly be related to higher rates of smoking in this cohort.

Other contributors to the mortality difference between male-to-female patients and the Dutch population at large were completed suicide (n=17, SMR 5.70 [95% CI 4.93-6.54]), AIDS (n=16, SMR 30.20 [95% CI 26.0-34.7]), and illicit drug use (n=5, SMR 13.20 [95% CI 9.70-17.6]). An additional major contributor was "unknown cause" (n=21, SMR 4.00 [95% CI 3.52-4.51]). Of the 17 male-to-female hormone treated patients who committed suicide, 13 (76.5%) had received prior psychiatric treatment and six (35.3%) had not undergone reassignment surgery because of concerns about mental health stability.

Overall mortality, and specifically breast cancer and cardiovascular disease, were not increased in the hormonetreated female-to-male patients. Asscheman et al. reported an elevated SMR for illicit drug use (n=1, SMR 25 Printed on 5/31/2018. Page 11 of 150 This study subsumes earlier publications on mortality (Asscheman et al. 1989 [n=425]; Van Kesteren et al. 1997 [n=816]).

*Gómez-Gil E, Zubiaurre-Elorza L, Esteva I, Guillamon A, Godás T, Cruz Almaraz M, Halperin I, Salamero M. Hormone- treated transsexuals report less social distress, anxiety and depression. Psychoneuroendocrinology.* 2012 May;37(5):662-70. Epub 2011 Sep 19.

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a cross-sectional design and non -specific psychiatric distress tools in Spain. The investigators assessed anxiety and depression in patients with gender dysphoria who attended a single-center specialty clinic with comprehensive endocrine, psychological, psychiatric, and surgical care. The clinic employed World Professional Association for Transgender Health (WPATH) guidelines. Patients were required to have met diagnostic criteria during evaluations by 2 experts. Investigators used the Hospital Anxiety and Depression Scale (HADS) and the Social Anxiety and Distress Scale (SADS) instruments. The SADS total score ranges from 0 to 28, with higher scores indicative of more anxiety. English language normative values are 9.1±8.0. HAD-anxiety and HAD-depression total score ranges from 0 to 21, with higher scores indicative of more pathology. Scores less than 8 are normal. ANOVA was used to explore effects of hormone and surgical treatment.

Of the 200 consecutively selected patients recruited, 187 (93.5% of recruited) were included in the final study population. Of the final study population, 74 (39.6%) were female-to-male patients; 113 (60.4%) were male-to-female patients (ratio 1:1.5); and 120 (64.2%) were using hormones. Of those using hormones, 36 (30.0%) were female-to-male; 84 (70.0%) were male-to-female (ratio 1:2.3). The mean age was 29.87±9.15 years (range 15-61). The current age of patients using hormones was  $33.6\pm9.1$  years (n=120) and older than the age of patients without hormone treatment ( $25.9\pm7.5$ ) (p=0.001). The age at hormone initiation, however, was  $24.6\pm8.1$  years.

Of those who had undergone reassignment surgery, 29 (36.7%) were female-to-male; 50 (63.3%) were male-tofemale (ratio 1:1.7). The number of patients not on hormones and who had undergone at least one genderrelated surgical procedure (genital or non-genital) was small (n=2). The number of female-to-male patients on hormones who had undergone such surgery (mastectomy, hysterectomy, and/or phalloplasty) was 28 (77.8%). The number of male-to-female patients on hormones who had undergone such surgery (mammoplasty, facial feminization, buttock feminization, vaginoplasty, orchiectomy, and/or vocal feminization (thyroid chondroplasty) was 49 (58.3%).

Analysis of the data revealed that although the mean scores HAD-Anxiety, HAD-Depression, and SADS were statistically lower (better) in those on hormone therapy than in those not on hormone therapy, the mean scores for HAD-Depression and SADS were in the normal range for gender dysphoric patients not using hormones. The HAD-Anxiety score was 9 in transsexuals without hormone treatment and 6.4 in transsexuals with hormone

treatment. The Rean Scores Mood AD = WAXIety PMAD Depression, Failed SADD Were in the patient of gender dysphoric patients using hormones. ANOVA revealed that results did not differ by whether the patient had undergone a gender related surgical procedure or not.

*Gómez-Gil E, Zubiaurre-Elorza L, de Antonio I, Guillamon A, Salamero M. Determinants of quality of life in Spanish transsexuals attending a gender unit before genital sex reassignment surgery. Qual Life Res. 2014 Mar;23(2):669-76. Epub 2013 Aug 13.* 

Gómez-Gil et al. conducted a prospective, non-blinded observational study using a non-specific quality of life tool. There were no formal controls for this mixed population  $\pm$  non-genital reassignment surgery undergoing various stages of treatment.

The investigators assessed quality of life in the context of culture in patients with gender dysphoria who were from a single-center (Barcelona, Spain), specialty and gender identity clinic. The clinic used WPATH guidelines. Patients were required to have met diagnostic criteria during evaluations by both a psychologist and psychiatrist. Patients could have undergone non-genital surgeries, but not genital reassignment surgeries (e.g., orchiectomy, vaginoplasty, or phalloplasty). The Spanish version of the World Health Organization Quality of Life-Abbreviated version of the WHOQOL-100 (WHOQOL- BREF) was used to evaluate quality of life, which has 4 domains (environmental, physical, psychological, and social) and 2 general questions. Family dynamics were assessed with the Spanish version of the Family Adaptability, Partnership Growth, Affection, and Resolve (APGAR) test. Regression analysis was used to explore effects of surgical treatment.

All consecutive patients presenting at the clinic (277) were recruited and, 260 (93.9%) agreed to participate. Of this number, 59 of these were excluded for incomplete questionnaires, 8 were excluded for prior genital reassignment surgery, and 193 were included in the study (the mean age of this group was  $31.2\pm9.9$  years (range 16-67). Of these, 74 (38.3%) were female-to-male patients; 119 (61.7%) were male-to-female patients (ratio1:1.6). Of these, 120 (62.2%) were on hormone therapy; 29 (39.2%) of female-to-male patients had undergone at least 1 non-genital, surgical procedure (hysterectomy n=19 (25.7%); mastectomy n=29 (39.2%)); 51 (42.9%) of male-to-female patients had undergone at least one non-genital surgical procedure with mammoplasty augmentation being the most common procedure, n=47 (39.5%), followed by facial feminization, n=11 (9.2%), buttocks feminization, n=9 (7.6%), and vocal feminization (thyroid chondroplasty), n=2 (1.7%).

WHOQOL-BREF domain scores for gender dysphoric patients with and without non-genital surgery were: "Environmental" 58.81±14.89 (range 12.50-96.88), "Physical" 63.51±17.79 (range 14.29-100), "Psychological" 56.09+16.27 (range 16.67- 56.09), "Social" 60.35±21.88 (range 8.33-100), and "Global QOL and Health" 55.44+27.18 (range 0-100 with higher score representing better QOL). The mean APGAR family score was 7.23±2.86 (range 0-10 with a score of 7 or greater indicative of family functionality).

Regression analysis, which was used to assess the relative importance of various factors to WHOQOL-BREF domains and general questions, revealed that family support was an important element for all four domains and

the general heattrand duality 002 fife worstions worns for a field a field of the source of the source of the domains except "Environmental." Having undergone non-genital reassignment surgery, age, educational levels, and partnership status, did not impact domain and general question results related to quality of life.

Hepp U, Kraemer B, Schnyder U, Miller N, Delsignore A. Psychiatric comorbidity in gender identity disorder. J Psychosom Res. 2005 Mar;58(3):259-61.

Hepp et al. conducted a single-site (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design. There was some acquisition of retrospective data. The investigators assessed current and lifetime psychiatry co-morbidity using structured interviews for diagnosis of Axis 1 disorders (clinical syndromes) and Axis 2 disorders (developmental or personality disorders) and HADS for dimensional evaluation of anxiety and depression. Statistical description of the cohort and intra-group comparisons was performed. Continuous variables were compared using t-tests and ANOVA.

A total of 31 patients with gender dysphoria participated in the study: 11 (35.5%) female-to-male; 20 (64.5%) male-to-female (ratio 1:1.8). The overall mean age was 32.2±10.3 years. Of the participants, seven had undergone reassignment surgery, 10 pre- surgical patients had been prescribed hormone therapy, and 14 pre-surgical patients had not been prescribed hormone therapy. Forty five and one half percent of female-to-male and 20% of male-to-female patients did not carry a lifetime diagnosis of an Axis 1 condition. Sixty three and six tenths percent of female-to-male and 60% of male-to-female patients did not carry a current diagnosis of an Axis 1 condition. Lifetime diagnosis of substance abuse and mood disorder were more common in male-to-female patients (50% and 55% respectively) than female-to-male patients (36.4% and 27.3% respectively). Current diagnosis of substance abuse and mood disorder were present in male-to-female patients (15% and 20% respectively) and absent in female-to-male patients. One or more personality disorders were identified 41.9%, but whether this was a current or lifetime condition was not specified. Of the patients, five (16.1%) had a Cluster A personality disorder (paranoid-schizoid), seven (22.6%) had a Cluster B personality disorder (borderline, antisocial, histrionic, narcissistic), six (19.4%) had a Cluster C personality disorder (avoidant, dependent, obsessive-compulsive), and two (6.5%) were not otherwise classified.

HADS scores were missing for at least one person. The HADS test revealed non-pathologic results for depression (female-to-male:  $6.64\pm5.03$ ; male-to-female:  $6.58\pm4.21$ ) and borderline results for anxiety (female-to-male:  $7.09\pm5.11$ ; male-to-female:  $7.74\pm6.13$ , where a result of 7-10 = possible disorder). There were no differences by natal gender. The investigators reported a trend for less anxiety and depression as measured by HADS in the patients who had undergone surgery.

Johansson A, Sundbom E, Höjerback T, Bodlund O. A five-year follow-up study of Swedish adults with gender identity disorder. Arch Sex Behav. 2010 Dec;39(6):1429-37. Epub 2009 Oct 9.

Johansson et al. conducted a two center (Lund and Umeå, Sweden) non-blinded, observational study using a

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semi-cross-sec**tional design (albated vertain exterior the acquisition of baseline Axis V data.** There were no formal controls in this mixed population with and without surgery.

The investigators assessed satisfaction with the reassignment process, employment, partnership, sexual function, mental health, and global satisfaction in gender-reassigned persons from two disparate geographic regions. Surgical candidates were required to have met National Board of Health and Welfare criteria including initial and periodic psychiatric assessment,  $\geq 1$  year of real-life experience in preferred gender, and  $\geq 1$  year of subsequent hormone treatment. In addition, participants were required to have been approved for reassignment five or more years prior and/or to have completed surgical reassignment (e.g., sterilization, genital surgery) two or more years prior. The investigators employed semi-structured interviews covering a self-designed list of 55 preformulated questions with a three or five point ordinal scale. Clinician assessment of Global Assessment of Functioning (GAF; Axis V) was also conducted and compared to initial finding during the study. Changes or differences considered to be biologically significant were not pre- specified except for GAF, which pre-specified a difference to mean change  $\geq 5$  points. Statistical corrections for multiple comparisons were not included. There was no stratification by treatment.

Of the pool of 60 eligible patients, 42 (70.0% of eligible) (17 [40.5%] female-to-male; 25 [59.5%] male-to-female; ratio 1:1.5) were available for follow-up. Of these, 32 (53.3% of eligible) (14 [43.8%] female-to-male; 18 [56.2%] male-to-female [ratio 1:1.3]) had completed genital gender reassignment surgery (not including one post mastectomy), five were still in the process of completing surgery, and five (one female-to-male; four male-to-female; ratio 1:4) had discontinued the surgical process prior to castration and genital surgery.

The age (ranges) of the patients at entry into the program, reassignment surgery, and follow-up were 27.8 (18-46), 31.4 (22-49), and 38.9 (28-53) years in the female-to-male group respectively and 37.3 (21-60), 38.2 (22-57), and 46.0 (25.0-69.0) years in the male- to-female group respectively. The differences in age by cohort group were statistically significant. Of participants, 88.2% of all enrolled female-to-male versus 44.0% of all enrolled female-to-male patients had cross-gender identification in childhood (versus during or after puberty) (p<0.01).

Although 95.2% of all enrolled patients self-reported improvement in GAF, in contrast, clinicians determined GAF improved in 61.9% of patients. Clinicians observed improvement in 47% of female-to-male patients and 72% of male-to- female patients. A  $\geq$ 5 point improvement in the GAF score was present in 18 (42.9%). Of note, three of the five patients who were in the process of reassignment and five of the five who had discontinued the process were rated by clinicians as having improved.

Of all enrolled 95.2% (with and without surgery) reported satisfaction with the reassignment process. Of these 42 patients, 33 (79%) identified themselves by their preferred gender and nine (21%) identified themselves as transgender. None of these nine (eight male-to-female) had completed reassignment surgery because of ambivalence secondary to lack of acceptance by others and dissatisfaction with their appearance. Of the patients who underwent genital surgery (n=32) and mastectomy only (n=one), 22 (66.7%) were satisfied while four (three female-to-male) were dissatisfied with the surgical treatment.

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Regarding relationships after surgery, 16 (38.1%) (41.2% of female- to-male; 36.0% of male-to-female patients) were reported to have a partner. Yet more than that number commented on partner relationships: (a) 62.2 % of the 37 who answered (50.0% of female- to- male; 69.6% of male-to-female patients) reported improved partner relationships (five [11.9%] declined to answer.); (b) 70.0% of the 40 who answered (75.0% of female-to-male; 66.7% of male-to-female patients) reported an improved sex life. Investigators observed that reported post-operative satisfaction with sex life was statistically more likely in those with early rather than late cross-gender identification. In addition 55.4% self-reported improved general health; 16.1% reported impaired general health; 11.9% were currently being treated with anti-depressants or tranquilizers.

This study subsumes earlier work by Bodlund et al. (1994, 1996). The nationwide mortality studies by Dhejne et al. (2011) may include all or part of this patient population.

*Leinung M, Urizar M, Patel N, Sood S. Endocrine treatment of transsexual persons: extensive personal experience. Endocr Pract. 2013 Jul-Aug;19(4):644-50. (United States study)* 

Leinung et al. conducted a single-center (Albany, New York) a partially prospective, non-blinded, observational study using a cross-sectional design and descriptive statistics. There were no formal controls. The investigators assessed employment, substance abuse, psychiatric disease, mood disorders, Human Immunodeficiency Virus (HIV) status in patients who had met WPATH guidelines for therapy, and who had initiated cross-sex hormone treatment.

A total of 242 patients treated for gender identity disorder in the clinic from 1992 through 2009 inclusive were identified. The number of those presenting for therapy almost tripled over time. Of these patients, 50 (20.7%) were female-to-male; 192 (79.3%) male-to-female (ratio 1:3.8).

The age of female-to-male and male-to-female patients with gender dysphoria at the time of clinic presentation was 29.0 and 38.0 years respectively.

The female-to-male and male-to-female patients with gender dysphoria at the time of hormone initiation were young: 27.5 and 35.5 years old respectively (p<0.5). Of the male-to-female cohort, 19 (7.8%) had received hormone therapy in the absence of physician supervision; Of the patient population, 91 (37.6%) had undergone gender-reassignment surgery (32 female-to-male [64.0% of all female-to- male; 35.2% of all surgical patients]; 59 male-to-female [30.7% of all male-to-female; 64.8% of all surgical patients]; ratio 1:1.8).

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Motmans J , Meier P, Ponnet K, T'Sjoen G. Female and male transgender quality of life: socioeconomic and medical differences. J Sex Med. 2012 Mar;9(3):743-50. Epub 2011 Dec 21.

Motmans et al., conducted a prospective, non-blinded, observational study using a cross-sectional design and a non-specific quality of life tool. No concurrent controls were used in this study. Quality of life in this Dutch-speaking population was assessed using the Dutch version of a SF-36 (normative data was used). Participants included subjects who were living in accordance with the preferred gender and who were from a single Belgian university specialty clinic at Ghent. The Dutch version of the SF-36 questionnaire along with its normative data were used. Variables explored included employment, pension status, ability to work, being involved in a relationship. Also explored, was surgical reassignment surgery and the types of surgical interventions. Intragroup comparisons by transgender category were conducted, and the relationships between variables were assessed by analysis of variance (ANOVA) and correlations.

The age of the entire cohort (n=140) was 39.89±10.21 years (female-to-male: 37.03±8.51; male-to-female: 42.26±10.39). Results of the analysis revealed that not all female-to-male patients underwent surgical reassignment surgery and, of those who did, not all underwent complete surgical reassignment. The numbers of female-to-male surgical interventions were: mastectomy 55, hysterectomy 55, metaoidplasty eight (with five of these later having phalloplasty), phalloplasty 40, and implantation of a prosthetic erectile device 20. The frequencies of various male-to-female surgical interventions were: vaginoplasty 48, breast augmentation 39, thyroid cartilage reduction 17, facial feminization 14, and hair transplantation three.

The final number of subjects with SF-36 scores was 103 (49 [47.6%] female-to-male; 54 [52.4%] male-to-female; ratio 1:1.1). For this measure, the scores for the vitality and mental health domains for the final female-to-male cohort (n= 49 and not limited to those having undergone some element of reassignment surgery) were statistically lower:  $60.61\pm18.16$  versus  $71.9\pm18.31$  and  $71.51\pm16.40$  versus  $79.3\pm16.4$  respectively. Scores were not different from the normative data for Dutch women: vitality:  $64.3\pm19.7$  or mental health  $73.7\pm18.2$ . None of the domains of the SF-36 for the final male-to-female cohort (n=54 and not limited to those having undergone some element of reassignment surgery) were statistically different from the normative data for Dutch women.

Analysis of variance indicated that quality of life as measured by the SF-36 did not differ by whether female-tomale patients had undergone genital surgery (metaoidoplasty or phalloplasty) or not. Also, ANOVA indicated that quality of life as measured by the SF-36 did not differ by whether male-to-female patients had undergone either breast augmentation or genital surgery (vaginoplasty) or not. Whether there is a were the second of the the second the second of the second the second of the seco

*Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 2006 Nov;15(9):1447-57. Epub 2006 Jun 7. (United States study)* 

Newfield et al. conducted a prospective, observational internet self-report survey of unknown blinding status using a cross- sectional design and a non-specific quality of life tool in a mixed population with and without hormone therapy and/or reassignment surgery. There were no formal controls.

The investigators recruited natal female participants identifying as male using email, internet bulletin boards, and flyers/postcards distributed in the San Francisco Bay Area. Reduction of duplicate entries by the same participant was limited to the use of a unique user name and password.

The investigators employed the Short-Form 36 (SF-36) Version 2 using U.S. normative data. They reported using both male and female normative data for the comparator SF-36 cohort. Data for the eight domains were expressed as normative scoring. The Bonferroni correction was used to adjust for the risk of a Type 1 error with analyses using multiple comparisons.

A total of 379 U.S. respondents classified themselves as males-or-females to males with or without therapeutic intervention. The mean age of the respondents who classified themselves as male or female-to-male was 32.6±10.8 years. Of these 89% were Caucasian, 3.6% Latino, 1.8% African American, 1.8% Asian, and 3.8% other. Of these, 254 (67.0%) reported prior or current testosterone use while 242 (63.8%) reported current testosterone use. In addition, 136 (36.7%) reported having had "top" surgery and 11 (2.9%) reported having "bottom" surgery.

Complete SF-36 data were available for 376 U.S. respondents. For the complete, non-stratified U.S. cohort the Physical Summary Score ( $53.45\pm9.42$ ) was statistically higher (better) than the natal gender unspecified SF-36 normative score ( $50\pm10$ ) (p=<0.001), but was within one standard deviation of the normative mean. The Mental Summary Score ( $39.63\pm12.2$ ) was statistically lower (worse) than the natal gender unspecified SF-36 normative score ( $50\pm10$ ) (p<0.001), but was well within two standard deviations of the normative mean. Subcomponents of this score: Mental Health ( $42.12\pm10.2$ ), Role Emotional ( $42.42\pm11.6$ ), Social Functioning ( $43.14\pm10.9$ ), and Vitality ( $46.22\pm9.9$ ) were statistically lower (worse) than the SF-36 normative sub-scores, but well within one standard deviation of the normative sub- score means. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

Additional intragroup analyses were even within one standard deviation of the normative mean. Interpretive information for these small biologic differences in a proprietary assessment tool was not provided.

#### b. Observational, surgical series, without concurrent controls

Blanchard R, Steiner BW, Clemmensen LH. Gender dysphoria, gender reorientation, and the clinical management of transsexualism. J Consult Clin Psychol. 1985 Jun; 53(3):295-304.

Blanchard et al. conducted a single-center (Ontario, Canada), prospective, non-blinded, cross-sectional study using a self-designed questionnaire and a non- specific psychological symptom assessment with normative data. The investigators assessed social adjustment and psychopathology in patients with gender dysphoria and who were at least one year post gender reassignment surgery. Reassignment surgery was defined as either vaginoplasty or mastectomy/construction of male chest contour with or without nipple transplants, but did not preclude additional procedures. Partner preference was determined using Blanchard's Modified Androphilia-Gynephilia Index, and the nature and extent of any psychopathology was determined with the Symptom Check List 90-Revised (SCL-90R). Differences in test scores considered to be biologically significant were not prespecified in the methods.

Of the 294 patients (111 natal females and 183 natal males, ratio: 1:1.65) initially evaluated, 263 were diagnosed with gender dysphoria. Of these 79 patients participated in the study (38 female-to-male; 32 male-to-female with male partner preference; 9 male-to-female with female partner preference). The respective mean ages for these 3 groups were 32.6, 33.2, and 47.7 years with the last group being older statistically (p=0.01).

Additional surgical procedures in female-to-male patients included: oophorectomy/hysterectomy (92.1%) and phalloplasty (7.9%). Additional surgical procedures in male-to-female patients with male partner preference included facial hair electrolysis 62.5% and breast implantation (53.1%). Additional procedures in male-to-female patients with female partner preference included facial hair electrolysis (100%) and breast implantation (33.3%). The time between reassignment surgery and questionnaire completion did not differ by group.

Psychopathology as measured by the Global Severity Index of the SCL-90R was absent in all three patient groups. Interpretation did not differ by the sex of the normative cohort.

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Of participants, 93.7% reported that they would definitely undergo reassignment surgery again. The remaining 6.3% (one female-to-male; one male-to-female with male partner preference; three male-to-female with female partner preference) indicated that they probably would undertake the surgery again. Post hoc analysis suggested that the more ambivalent responders had more recently undergone surgery. Of responders, 98.7% indicated that they preferred life in the reassigned gender. The one ambivalent subject was a skilled and well compensated tradesperson who was unable to return to work in her male dominated occupation.

*Eldh J, Berg A, Gustafsson M. Long-term follow up after sex reassignment surgery. Scand J Plast Reconstr Surg Hand Surg. 1997 Mar;31(1):39-45.* 

Eldh et al. conducted a non-blinded, observational study using a prospective cross-sectional design with an investigator designed questionnaire and retrospective acquisition of pre-operative data. The investigators assessed economic circumstances, family status, satisfaction with surgical results, and sexual function in patients who had undergone gender reassignment surgery.

Of the 175 patients who underwent reassignment surgery in Sweden, 90 responded. Of this number, 50 were female-to-male and 40 were male-to-female (ratio: 1:0.8). Patients reportedly were generally satisfied with the appearance of the reconstructed genitalia (no numbers provided). Of the patients who had undergone surgery prior to 1986, seven (14%) were dissatisfied with shape or size of the neo-phallus; eight (16%) declined comment. There were 14 (35%), with 12 having surgery prior to 1986 and two between 1986 and 1995 inclusive, were moderately satisfied because of insufficient vaginal volume; 8 (20%) declined comment. A neo-clitoris was not constructed until the later surgical cohort. Three of 33 reported no sensation or no sexual sensation. Eight had difficulties comprehending the question and did not respond.

A total of nine (18%) patients had doubts about their sexual orientation; 13 (26%) declined to answer the question. The study found that two female-to- male patients and two male-to-female patients regretted their reassignment surgery and continued to live as the natal gender, and two patients attempted suicide.

*Hess J, Rossi Neto R, Panic L, Rübben H, Senf W. Satisfaction with male-to-female gender reassignment surgery. Dtsch Arztebl Int.* 2014 Nov 21;111(47):795-801.

Hess at al. contracted a prospective threed posservation assessed post-operative satisfaction in male-to-female patients with gender dysphoria who were followed in a urology specialty clinic (Essen, Germany). Patients had met the ICD-10 diagnostic criteria, undergone gender reassignment surgeries including penile inversion vaginoplasty, and a Likert-style questionnaire with 11 elements. Descriptive statistics were provided.

There were 254 consecutive eligible patients who had undergone surgery between 2004 and 2010 identified and sent surveys, of whom 119 (46.9%) responded anonymously. Of the participants, 13 (10.9%) reported dissatisfaction with outward appearance and 16 (13.4%) did not respond; three (2.5%) reported dissatisfaction with surgical aesthetics and 25 (21.0%) did not respond; eight (6.7%) reported dissatisfaction with functional outcomes of the surgery and 26 (21.8%) did not respond; 16 (13.4%) reported they could not achieve orgasm and 28 (23.5%) did not respond; four (3.4%) reported feeling completely male/more male than female and 28 (23.5%) did not respond; and 16 (13.4%) reported as a woman, two (1.7%) did not understand the question, and 17 (14.3%) did not respond; and 16 (13.4%) reported that life was harder and 24 (20.2%) did not respond.

*Lawrence A. Patient-reported complications and functional outcomes of male-to-female sex reassignment surgery. Arch Sex Behav. 2006 Dec;35(6):717-27. Epub 2006 Nov 16. (United States study)* 

Lawrence conducted a prospective, blinded observational study using a cross-sectional design and a partially selfdesigned quality of life tool using yes/no questions or Likert scales. The investigator assessed sexual function, urinary function, and other pre/post-operative complications in patients who underwent male-to-female gender reassignment surgery. Questions addressed core reassignment surgery (neo-vagina and sensate neo-clitoris) and related reassignment surgery (labiaplasty, urethral meatus revision, vaginal deepening/widening, and other procedures), use of electrolysis, and use of hormones.

Questionnaires were designed to be completed anonymously and mailed to 727 eligible patients. Of those eligible, 232 (32%) returned valid questionnaires. The age at the time reassignment surgery was  $44\pm9$  (range 18-70) years and mean duration after surgery was  $3\pm1$  (range 1-7) years.

Happiness with sexual function and the reassignment surgery was reported to be lower when permanent vaginal stenosis, clitoral necrosis, pain in the vagina or genitals, or other complications such as infection, bleeding, poor healing, other tissue loss, other tissue necrosis, urinary incontinence, and genital numbness were present. Quality of life was impaired when pain in the vagina or genitals was present.

Satisfaction with sexual function, gender reassignment surgery, and overall QOL was lower when genital sensation was impaired and when vaginal architecture and lubrication were perceived to be unsatisfactory. Intermittent regret regarding reassignment surgery was associated with vaginal hair and clitoral pain. Vaginal stenosis was associated with surgeries performed in the more distant past; whereas, more satisfaction with vaginal depth and width was present in more recent surgical treatment.

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Salvador J, Massuda R, Andreazza T, Koff WJ, Silveira E, Kreische F, de Souza L, de Oliveira MH, Rosito T, Fernandes BS, Lobato MI. Minimum 2-year follow up of sex reassignment surgery in Brazilian male-to-female transsexuals. Psychiatry Clin Neurosci. 2012 Jun; 66(4):371-2. PMID: 22624747.

Salvador et al. conducted a single center (Port Alegre, Brazil) prospective, non-blinded, observational study using a cross-sectional design (albeit over an extended time interval) and a self-designed quality of life tool. The investigators assessed regret, sexual function, partnerships, and family relationships in patients who had undergone gender reassignment surgery at least 24 months prior.

Out of the 243 enrolled in the clinic over a 10 year interval, 82 underwent sex reassignment surgery. There were 69 participants with a minimum 2-year follow up, of whom 52 patients agreed to participate in the study. The age at follow-up was 36.3±8.9 (range 15-58) years with the time to follow-up being 3.8±1.7 (2-7) years. A total of 46 participants reported pleasurable neo-vaginal sex and post-surgical improvement in the quality of their sexual experience. The quality of sexual intercourse was rated as satisfactory to excellent, average, unsatisfactory, or not applicable in the absence of sexual contact by 84.6%, 9.6%, 1.9%, and 3.8% respectively. Of the participants, 78.8% reported greater ease in initiating and maintaining relationships; 65.4% reported having a partner; 67.3% reported increased frequency of intercourse; 36.8% reported improved familial relationships. No patient reported regret over reassignment surgery. The authors did not provide information about incomplete questionnaires.

*Tsoi WF. Follow-up study of transsexuals after sex-reassignment surgery. Singapore Med J. 1993 Dec; 34(6):515 -7.* 

Tsoi conducted a single-center (Singapore) prospective, non-blinded, observational study using a cross-sectional design and a self-designed quality of life tool. The investigator assessed overall life satisfaction, employment, partner status, and sexual function in gender-reassigned persons who had undergone gender reassignment surgery between 1972 and 1988 inclusive and who were approximately 2 to 5 years post-surgery. Acceptance criteria for surgery included good physical health, good mental health, absence of heterosexual tendencies, willingness to undergo hormonal therapy for  $\geq 6$  months, and willingness to function in the life of the desired gender for  $\geq 6$  months. Tsoi also undertook retrospective identification of variables that could predict outcomes.

The size of the pool of available patients was not identified. Of the 81 participants, 36 (44.4%) were female-to-male and 45 (55.6%) were male-to-female (ratio 1:1.25).

The mean ages at the time of the initial visit and operation were: female-to-male  $25.4\pm4.4$  (range 14-36) and  $27.4\pm4.0$ ; (range 14-36); male-to-female  $22.9\pm4.6$  (range 14-36) and  $24.7\pm4.3$  (14-36) years respectively. Of all participants, 14.8% were under age 20 at the time of the initial visit. All were at least 20 at the time of gender

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All participants reported dressing without difficulty in the reassigned gender; 95% of patients reported good or satisfactory adjustment in employment and income status; 72% reported good or satisfactory adjustment in relationships with partners. Although the quality of life tool was self-designed, 81% reported good or satisfactory adjustment to their new gender, and 63% reported good or acceptable satisfaction with sexual activity. Of the female-to-male patients, 39% reported good or acceptable satisfaction with sex organ function in comparison to 91% of male-to-female patients (p<0.001). (The author reported that a fully functioning neo-phallus could not be constructed at the time.) The age of non-intercourse sexual activity was the only predictor of an improved outcome.

Weyers S, Elaut E, De Sutter P, Gerris J, T'Sjoen G, Heylens G, De Cuypere G, Verstraelen H. Long-term assessment of the physical, mental, and sexual health among transsexual women. J Sex Med. 2009 Mar;6(3):752 -60. Epub 2008 Nov 17.

Weyers at al. (2009) conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments including a non-specific quality of life tool and a semi-specific quality of life tool (using normative data) along with two self-designed tools.

The investigators assessed general quality of life, sexual function, and body image from the prior four weeks in Dutch-speaking male-to-female patients with gender dysphoria who attended a single-center (Ghent, Belgium), specialized, comprehensive care university clinic. Investigators used the Dutch version of the SF-36 and results were compared to normative data from Dutch women and U.S. women. The 19 items of the Dutch version of the Female Sexual Function Index (FSFI) were used to measure sexual desire, function, and satisfaction. A self-designed seven question visual analog scale (VAS) was used to measure satisfaction with gender related body traits and appearance perception by self and others. A self-designed survey measured a broad variety of questions regarding personal medical history, familial medical history, relationships, importance of sex, sexual orientation, gynecologic care, level of regret, and other health concerns. For this study, hormone levels were also obtained.

The study consisted of 50 (71.5% of the eligible recruits) participants. Analysis of the data revealed that the patient's average age was  $43.1 \pm 10.4$  years, and all of the patients had vaginoplasty. This same population also had undergone additional feminization surgical procedures (breast augmentation 96.0%, facial feminization 36.0%, vocal cord surgery 40.0%, and cricoid cartilage reduction 30.0%). A total of two (4.0%) participants reported "sometimes" regretting reassignment surgery and 23 (46.0%) were not in a relationship. For the cohort, estradiol, testosterone, and sex hormone binding globulin levels were in the expected range for the reassigned gender. The SF-36 survey revealed that the subscale scores of the participants did not differ substantively from those of Dutch and U.S. women. VAS scores of body image were highest for self-image, appearance to others, breasts, and vulva/vagina (approximately 7 to 8 of 10). Scores were lowest for body hair, facial hair, and voice characteristics (approximately 6 to 7 of 10).

The total FSFI Same was 16.99920.04 Work of Paramental #36.07 the First sole and a start start of the study, data on test population controls were not provided.

A post hoc exploration of the data suggested the following: perceived improvement in general health status was greater in the subset that had undergone reassignment surgery within the last year; sexual orientation impacted the likelihood of being in a relationship; SF-36 scores for vitality, social functioning, and mental health were nominally better for those in relationships, but that overall SF-36 scores did not differ by relationship status; sexual orientation and being in a relationship impacted FSFI scores; and reported sexual function was higher in those with higher satisfaction with regards to their appearance.

Wierckx K, Van Caenegem E, Elaut E, Dedecker D, Van de Peer F, Toye K, Weyers S, Hoebeke P, Monstrey S, De Cuypere G, T'Sjoen G. Quality of life and sexual health after sex reassignment surgery in transsexual men. J Sex Med. 2011 Dec;8 (12):3379-88. Epub 2011 Jun 23.

Wierckx at al. conducted a prospective, non-blinded, observational study using a cross-sectional design and several measurement instruments (a non-specific quality of life tool with reported normative data along with three self-designed tools). The investigators assessed general quality of life, sexual relationships, and surgical complications in Dutch-speaking female-to-male patients with gender dysphoria who attended a single-center, specialized, comprehensive care, university clinic (Ghent, Belgium). Investigators used the Dutch version of the SF-36 with 36 questions, eight subscales, and two domains evaluating physical and mental health. Results were compared to normative data from Dutch women and Dutch men. Self -designed questionnaires to evaluate aspects of medical history, sexual functioning (there were separate versions for those with and without partners), and surgical results were also used. The Likert-style format was used for many of the questions.

A total of 79 female-to-male patients with gender dysphoria had undergone reassignment surgery were recruited; ultimately, 47 (59.5%) chose to participate. Three additional patients were recruited by other patients. One of the 50 participants was later excluded for undergoing reassignment surgery within the one year window. The age of patients was:  $30\pm8.2$  years (range 16 to 49) at the time of reassignment surgery and  $37.1\pm8.2$  years (range 22 to 54) at the time of follow-up. The time since hysterectomy, oopherectomy, and mastectomy was 8 years (range 2 to 22). The patient population had undergone additional surgical procedures: metaidoiplasty (n=9; 18.4%), phalloplasty (n=8 after metaidoiplasty, 38 directly; 93.9% total), and implantation of erectile prosthetic device (n=32; 65.3%). All had started hormonal therapy at least two years prior to surgery and continued to use androgens.

The SF-36 survey was completed by 47 (95.9%) participants. The "Vitality" and the "Mental Health" scales were lower than the Dutch male population:  $62.1\pm20.7$  versus  $71.9\pm18.3$  and  $72.6\pm19.2$  versus  $79.3\pm16.4$  respectively. These subscale scores were equivalent to the mean scores of the Dutch women.

None of the patterparts were disastismed with the may the description of an erectile prosthetic device; 25 (51.0%) reported at least one post-operative complication of an erectile prosthetic device; non-post-operative complication of an erectile prosthetic device at least one post-operative disastismed with an erectile prosthetic device, reported at least one post-operative with implantation of an erectile prosthetic device, infection, urethrostenosis, or fistula formation); 16 (50.0% of the 32 with an erectile prosthetic device) reported at least one post-operative complication of an erectile prosthetic device, infection, leakage, incorrect positioning, or lack of function).

A total of 18 (36.7%) participants were not in a relationship; 12.2% reported the inability to achieve orgasm with self-stimulation less than half the time; 12.2% did not respond to the question. Of those participants with partners, 28.5% reported the inability to achieve orgasm with intercourse less than half the time and 9.7% did not respond to this question. Also, 61.3% of those with partners reported (a) no sexual activities (19.4%) or (b) activities once or twice monthly (41.9%), and there were 12.9% who declined to answer.

# c. Observational, surgical patients, cross-sectional, with controls

Ainsworth TA, Spiegel JH. Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. Qual Life Res. 2010 Sep;19(7):1019-24.

Ainsworth and Spiegel conducted a prospective, observational study using a cross-sectional design and a partially self-designed survey tool. The blind status is unknown. Treatment types served as the basis for controls.

The investigators, head and neck surgeons who provided facial feminization services, assessed perception of appearance and quality of life in male-to-female subjects with self-reported gender dysphoria. Patients could have received no therapeutic intervention, hormone therapy, reassignment surgery, and/or facial feminization surgery and an unrestricted length of transition. (Transition refers to the time when a transgender person begins to live as the gender with which they identify rather than the gender assigned at birth.) Criteria for the various types of interventions were not available because of the survey design of the study. Patients were recruited via website or at a 2007 health conference. Pre-specified controls to eliminate duplicate responders were not provided. The investigators employed a self-designed Likert-style facial feminization outcomes evaluation questionnaire and a "San Francisco 36" health questionnaire. No citations were provided for the latter. It appears to be the Short-form (SF) 36-version 2. Changes or differences considered to be biologically significant were not pre-specified. Power corrections for multiple comparisons were not provided.

The investigators reported that there were 247 participants. (The numbers of incomplete questionnaires was not reported.) Of the 247 participants, 25 (10.1%) received only primary sex trait reassignment surgery, 28 (11.3%) received facial surgery without primary sex trait reassignment surgery, 47 (19.0%) received both facial and primary sex trait reassignment surgery, and 147 (59.5%) received neither facial nor reassignment surgery.

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The mean age for each of these cohorts was: 50 years (no standard deviation [S.D.]) only reassignment surgery, 51 years (no S.D.) only facial surgery, 49 years (no S.D.) both types of surgery, and 46 years (no S.D.) (neither surgery). Of the surgical cohorts: 100% of those who had undergone primary sex trait reassignment surgery alone used hormone therapy, 86% of those who had undergone facial feminization used hormone therapy, and 98% of those who had undergone surgery and facial feminization used hormone therapy. In contrast to the surgical cohorts, 66% of the "no surgery" cohort used hormonal therapy, and a large proportion (27%) had been in transition for less than one year.

The investigators reported higher scores on the facial outcomes evaluation in those who had undergone facial feminization. Scores of the surgical cohorts for the presumptive SF-36 comprehensive mental health domain did not differ from the general U.S. female population. Scores of the "no surgery" cohort for the comprehensive mental health domain were statistically lower than those of the general U.S. female population, but within one standard deviation of the normative mean. Mean scores of all the gender dysphoric cohorts for the comprehensive physical domain were statistically higher than those of the general female U.S. population, but were well within one standard deviation of the normative mean. Analyses of inter-cohort differences for the SF-36 results were not conducted. Although the investigators commented on the potential disproportionate impact of hormone therapy on outcomes and differences in the time in "transition", they did not conduct any statistical analyses to correct for putative confounding variables.

*Kraemer B, Delsignore A, Schnyder U, Hepp U. Body image and transsexualism. Psychopathology. 2008;41(2):96* -100. *Epub 2007 Nov 23.* 

Kraemer et al. conducted a single center (Zurich, Switzerland) prospective, non-blinded, observational study using a cross-sectional design comparing pre-and post- surgical cohorts. Patients were required to meet DSM III or DSM IV criteria as applicable to the time of entry into the clinic. Post-surgical patients were from a long-term study group (Hepp et al., 2002). Pre-surgical patients were recent consecutive referrals. The assessment tool was the Fragebogen zur Beurteilung des eigenen Korpers (FBeK) which contained three domains.

There were 23 pre-operative patients: 7 (30.4%) female-to-male and 16 (69.6%) male-to-female (ratio 1:2.3). There were 22 post-operative patients: 8 (36.4%) female-to-male and 14 (63.6%) male-to-female (ratio 1:1.8). The mean ages of the cohorts were as follows: pre-operative  $33.0\pm11.3$  years; post-operative  $38.2\pm9.0$  years. The mean duration after reassignment surgery was  $51\pm25$  months (range 5-96).

The pre-operative groups had statistically higher insecurity scores compared to normative data for the natal sex: female-to-male  $9.0\pm3.8$  versus  $5.1\pm3.7$ ; male-to-female  $8.1\pm4.5$  versus  $4.7\pm3.1$  as well as statistically lower self-confidence in one's attractiveness: female-to-male  $3.1\pm2.9$  versus  $8.9\pm3.1$ ; male-to-female  $7.0\pm2.9$  vs  $9.5\pm2.6$ .

Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of Printed on 5/31/2018. Page 26 of 150

Mate-Kole at al. conducted a single site (London, United Kingdom) prospective non-blinded, observational study using a cross-sectional design and two psychological tests (one with some normative data). Concurrent controls were used in this study design. The investigators assessed neuroticism and sex role in natal males with gender dysphoria. Patients at various stages of management, (i.e., under evaluation, using cross-sex hormones, or post reassignment surgery [6 months to 2 years]) were matched by age of cross-dressing onset, childhood neuroticism, personal psychiatric history, and family psychiatric history. Both a psychologist and psychiatrist conducted assessments. The instruments used were the Crown Crisp Experiential Index (CCEI) for psychoneurotic symptoms and the Bem Sex Role Inventory. ANOVA was used to identify differences between the three treatment cohorts.

For each cohort, investigators recruited 50 male-to-female patients from Charing Cross Hospital. The mean ages of the three cohorts were as follows: 34 years for patients undergoing evaluation; 35 years for wait-listed patients; and 37 years for post-operative patients. For the cohorts, 22% of those under evaluation, 24% of those on hormone treatment only, and 30% of those post-surgery had prior psychiatric histories, and 24%, 24%, while 14% in each cohort, respectively, had a history of attempted suicide. More than 30% of patients in each cohort had a first degree relative with a history of psychiatric disease.

The scores for the individual CCEI domains for depression and somatic anxiety were statistically higher (worse) for patients under evaluation than those on hormone treatment alone. The scores for all of the individual CCEI domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were statistically lower in the post-operative cohort than in the other two cohorts.

The Bem Sex Role Inventory masculinity score for the combined cohorts was lower than for North American norms for either men or women. The Bem Sex Role Inventory femininity score for the combined cohorts was higher than for North American norms for either men or women. Those who were undergoing evaluation had the most divergent scores from North American norms and from the other treatment cohorts. Absolute differences were small. All scores of gender dysphoric patients averaged between 3.95 and 5.33 on a 7 point scale while the normative scores averaged between 4.59 and 5.12.

*Wolfradt U, Neumann K. Depersonalization, self-esteem and body image in male-to-female transsexuals compared to male and female controls. Arch Sex Behav. 2001 Jun;30(3):301-10.* 

Wolfradt and Neumann conducted a controlled, prospective, non-blinded, observational study using a crosssectional design. The investigators assessed aspects of personality in male-to-female patients who had undergone vocal cord surgery for voice feminization and in healthy non-transgender volunteers from the region. The patients had undergone gender reassignment surgery 1 to 5 years prior to voice surgery. The volunteers were matched by age and occupation.

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The primary hypothesis was that depersonalization, with the sense of being detached from one's body or mental processes, would be more common in male-to- female patients with gender dysphoria. German versions of the Scale for Depersonalization Experiences (SDPE), the Body Image Questionnaire (BIQ), a Gender Identity Trait Scale (GIS), and the Self-Esteem Scale (SES) were used in addition to a question regarding global satisfaction. Three of the assessments used a 5 point scale (BIQ, GIS, and SDPE) for questions. One used a 4 point scale (SES). Another used a 7 point scale (global satisfaction). The study consisted of 30 male-to-female patients, 30 healthy female volunteers, and 30 healthy male volunteers. The mean age of study participants was 43 years (range 29- 67).

Results of the study revealed that there were no differences between the three groups for the mean scores of measures assessing depersonalization, global satisfaction, the integration of masculine traits, and body-image-rejected (subset). Also, the sense of femininity was equivalent for male-to-female patients and female controls and higher than that in male controls. The levels of self-esteem and body image-dynamic (subset) were equivalent for male-to-female patients and none of the numeric differences between means exceeded 0.61 units.

*Kuhn A, Bodmer C, Stadlmayr W, Kuhn P, Mueller M, Birkhäuser M. Quality of life 15 years after sex reassignment surgery for transsexualism. Fertil Steril. 2009 Nov;92(5):1685-1689.e3. Epub 2008 Nov 6.* 

Kuhn et al. conducted a prospective, non-blinded, observational study using a cross-sectional design and semimatched control cohort. The investigators assessed global satisfaction in patients who were from gynecology and endocrinology clinic (Bern, Switzerland), and who had undergone some aspect of gender reassignment surgery in the distant past, but were still receiving cross-sex hormones from the clinic. The quality of life assessment tools included a VAS and the King's Health Questionnaire (KHQ), which consists of eight domains with scores between zero and five or one and five, with lower scores indicating higher preference. The KHQ and the numerical change/difference required for clinical significance (≥5 points in a given domain, with higher scores being more pathologic) were included in the publication. Twenty healthy female controls from the medical staff who had previously undergone an abdominal or pelvic surgery were partially matched by age and body mass index (BMI), but not sex. No corroborative gynecologic or urologic evaluations were undertaken.

Of the 55 participants, three (5.4%) were female-to-male and 52 (94.5%) were male-to-female (ratio 1:17.3). Reassignment surgery had been conducted 8 to 23 years earlier (median 15 years). The median age of the patients at the time of this study was 51 years (range 39-62 years). The patients had undergone a median of nine surgical procedures in comparison to the two undergone by controls. Reassignment patients were less likely to be married (23.6% versus 65%; p=0.002); partnership status was unknown in five patients. The scores of VAS global satisfaction (maximal score eight) were lower for surgically reassigned patients (4.49±0.1 SEM) than controls (7.35±0.26 SEM) (p<0.0001).

The abstract stated that quality of life was lower in reassignment patients 15 years after surgery relative to controls. One table in the study, Table 2, delineated statistically and biologically significant differences for four of the eight KHQ domains between the patients and controls: physical limitation:  $37.6\pm2.3$  versus  $20.9\pm1.9$  (p<0.0001), personal limitation:  $20.9\pm1.9$  versus  $11.6\pm0.4$  (p<0.001), role limitation: 27.8+2.4 versus 34.6+1.7 (p=0.046), and general health:  $31.7\pm2.2$  versus  $41.0\pm2.3$  (p<0.02). There is a related paper by Kuhn Printed on 5/31/2018. Page 28 of 150

Haraldsen IR, Dahl AA. Symptom profiles of gender dysphoric patients of transsexual type compared to patients with personality disorders and healthy adults. Acta Psychiatr Scand. 2000 Oct;102(4):276-81.

Haraldsen and Dahl conducted a single-center (Oslo, Norway) partially prospective, non-blinded, observational study using a cross-sectional design and a non-specific psychometric test. There was a control group, but it was not concurrent.

In the germane sub-study, the investigator assessed psychopathology in patients with gender dysphoria. Patients, who were independently evaluated by two senior psychiatrists, were required to meet DSM III-R or DSM IV diagnostic criteria and the Swedish criteria for reassignment surgery. The Norwegian version of the SCL-90 was used. The testing was conducted from 1987 to 1989 for those who had undergone reassignment surgery between 1963 and 1987 and from 1996 to 1998 for pre- surgical patients who had applied for reassignment surgery between 1996 and 1998. In addition, Axis I, Axis II, and Axis V (Global Functioning) was assessed.

Of 65 post-surgical and 34 pre-surgical patients, 59 post-surgical and 27 pre-surgical patients ultimately entered the study. The combined cohorts consisted of 35 (40.7%) female-to-male patients and 51 (59.3%) male-to-female patients (ratio 1:1.5). The ages were female-to-male  $34\pm9.5$  years and female-to-male  $33.3\pm10.0$  years. The other control group consisted of patients with personality disorder. Of these, 101 (27 men ( $33.9\pm7.3$  years) and 74 women ( $31.6\pm8.2$ ) were tested during a treatment program. One year later, 98% were evaluated. A total of 28 (32.5%) of the pre- and post- reassignment surgery patients had an Axis I diagnosis compared to 100 (99.0%) of those with personality disorders. Depression and anxiety were the most common diagnoses in both groups, but were approximately three to four times more common in the personality disorder cohort. Seventeen (19.8%) of the pre- and post-reassignment surgery patients had an Axis II diagnosis whereas the mean number of personality disorders in the personality disorder cohort was  $1.7\pm1$ . The Global Assessment of Function was higher (better) in the gender dysphoric groups ( $78.0\pm8.9$ ) than in the personality disorder cohort ( $53.0\pm9.0$ ).

Global Severity Indices (GSI) were highest for those with personality disorder regardless of gender and exceeded the cut-point score of 1.0. The GSI scores for females-to-males and males-to-females were  $0.67\pm57$  and  $0.56\pm0.45$ . Although they were nominally higher than the healthy normative controls (males:  $0.32\pm0.36$  and females  $0.41\pm0.43$ ), they were well within the non- pathologic range. The same was true for the subscales.

SCL-90 GSI scores did not differ substantively between pre- and post-surgical patients, nor did the SCI subscale scores differ substantively between pre- and post-surgical patients. Any small non-significant differences tracked with the age and sex differences.

Beatrice conducted a prospective, non-blinded, observational study using a cross-sectional design and control cohorts in the U.S. The investigator assessed psychological adjustment and functioning (self-acceptance) in male-to-female patients with gender dysphoria (with and without GRS), transvestites from two university specialty clinics, and self-identified heterosexual males recruited from the same two universities. The criteria to qualify for the study included being known to the clinic for at least one year, cross-dressing for at least one year without arrest, attendance at 10 or more therapy sessions, emotionally self-supporting, and financially capable of payment for reassignment surgery, and all of these criteria were met by the pre-operative cohort as well as the post-operative cohort. The cohorts were matched to the post-operative cohort (age, educational level, income, ethnicity, and prior heterosexual object choice). The post-operative cohort was selected not on the basis of population representation, but on the basis of demographic feasibility for a small study. The instruments used were the Minnesota Multiphasic Personality Inventory (MMPI) and the Tennessee Self-Concept Scale (TSCS). Changes or differences considered to be biologically significant were not pre-specified.

Of the initial 54 recruits, ten subjects were left in each of the cohorts because of exclusions identified due to demographic factors. The mean age of each cohort were as follows: pre-operative gender dysphoric patients 32.5 (range 27-42) years, postoperative patients 35.1 (30-43) years old, transvestite 32.5 (29-37) years old, and heterosexual male 32.9 (28-38) years old. All were Caucasian. The mean age for cross-dressing in pre-operative patients (6.4 years) and post-operative patients (5.8 years) was significantly lower than for transvestites (11.8 years).

The scores for self-acceptance did not differ by diagnostic category or surgical status as measured by the TSCS instrument. As measured by the T-scored MMPI instrument (50±10), levels of paranoia and schizophrenia were higher for post-operative (GRS) patients (63.0 and 68.8) than transvestites (55.6 and 59.6) and heterosexual males (56.2 and 51.6). Levels of schizophrenia were higher for pre-operative patients (65.1) than heterosexual males (51.6). There were no differences between patients with gender dysphoria. Scores for the Masculine-Feminine domain were equivalent in those with transvestitism and gender dysphoria with or without surgery, but higher than in heterosexual males. The analysis revealed that despite the high level of socio-economic functioning in these highly selected subjects, the MMPI profiles based on the categories with the highest scores were notable for antisocial personality, emotionally unstable personality, and possible manic psychosis in the pre-operative GRS patients. By contrast, the same MMPI profiling in heterosexual males and transvestites was notable for the absence of psychological dysfunction.

# d. Observational, surgical patients, longitudinal, with controls

Dhejne C, Lichtenstein P, Boman M, Johansson A, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One. 2011;6(2):e16885. Epub 2011 Feb 22.

Dhejne et al. conducted a retrospective, Non-Dinder, observation assessed condition and reality asing a longitudinal and a population-based matched cohort. The investigators assessed conditions such as, but not limited to, mortality, suicide attempts, psychiatric hospitalization, and substance abuse in gender-reassigned persons and randomly selected unexposed controls matched by birth year and natal sex (1:10) as well as by birth year and the reassigned gender (1:10). Data were extracted from national databases including the Total Population Register (Statistics Sweden), the Medical Birth Register, the Cause of Death Register (Statistics Sweden), the Hospital Discharge Register (National Board of Health and Welfare), the Crime Register (National Council of Crime), and those from the Register of Education for highest educational level. The criteria required to obtain the initial certificate for reassignment surgery and change in legal status from the National Board of Health and Welfare were the 2002 WPATH criteria and included evaluation and treatment by one of six specialized teams, name change, a new national identity number indicative of gender, continued use of hormones, and sterilization/castration. Descriptive statistics with hazard ratios were provided.

Investigators identified 804 patients with gender identity disorder (or some other disorder) in Sweden during the period from 1973 to 2003 inclusive. Of these patients, 324 (40.3%) underwent gender-reassignment surgery (133 female-to-male [41.0%]; 191 male-to-female [59.0%]; ratio 1:1.4). The average follow-up time for all-cause mortality was 11.4 years (median 9.1). The average follow-up time for psychiatric hospitalization was 10.4 years (median 8.1).

The mean ages in female-to-male and male-to-female reassigned patients were:  $33.3\pm8.7$  (range 20–62) and  $36.3\pm10.1$  (range 21–69) years, respectively. Immigrant status was two times higher in reassigned patients (n=70, 21.6%) than in either type of control (birth [natal] sex matched n=294 [9.1%] or reassigned gender matched n=264 [8.1%]). Educational attainment (10 or more years) was somewhat lower for reassigned patients (n=151 [57.8%]) than in either type of control (birth sex matched n=1,725 [61.5%] or reassigned gender matched n=1804 [64.3%]) (cohort data were incomplete). The biggest discordance in educational attainment was for female-to-male reassigned patients regardless of the control used. Prior psychiatric morbidity (which did not include hospitalization for gender dysphoria) was more than four times higher in reassigned patients (n=58, 17.9%) than in either type of control (birth sex matched n=123 [3.8%] or reassigned gender matched n=114 [3.5%]).

All-cause mortality was higher for patients who underwent gender reassignment surgery (n=27 [8.3%]) than in controls (hazard ratio 2.8 [CI 1.8-4.3]) even after adjustment for covariants (prior psychiatric morbidity and immigration status). Divergence in the survival curves began at 10 years. Survival rates at 20 year follow-up (as derived from figure 1) were: female control 97%, male controls 94%, female-to-male patients 88%, and male-to-female patients 82%. The major contributor to this mortality difference was completed suicide (n=10 [3.1%]; adjusted hazard ratio 19.1 [CI 5.8-62.9]). Mortality due to cardiovascular disease was modestly higher for reassigned patients (n=9 [2.8%]) than in controls (hazard ratio 2.5 [CI 1.2-5.3]).

Suicide attempts were more common in patients who underwent gender reassignment surgery (n= 29 [9.0%] than in controls (adjusted hazard ratio 4.9 [CI 2.9–8.5]). Male-to-female patients were at higher adjusted risk for attempted suicide than either control whereas female-to-male patients were at higher adjusted risk compared to only male controls and maintained the female pattern of higher attempted suicide risk. Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common in reassigned persons n = 64 [20.0%] than in controls (hazard ratio 2.8 [CI 2.0–3.9]) even after adjusting for prior psychiatric morbidity. Hospitalization for substance abuse was not greater than either type of control.

The nationwide and the Dhejne et al. (2014) population.

Dhejne C, Öberg K, Arver S, Landén M. An analysis of all applications for sex reassignment surgery in Sweden, 1960-2010: prevalence, incidence, and regrets. Arch Sex Behav. 2014 Nov;43(8):1535-45. Epub 2014 May 29 and Landén M, Wålinder J, Hambert G, Lundström B. Factors predictive of regret in sex reassignment. Acta Psychiatr Scand. 1998 Apr;97(4):284 (Dhejne et al., 2014; Landén et al., 1998) Sweden-All

Dhejne et al. conducted a non-blinded, observational study that was longitudinal for the capture of patients with "regret" in a national database. This same group (Landén et al., 1998) conducted a similar study along with retrospective acquisition of clinical data to explore the differences between the cohorts with and without regret. There were no external controls; only intra- group comparisons for this surgical series.

The investigators assessed the frequency of regret for gender reassignment surgery. Data were extracted from registries at the National Board of Health and Welfare to which patients seeking reassignment surgery or reversal of reassignment surgery make a formal application and which has maintained such records since a 1972 law regulating surgical and legal sex reassignment. The investigators reviewed application files from 1960 through 2010. The specific criteria to qualify for gender surgery were not delineated. Patients typically underwent diagnostic evaluation for at least one year. Diagnostic evaluation was typically followed by the initiation of gender confirmation treatment including hormonal therapy and real-life experience. After two years of evaluation and treatment, patients could make applications to the national board. Until recently sterilization or castration were the required minimal surgical procedures (Dhejne et al., 2011). Secular changes in this program included consolidation of care to limited sites, changes in accepted diagnostic criteria, and provision of non-genital surgery, e.g., mastectomy during the real-life experience phase, and family support.

There were 767 applicants for legal and surgical reassignment (289 [37.7%] female-to-male and 478 [62.3%] male-to-female; ratio 1:1.6). The number of applicants doubled each ten year interval starting in 1981.

Of the applicants, 88.8% or 681 (252 [37.0%] female-to-male and 429 [63.0%] male-to-female; ratio 1:1.7] had undergone surgery and changed legal status by June 30, 2011. This number included eight (four [50.0%] female-to-male and four [50.0%] male to female; ratio 1:1) people who underwent surgery prior to the 1972 law. This number appears to include 41 (two [4.9%] female-to-male and 39 [95.1%] male-to-female; ratio 1:19.5) people who underwent surgery abroad at their own expense (usually in Thailand or the U.S.). This cohort (6% of 681) includes one person who was denied reassignment surgery by Sweden.

Twenty-five (3.3%) of the applications were denied with the two most common reasons being an incomplete application or not meeting the diagnostic criteria. An additional 61(8.0%) withdrew their application, were wait-listed for surgery, postponed surgery (perhaps in hopes of the later revocation of the sterilization requirement), or were granted partial treatment.

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The formal application for reversal of the legal gender status, the "regret rate", was 2.2%. No one who underwent sex- reassignment surgery outside of Sweden (36 of these 41 had surgery after 1991) has requested reversal. The authors noted, however, that this preliminary number may be low because the median time interval to reversal request was eight years-only three of which had elapsed by publication submission- and because it was the largest serial cohort. This number did not include other possible expressions of regret including suicide (Dhejne et al., 2011).

Dhejne et al. in 2014 reported that the female-to-male (n=5): male-to-female (n=10) ratio among those who made formal applications for reversal was 1:2. The investigators also reported that the female-to-male applicants for reversal were younger at the time of initial surgical application (median age 22 years) than the complete female-to-male cohort at the time of surgical application (median age 27 years). By contrast the male-to-female applicants for reversal were older at the time of initial surgical application (median age 35 years) than the complete male-to-female cohort at the time of initial surgical application (median age 32 years). Other clinical data to explore the differences between the cohorts with and without regret were not presented in this update publication.

In their earlier publication, in addition to determining a regret rate (3.8%), Landén et al. extracted data from medical records and government verdicts. Pearson Chi-square testing with Yates' correction for small sample sizes was used to identify candidate variables predictive of regret. They observed that: (a) 25.0% of the cohort with regrets and 11.4% of the cohort without regrets were unemployed, (b) 16.7% of the cohort with regrets and 15.4% of the cohort without regrets were on "sick benefit", (c) 15.4% of the cohort with regrets and 13.9% of the cohort without regrets had problems with substance abuse, (d) 69.2% of the cohort with regrets and 34.6% of the cohort without regrets had undergone psychiatric treatment, (e) 15.4% of the cohort with regrets and 8.8% of the cohort without regrets had a mood disorder, and (f) 15.4% of the cohort with regrets and 1.5% of the cohort without regrets had a psychotic disorder.

The putative prognostic factors that were statistically different between the cohorts with and without regret included prior psychiatric treatment, a history of psychotic disorder, atypical features of gender identity, and poor family support. Factors that trended towards statistical difference included having an unstable personality, sexual orientation and transvestitism. Univariate regression analyses further clarified the most important variables. These variables were tested with logistic regression. Initial modeling included the variable "history of psychotic disorder". Although this variable was predictive, it was excluded from future analyses because it was already a contraindication to reassignment surgery. Additional multivariate regression analyses identified poor family support as the most predictive variable and atypical features of gender identity as the second most important variable. Presence of both variables had a more than additive effect.

The nationwide mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landén (1998) patient population and most of the Dhejne (2014) population. There is a related paper by Landén et al. 1998b that included the criteria to qualify for surgical intervention at that time.

Heylens G, Verroken C, De Cock S, T'Sjoen G, De Cuypere G. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. J Sex Med. 2014 Jan;11(1):119-26. Epub 2013 Oct 28. Printed on 5/31/2018. Page 33 of 150

Heylens et al. conducted a prospective, non-blinded observational study using a longitudinal design in which patients served as their own controls. They used a non-specific psychiatric test with normative data along with two self-designed questionnaires. The investigators assessed psychosocial adjustment and psychopathology in patients with gender identity disorders. Patients were to be sequentially evaluated prior to institution of hormonal therapy, then 3 to 6 months after the start of cross-sex hormone treatment, and then again one to 12 months after reassignment surgery. The Dutch version of the SCL-90R with eight subscales (agoraphobia, anxiety, depression, hostility, interpersonal sensitivity, paranoid ideation/psychoticism, and sleeping problems) and a global score (psycho-neuroticism) was used serially. A seven parameter questionnaire was used serially to assess changes in social function. Another cross-sectional survey assessed emotional state. The cohorts at each time point consisted of patients who were in the treatment cohort at the time and who had submitted survey responses.

Ninety of the patients who applied for reassignment surgery between June 2005 and March 2009 were recruited. Fifty seven entered the study. Forty-six (51.1% of the recruited population) underwent reassignment surgery. Baseline questionnaire information was missing for 3 patients. Baseline SCL-90 scores were missing for 1 patient but included SCL-90 scores from some of the 11 recruits who had not yet undergone reassignment surgery. Time point 2 (after hormone therapy) SCL-90 information was missing for 10, but included SCL-90 scores from some of the 11 recruits who had not yet undergone reassignment surgery. At time point 3, 42 (91.3% of those who underwent reassignment surgery) patients completed some part of the SCL-90 survey and the psychosocial questionnaires. Some questionnaires were incomplete. The investigators reported response rates of 73.7% for the psychosocial questionnaires and 82.5% for the SCL-90.

Of those who responded at follow-up after surgery, 88.1% reported having good friends; 52.4% reported the absence of a relationship; 47.6% had no sexual contacts; 42.9% lived alone; 40.5% were unemployed, retired, students, or otherwise not working; 2.4% reported alcohol abuse; and 9.3% had attempted suicide. The frequency of these parameters reportedly did not change statistically during the study interval, but there was no adjustment for the inclusion of patients who did not undergo surgery.

In a cross-sectional, self-report mood survey, of the 42 study entrants who completed the entire treatment regimen including reassignment surgery and the final assessment (refers to the initial 57) reported improved body-related experience (97.6%), happiness (92.9%), mood (95.2%), and self-confidence (78.6%) and reduced anxiety (81.0%). Of participants, 16.7% reported thoughts of suicide. Patients also reported on the intervention phase that they believed was most helpful: hormone initiation (57.9%), reassignment surgery (31.6%), and diagnostic-psychotherapy phase (10.5%).

The global "psycho-neuroticism" SCL-90R score, along with scores of 7 of the 8 subscales, at baseline were statistically more pathologic than the general population. After hormone therapy, the score for global "psycho-neuroticism" normalized and remained normal after reassignment surgery. More specifically the range for the global score is 90 to 450 with higher scores being more pathologic. The score for the general population was  $118.3\pm32.4$ . The respective scores for the various gender dysphoric cohorts were  $157.7\pm49.8$  at initial presentation,  $119.7\pm32.1$  after hormone therapy, and  $127.9\pm37.2$  after surgery. The scores for the general population and the scores after either hormone treatment or surgical treatment did not differ.

Kockott G, Fahransen M. 17anse 2018 Which a Period and the good strigged y 2018 Aug and 22 Aroli Ster Behav. 1987 Dec; 16 (6): 511-22.

Kockott and Fahrner conducted a single center (Munich, Germany) prospective, observational study using a longitudinal design. Treatment cohorts were used as controls, and patients served as their own controls. The investigators assessed psychosocial adjustment in patients with gender identity issues. Patients were to have met DSM III criteria. Trans-sexuality, transvestitism, and homosexuality were differentiated. The criteria required for patients to receive hormone therapy and/or reassignment surgery were not delineated. After receiving hormone therapy, patients were later classified by surgical reassignment status (pre-operative and post-operative) and desire for surgery (unchanged desire, hesitant, and no longer desired).

The first investigative tool was a semi-structured in-person interview consisting of 125 questions. The second investigative tool was a scale that organized the clinical material into nine domains which were then scored on a scale. The Psychological Integration of Trans-sexuals (PIT) instrument developed according to the scale used by Hunt and Hampson (1980) for assessment of 17 post-operative patients. There were 15 interviews and two separate interviewers. There were 80 patients identified, but 58 (72.5%) patients (26 pre-operative; 32 post-operative) were ultimately included in the analysis. The duration of follow-up was longer for post-operative patients (6.5 years) than for pre-operative patients (4.6 years) (including time for one patient subsequently excluded). The mean age of the post-operative patients was  $35.5\pm13.1$  years, and the age of the patients who maintained a continued desire for surgery was  $31.7\pm10.2$  years. The age of the patients who hesitated about surgery was somewhat older,  $40.3\pm9.4$  years. The age of the patients who were no longer interested in surgery was  $31.8\pm6.5$  years. All were employed or in school at baseline. Patients with hesitation were financially better-off, had longer-standing relationships even if unhappy, and had a statistical tendency to place less value on sex than those with an unchanged wish for surgery.

Post-operative patients more frequently reported contentment with the desired gender and the success of adaption to the gender role than the pre-operative patients with a persistent desire for surgery. Post-operative patients more frequently reported sexual satisfaction than pre-operative patients with a continuing desire for surgery. Post-operative patients also more frequently reported financial sufficiency and employment than pre-operative patients with a persistent desire for surgery. Suicide attempts were stated to be statistically less frequent in the post-surgical cohort.

Psychosocial adjustment scores were in the low end of the range with "distinct difficulties" (19-27) at the initial evaluation for the post-operative patients (19.7), the pre-operative patients with a persistent wish for surgery (20.2), and the hesitant patients (19.7). At initial evaluation, psychosocial adjustment scores for patients no longer wanting surgery were at the high end of the range with "few difficulties" (10-18). At the final evaluation, Psychosocial adjustment scores were at the high end of the range "few difficulties" (10-18) for the post-operative patients (13.2) and the patients no longer wanting surgery (16.5). Psychosocial adjustment scores at the final evaluation were in the borderline range between "few difficulties" (10-18) and "distinct difficulties" (19-27) for both the pre-operative patients with a persistent desire for surgery (18.7), and the hesitant patients (19.1).

The changes in the initial score and the final follow-up score within each group were tracked and reported to be statistically significant for the post-operative group, but not for the other groups. Statistical differences between groups were not presented. Moreover, the post-operative patients had an additional test immediately prior to surgery. The first baseline score (19.7) would have characterized the patients as having "distinct difficulties" in Printed on 5/31/2018. Page 35 of 150

psychosocial adjasment while the second basement of # (10.4) would have the prospect of any intervention except the prospect of having imminent reassignment surgery. No statistics reporting on the change between scores of the initial test and the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the change between scores of the test immediately prior to surgery and the scores of the final follow-up were provided.

Meyer JK, Reter DJ. Sex reassignment. Follow-up. Arch Gen Psychiatry. 1979 Aug;36(9):1010-5. (United States study)

Meyer and Reter conducted a single-center (Baltimore, Maryland, U.S.) prospective, non-blinded, observational study using a longitudinal design and retrospective baseline data. Interview data were scored with a self-designed tool. There were treatment control cohorts, and patients served as their own controls. The investigators assessed patients with gender dysphoria. The 1971 criteria for surgery required documented cross-sex hormone use as well as living and working in the desired gender for at least one year in patients subsequently applying for surgery. Clinical data including initial interviews were used for baseline data. In follow-up, the investigators used extensive two to four hour interviews to collect information on (a) objective criteria of adaptation, (b) familial relationships and coping with life milestones, and (c) sexual activities and fantasies. The objective criteria, which were the subject of the publication, included employment status (Hollingshead job level), cohabitation patterns, and need for psychiatric intervention. The investigators designed a scoring mechanism for these criteria and used it to determine a global adjustment score. The score value or the change score that was considered to be biologically significant was not pre-specified in the methods.

The clinic opened with 100 patients, but when the follow-up was completed, 52 patients were interviewed and 50 gave consent for publication. Of these, 15 (four female-to-male, 11 male-to-female; ratio 1:2.8) were part of the initial operative cohort, 14 (one female-to-male; 13 male-to-female; ratio 1:13) later underwent reassignment surgery at the institution or elsewhere, and 21 (five female-to-male; 16 male-to-female; ratio 1:3.2) did not undergo surgery. The mean ages of these cohorts were 30.1, 30.9, and 26.7 years respectively. The mean follow-up time was 62 months (range 19-142) for those who underwent surgery and 25 months (range 15-48) for those who did not. Socioeconomic status was lowest in those who subsequently underwent reassignment surgery.

Of patients initially receiving surgery, 33% had some type of psychiatric contact prior to the initial clinic evaluation and 8% had psychiatric contact during the follow-up. Of the patients who had not under gone surgery or who had done so later, 72% had some type of psychiatric contact prior to the initial clinic evaluation and 28% had psychiatric contact during follow-up. There was a single female-to-male patient with multiple surgical complications who sought partial reassignment surgery reversal.

The adjustment scores improved over time with borderline statistical significance for the initial operative group and with statistical significance for the never operated group. The absolute score value at follow-up was the same for both groups (1.07+1.53 and 1.10+1.97 respectively). By contrast, the adjustment scores did not improve for those who were not in the cohort initially approved for surgery, but who subsequently underwent surgery later. This was particularly true if the surgery was performed elsewhere. The absolute score value at follow-up was 0.21+1.89. *Rakic Z, Starcevic V, Maric J, Kelin K. The outcome of sex reassignment surgery in Belgrade: 32 patients of both sexes. Arch Sex Behav. 1996 Oct;25(5):515-25.* 

Rakic et al. single-center (Belgrade, Yugoslavia) conducted a prospective, non-blinded, observational study using a cross-sectional design and an investigator- designed quality of life tool that asked longitudinal (pre- and post-treatment) questions. Patients served as their own controls. The authors state that the study was not designed to assess the predictors of poor outcomes.

The investigators assessed global satisfaction, body image, relationships, employment status, and sexual function in patients with gender dysphoria who underwent reassignment surgery between 1989 and 1993 and were at least six months post-operative. The criteria to qualify for gender surgery were delineated (1985 standards from the Harry Benjamin International Gender Dysphoria Association) and included cross-gender behavior for at least one year and sexual orientation to non-natal sex. The questionnaire consisted of 10 questions using yes/no answers or Likert-type scales. Findings were descriptive without statistical analysis. As such, changes or differences considered to be biologically significant were not pre-specified, and there were no adjustments for multiple comparisons.

Of the 38 patients who had undergone reassignment surgery, 34 were eligible for the study and 32 participated in the study (two were lost to follow-up and four were in the peri-operative period) - 10 (31.2%) female-to-male and 22 (68.8%) male-to-female (ratio 1:2.2). The duration of follow-up was  $21.8 \pm 13.4$  months (range 6 months to 4 years). The age was female-to-male  $27.8\pm5.2$  (range 23-37) and male-to-female  $26.4\pm7.8$  (range 19-47).

Using an investigator-designed quality of life tool, all patients reported satisfaction with having undergone the surgery. Of the total participants, four (12.5%) (all male-to-female) and eight (25%) (87.5% male-to-female) reported complete dissatisfaction or partial satisfaction with their appearance. Regarding relationships, 80% of female-to-male and 100% of male-to-female patients were dissatisfied with their relationships with others prior to surgery; whereas, no female-to-male patients and 18.1% of male-to-female patients were dissatisfied with relationships after surgery. Regarding sexual partners, 60% of female-to-male and 72.7% of male-to-female patients reported not having a sexual partner prior to surgery; whereas, 20% of female-to-male patients and 27.3% of male-to-female patients did not have a sexual partner after surgery. Of those with partners at each time interval, 100% of female-to-male and 50% of male-to-female patients reported not experiencing orgasm prior to surgery; whereas, 75% of female-to-male and 37.5% of male-to-female patients reported not experiencing orgasm after surgery.

Ruppin U, Pfäfflin F. Long-term follow-up of adults with gender identity disorder. Arch Sex Behav. 2015 Jul;44(5):1321-9. Epub 2015 Feb 18.

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Ruppin and Pfafflin conducted a single-center (Ulm, Germany) partially prospective, non-blinded, observational study using a longitudinal design and non-specific psychometric tests and a self-designed interview tool and questionnaire. Patients served as their own controls.

The investigators assessed psychological symptoms, interpersonal difficulties, gender role stereotypes, personality characteristics, societal function, sexual function, and satisfaction with new gender role in patients with gender dysphoria. Patients were required to have met the ICD-10 criteria for trans-sexualism, been seen by the clinic by prior to 2001, and completed an official change in gender including name change prior to 2001. Assessment tools included German versions of standardized surveys with normative data: the SCL 90R, the Inventory of Interpersonal Problems (IIP), Bem Sex Role Inventory (BSRI), and the Freiburg Personality Inventory (FPI-R), along with semi-structured interviews with self-designed questionnaires. The prospective survey results were compared to retrospective survey results. Changes or inter-group differences considered to be biologically significant were not pre-specified. Diagnostic cut points were not provided. Statistical corrections for multiple comparisons were not included.

Overall, 140 patients received recruitment letters and then 71 (50.7%) agreed to participate. Of these participants, 36 (50.7%) were female-to-male; 35 (49.3%) were male-to-female (ratio 1:0.97). The ages of the patients were: 41.2±5.78 years (female-to-male) and 52.9±10.82 years (male-to-female). The intervals for follow-up were 14.1±1.97 years and 13.7±2.17 years, respectively.

All female-to-male patients had undergone mastectomy; 91.7% had undergone oopherectomy and/or hysterectomy; 61.1% had undergone radial forearm flap phalloplasty or metaoidioplasty. Of male-to-female patients, 94.3% had undergone vaginoplasty and perhaps an additional procedure (breast augmentation, larynx surgery, or vocal cord surgery). Two male-to-female patients had not undergone any reassignment surgery, but were still included in the analyses.

A total of 68 patients ranked their well-being as 4.35±0.86 out of five (three patients did not respond to this question). Of respondents, 40% reported not being in a steady relationship. Regular sexual relationships were reported by 57.1% of 35 female- to-male respondents and 39.4% of 33 male-to-female respondents (three patients did not respond to this question). A total of 11 patients reported receiving out-patient psychotherapy; 69 did not express a desire for gender role reversal (two did not respond to this question). The response rate was less than 100% for most of the self-designed survey questions.

Changes from the initial visit to the follow-up visit were assessed for the SCL-90R in 62 of 71 patients. The effect size was statistically significant and large only for the "Interpersonal Sensitivity" scale (one of 10 parameters). The absolute magnitude of mean change was small: from  $0.70\pm0.67$  to  $0.26\pm0.34$  (scale range 0-4). The duration of follow-up did not correlate with the magnitude of change on the various scales. Differences in baseline SCL-90R scores of 62 participants were compared with the score of 63 of the 69 eligible recruits who declined to enter the study and were notable for higher "Depression" scores for the latter.

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Changes from the initial visit to the follow-up visit were assessed for the IIP in 55 of 71 patients. The effect size was statistically significant and large only for the "Overly Accommodating" scale (one of eight parameters). The absolute magnitude of mean change was small: from 11.64±5.99 to 7.04±4.73 (scale range 0-32). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the FPI-R in 58 of 71 patients. The effect size was statistically significant and large only for the "Life Satisfaction" scale (one of 12 parameters). The absolute magnitude of mean change was substantive: from 4.43±2.99 to 8.31±2.63 (scale range 0-12). The duration of follow-up did not correlate with the magnitude of change on the various scales.

Changes from the initial visit to the follow-up visit were assessed for the BSRI in 16 of 36 female to male patients and 19 of 35 male to female patients. The "Social Desirability" score increased for the female-to-male respondents. At endpoint, both categories of respondents reported androgynous self-images.

This current report is an update of prior publications by Pfafflin including work with Junge which was published in a variety of formats and initially in German.

*Smith YL, Van Goozen SH, Kuiper AJ, Cohen-Kettenis PT. Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals. Psychol Med. 2005 Jan;35(1):89-99.* 

Smith et al. conducted a single-center (Amsterdam, Netherlands) prospective, non-blinded, observational study using a longitudinal design and psychological function tools. Patients served as their own control prior to and after reassignment surgery. The investigators assessed gender dysphoria, body dissatisfaction, physical appearance, psychopathology, personality traits, and post-operative function in patients with gender dysphoria. Patients underwent some aspect of reassignment surgery. The test instruments included the Utrecht Gender Dysphoria Scale (12 items), the Body Image Scale adapted for a Dutch population (30 items), Appraisal of Appearance Inventory (3 observers, 14 items), the Dutch Short MMPI (83 items), the Dutch version of the Symptom Checklist (SCL)(90 items), and clinic-developed or modified questionnaires. Pre-treatment data was obtained shortly after the initial interview. Post- surgery data were acquired at least one year post reassignment surgery.

Three hundred twenty five consecutive adolescents and adults were screened for the study. One-hundred three (29 [28.2%] female-to-male patients and 74 [71.8%] male-to-female patients [ratio 1:2.6]) never started hormone therapy; 222 (76 [34.2%] female-to-male patients and 146 [65.8%] male-to-female patients [ratio 1:1.9]) initiated hormone therapy. Of the patients who started hormone therapy, 34 (5 [14.7%] female-to-male patients and 29 [85.3%] male-to-female patients [ratio 1:5.8]) discontinued hormone therapy.

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Of the 126 adults who provided post-surgical data, 50 (40.0%) reported having a steady sexual partner, three (2.3%) were retired, and 58 (46.0%) were unemployed. Regarding regret, six patients expressed some regret regarding surgery, but did not want to resume their natal gender role, and one male-to-female had significant regret and would not make the same decision.

Post-surgery Utrecht dysphoria scores dropped substantially and approached reportedly normal values. The patients' appearance better matched their new gender. No one was dissatisfied with his/her overall appearance at follow-up. Satisfaction with primary sexual, secondary sexual, and non-sexual body traits improved over time. Male-to-female patients, however, were more dissatisfied with the appearance of primary sex traits than female-to-male patients. Regarding mastectomy, 27 of 38 (71.1%) female-to-male respondents (not including 11 non-respondents) reported incomplete satisfaction with their mastectomy procedure. For five of these patients, the incomplete satisfaction was because of scarring. Regarding vaginoplasty, 20 of 67 (29.8%) male-to-female respondents (not including 10 non-respondents) reported incomplete satisfaction with their vaginoplasty.

Most of the MMPI scales were already in the normal range at the time of initial testing and remained in the normal range after surgery. SCL global scores for psycho- neuroticism were minimally elevated before surgery 143.0 $\pm$ 40.7 (scoring range 90 to 450) and normalized after surgery 120.3 $\pm$ 31.4. (An analysis using patient level data for only the completers was not conducted.)

*Udeze B, Abdelmawla N, Khoosal D, Terry T. Psychological functions in male-to- female people before and after surgery. Sexual and Relationship Therapy. 2008 May; 23(2):141-5. (Not in PubMed) and Megeri D, Khoosal D. Anxiety and depression in males experiencing gender dysphoria. Sexual and Relationship Therapy. 2007 Feb; 22(1):77-81. (Not in PubMed)* 

Udeze et al. conducted a single-center (Leicester, United Kingdom) prospective, non-blinded, longitudinal study assessing a randomized subset of patients who had completed a non-specific psychological function tool prior to and after male-to-female reassignment surgery. Patients served as their own controls. The investigators used the WPATH criteria for patient selection. Psychiatric evaluations were routine. All patients selected for treatment were routinely asked to complete the self-administered SCL-90R voluntarily on admission to the program and post-operatively. A post-operative evaluations (psychiatric and SCL-90R assessment) were conducted within six months to minimize previously determined loss rates. The patient pool was domestic and international. There were 546 gender dysphoric patients from all over the United Kingdom and abroad, of whom 318 (58.2%) progressed to surgery. Of these, 127 were from the local Leicester area in the United Kingdom and 38 (29.9%) progressed to surgery. The mean age for the selected male-to-female patients at the time of study was 47.33±13.26 years (range 25 to 80) and reflected an average wait time for surgery of 14 months (range 2 months to 6 years). For this investigation, 40 male-to-female subjects were prospectively selected.

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The raw SCL-90 global scores for psycho-neuroticism were unchanged over time: 48.33 prior to surgery and 49.15 after surgery. If the scale was consistent with T-scoring, the results were non-pathologic. No psychiatric disorders were otherwise identified prior to or after surgery.

Investigators from the same clinical group (Megeri, Khoosal, 2007) conducted additional testing to specifically address anxiety and depression with the Beck Depression Inventory, General Health Questionnaire (with 4 subscales), HADS, and Spielberger State and Trait Anxiety Questionnaire (STAI-X1 and STA-X2). The test population and study design appear to be the same. No absolute data were presented. Only changes in scores were presented. There were no statistically significant changes.

# e. Randomized, surgical patients, longitudinal, with controls

*Mate-Kole C, Freschi M, Robin A. A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. Br J Psychiatry. 1990 Aug;157:261-4.* 

Mate-Kole at al. conducted a prospective, non-blinded, controlled, randomized, longitudinal study using investigator-designed patient self-report questionnaires and non-specific psychological tests with some normative data. The investigators assessed neuroticism and sex role in natal males with gender dysphoria who had qualified for male-to-female reassignment surgery at a single-center specialty clinic (London, United Kingdom). Forty sequential patients were alternately assigned to early reassignment surgery or to standard wait times for reassignment surgery. Patients were evaluated after acceptance and 2 years later. The criteria used to qualify for gender surgery were the 1985 standards from the Harry Benjamin International Gender Dysphoria Association. These included a  $\geq$ 2 year desire to change gender, a  $\geq$ 1 year demonstrable ability to live and be self-supporting in the chosen gender, and psychiatric assessment for diagnosis and reassessment at six months for diagnostic confirmation and exclusion of psychosis.

Reassignment surgery was defined as orchidectomy, penectomy, and construction of a neo-vagina. The instruments used were the CCEI for psychoneurotic symptoms and the Bem Sex Role Inventory along with an incompletely described investigator- designed survey with questions about social life and sexual activity.

The mean age and range of the entire cohort was 32.5 years (21-53). Members of the early surgery cohort had a history of attempted suicide (one patient), psychiatric treatment for non-gender issues (six patients), and first degree relatives with psychiatric histories (four patients). Members of the standard surgery cohort were similar, with a history of attempted suicide (two patients), psychiatric treatment for non-gender issues (five patients), and first degree relatives with psychiatric histories (six patients). The early surgery group had surgery approximately 1.75 years prior to the follow-up evaluation. In both groups, cross-dressing began at about age 6.

At baseline, the Bem Sex Role Inventory femininity scores were slightly higher than masculinity scores for both cohorts and were similar to Bem North American female normative scores. The scores did not change in either group over time.

At baseline, the scores for the CCEI individual domains (free floating anxiety, phobic anxiety, somatic anxiety, depression, hysteria, and obsessionality) were similar for the cohorts. The total CCEI scores for the two cohorts were consistent with moderate symptoms (Birchnell et al. 1988). Over the two year interval, total CCEI scores increased for standard wait group and approached the relatively severe symptom category. During the same interval, scores dropped into the asymptomatic rage for the post-operative patients.

The investigator-designed survey assessed changes in social and sexual activity of the prior two years, but the authors only compared patients in a given cohort to themselves. Though the researchers did not conduct statistical studies to compare the differences between the two cohorts, they did report increased participation in some, but not all, types of social activities such as sports (solo or group), dancing, dining out, visiting pubs, and visiting others. Sexual interest also increased. By contrast, pre-operative patients did not increase their participation in these activities.

# 2. External Technology Assessments

- a. CMS did not request an external technology assessment (TA) on this issue.
- b. There were no AHRQ reviews on this topic.
- c. There are no Blue Cross/Blue Shield Health Technology Assessments written on this topic within the last three years.

There were two publications in the COCHRANE database, and both were tangentially related. Both noted that there are gaps in the clinical evidence base for gender reassignment surgery. *Twenty Years of Public Health Research: Inclusion of Lesbian, Gay, Bisexual, and Transgender Populations Boehmer U. Am J Public Health. 2002; 92: 1125–30.* 

"Findings supported that LGBT issues have been neglected by public health research and that research unrelated to sexually transmitted diseases is lacking."

A systematic review of lesbian, gay, bisexual and transgender health in the West Midlands region of the UK compared to published UK research. West Midlands Health Technology Assessment Collaboration. Health Technology Assessment Database. Meads, et al., 2009. No.3.

"Further research is needed but must use more sophisticated designs with comparison groups. This systematic review demonstrated that there are so many gaps in knowledge around LGBT health that a wide variety of studies are needed."

e. There were no National Institute for Health and Care Excellence (NICE) reviews/guidance documents on this topic.

There was a technology assessment commissioned by the New Zealand Ministry of Health and conducted by New Zealand Health Technology Assessment (NZHTA) (Christchurch School of Medicine and the University of Otago).

*Tech Brief Series: Transgender Re-assignment Surgery Day P. NZHTA Report. February 2002;1(1). http://nzhta.chmeds.ac.nz/publications/trans\_gender.pdf* 

The research questions included the following:

1. Are there particular subgroups of people with transsexualism who have met eligibility criteria for gender reassignment surgery (GRS) where evidence of effectiveness of that surgery exists?

2. If there is evidence of effectiveness, what subgroups would benefit from GRS?"

The authors concluded that there was not enough evidence to answer either of the research questions.

#### 3. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting

CMS did not convene a MEDCAC meeting.

#### 4. Evidence-Based Guidelines

a. American College of Obstetricians and Gynecologists (ACOG)

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Though ACOG did not have any evidence-based guidelines on this topic, they did have the following document: Health Care for Transgender Individuals: Committee Opinion Committee on Health Care for Underserved Women; The American College of Obstetricians and Gynecologists. Dec 2011, No. 512. Obstet Gyncol. 2011;118:1454-8.

"Questions [on patient visit records]

should be framed in ways that do not make assumptions about gender identity, sexual orientation, or behavior. It is more appropriate for clinicians to ask their patients which terms they prefer. Language should be inclusive, allowing the patient to decide when and what to disclose. The adoption and posting of a nondiscrimination policy can also signal health care providers and patients alike that all persons will be treated with dignity and respect. Assurance of confidentiality can allow for a more open discussion, and confidentiality must be ensured if a patient is being referred to a different health care provider. Training staff to increase their knowledge and sensitivity toward transgender patients will also help facilitate a positive experience for the patient."

b. American Psychiatric Association

Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder. Byne, W, Bradley SJ, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Richard R. Pleak RR, Tompkins DA. Arch Sex Behav. 2012; 41:759–96.

The American Psychiatric Association (APA) was unable to identify any Randomized Controlled Trials (RTCs) regarding mental health issues for transgender individuals.

"There are some level B studies examining satisfaction/regret following sex reassignment (longitudinal follow-up after an intervention, without a control group); however, many of these studies obtained data retrospectively and without a control group (APA level G). Overall, the evidence suggests that sex reassignment is associated with an improved sense of well-being in the majority of cases, and also indicates correlates of satisfaction and regret. No studies have directly compared various levels of mental health screening prior to hormonal and surgical treatments on outcome variables; however, existing studies suggest that comprehensive mental health screening may be successful in identifying those individuals most likely to experience regrets."

Relevant Descriptions of APA Evidence Coding System/Levels:

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[B] Clinical trial. A prospective study in which an intervention is made and the results of that intervention are tracked longitudinally. Does not meet standards for a randomized clinical trial."

[G] Other. Opinion-like essays, case reports, and other reports not categorized above."

c. Endocrine Society

Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline.

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ 3rd, Spack NP, Tangpricha V, Montori VM; Endocrine Society. J Clin Endocrinol Metab. 2009; 94:3132-54.

This guideline primarily addressed hormone management and surveillance for complications of that management. A small section addressed surgery and found the quality of evidence to be low.

"This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

d. World Professional Association for Transgender Health (WPATH)

Standards of Care for the Health 26 transsex Day Unansty Ended and Gendel Nonconforming People (Version 7). Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, Fraser L, Green J, Knudson G, Meyer WJ, Monstrey S, Adler RK, Brown GR, Devor AH, Ehrbar R, Ettner R, Eyler E, Garofalo R, Karasic DH, Lev AI, Mayer G, Meyer-Bahlburg H, Hall BP, Pfäfflin F, Rachlin K, Robinson B, Schechter LS, Tangpricha V, van Trotsenburg M, Vitale A, Winter S, Whittle S, Kevan R. Wylie KR, Zucker K. www.wpath.org/\_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf Int J Transgend. 2011;13:165–232.

The WPATH is "an international, multidisciplinary, professional association whose mission is to promote evidencebased care, education, research, advocacy, public policy, and respect in transsexual and transgender health."

WPATH reported, "The standards of care are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b)."

The WPATH standards of care (SOC) "acknowledge the role of making informed choices and the value of harm-reduction approaches."

The SOC noted, "For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;
- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience."
- e. American Psychological Association

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Suggested citation until formally published in the American Psychologist: American Psychological Association. (2015): *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People Adopted by the Council of Representatives, August 5 & 7, 2015. www.apa.org/practice/guidelines/transgender.pdf* 

"The purpose of the Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (hereafter Guidelines) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people."

"These Guidelines refer to psychological practice (e.g., clinical work, consultation, education, research, training) rather than treatment."

#### 5. Other Reviews

a. Institute of Medicine (IOM)

The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Robert Graham (Chair); Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. (Study Sponsor: The National Institutes of Health). Issued March 31, 2011. http://www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and- Transgender-People.aspx

"To advance understanding of the health needs of all LGBT individuals, researchers need more data about the demographics of these populations, improved methods for collecting and analyzing data, and an increased participation of sexual and gender minorities in research. Building a more solid evidence base for LGBT health concerns will not only benefit LGBT individuals, but also add to the repository of health information we have that pertains to all people."

"Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population. Scientific rigor includes incorporating and

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monitoring culturally competent and implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

b. National Institutes of Health (NIH)

National Institutes of Health Lesbian, Gay, Bisexual, and Transgender (LGBT) Research Coordinating Committee. Consideration of the Institute of Medicine (IOM) report on the health of lesbian, gay, bisexual, and transgender (LGBT) individuals. Bethesda, MD: National Institutes of Health; 2013. http://report.nih.gov/UploadDocs/LGBT%20Health%20Report\_FINAL\_2013-01-03-508%20compliant.pdf

In response to the IOM report, the NIH LBGT research Coordinating Committee noted that most of the health research for this set of populations is "focused in the areas of Behavioral and Social Sciences, HIV (human immunodeficiency virus)/AIDS, Mental Health, and Substance Abuse. Relatively little research has been done in several key health areas for LGBT populations including the impact of smoking on health, depression, suicide, cancer, aging, obesity, and alcoholism."

6. Pending Clinical Trials

ClinicalTrials.gov

There is one currently listed and recently active trial directed at assessment of the clinical outcomes pertaining to individuals who have had gender reassignment surgery. The study appears to be a continuation of work conducted by investigators cited in the internal technology assessment.

NCT01072825 (Ghent, Belgium sponsor) European Network for the Investigation of Gender Incongruence (ENIGI) is assessing the physical and psychological effects of the hormonal treatment of transgender subjects in two years prior to reassignment surgery and subsequent to surgery. This observational cohort study started in 2010 and is still in progress.

Consistent with the authority at 1862(I)(4) of the Act, CMS consulted with outside experts on the topic of treatment for gender dysphoria and gender reassignment surgery.

Given that the majority of the clinical research was conducted outside of the United States, and some studies either took place in or a suggested continuity-of-care and coordination-of-care were beneficial to health outcomes, we conducted expert interviews with centers across the U.S. that provided some form of specialtyfocused or coordinated care for transgender patients. These interviews informed our knowledge about the current healthcare options for transgender people, the qualifications of the professionals involved, and the uniqueness of treatment options. We are very grateful to the organizations that made time to discuss treatment for gender dysphoria with us.

From our discussions with the all of the experts we spoke with, we noted the following practices in some centers: (1) specialized training for all staff about transgender healthcare and transgender cultural issues; (2) use of an intake assessment by either a social worker or health care provider that addressed physical health, mental health, and other life factors such as housing, relationship, and employment status; (3) offering primary care services for transgender people in addition to services related to gender-affirming therapy/treatments; (4) navigators who connected patients with name-change information or other legal needs related to gender; (5) counseling for individuals, groups, and families; (6) an informed-consent model whereby individuals were often referred to as "clients" instead of "patients," and (7) an awareness of depression among transgender people (often measured with tools such as the Adult Outcomes Questionnaire and the Patient Health Questionnaire).

#### 8. Public Comments

We appreciate the thoughtful public comments we received on the proposed decision memorandum. In CMS' experience, public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link: <a href="https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=282&ExpandComments=n#Results">https://www.cms.gov/medicare-coverage</a>

#### a. Initial Comment Period: December 3, 2015 – January 2, 2016

During the initial comment period, we received 103 comments. Of those, 78% supported coverage of gender reassignment surgery, 15% opposed, and 7% were neutral. The majority of comments supporting coverage were from individuals and advocacy groups.

## b. Second Comment Period: June 2, 2016 – July 2, 2016

During the second 30-day public comment period, we received a total of 45 public comments, 7 of which were not posted on the web due to personal health information content. Overall, 82% supported coverage of gender reassignment surgery, 11% opposed, and 7% were neutral or silent in their comment whether they supported or opposed coverage. Half of the comments were submitted by individuals who expressed support for coverage of gender reassignment surgery (51%). We also received comments from physicians, providers, and other health professionals who specialize in healthcare for transgender individuals (17%). We received one comment from a municipality, the San Francisco Department of Public Health. Associations (American Medical Association, American College of Physicians, American Academy of Nursing, American Psychological Association, and LBGT PA Caucus) and advocates (Center for American Progress with many other signatories, Jamison Green & Associates) also submitted comments.

Below is a summary of the comments CMS received. In some instances, commenters identified typographical errors, context missed, and opportunities for CMS to clarify wording and classify articles for ease of reading in the memorandum. As noted earlier, when appropriate and to the extent possible, we updated the decision memorandum to reflect those corrections, improved the context, and clarified the language. In light of public comments, we re-evaluated the evidence and our summaries. We updated our summaries of the studies and clarified the language when appropriate.

#### **1.** Contractor Discretion and National Coverage Determination

**Comment**: Some commenters, including advocates, associations, and providers, supported CMS' decision for MAC contractor discretion/case-by-case determination for gender reassignment surgery. One stakeholder stated, "We agree with the conclusion that a NCD is not warranted at this time."

**Response**: We appreciate the support and understanding among stakeholders for our proposed decision to have the MACs determine coverage on a case-by-case basis. We have clarified in this final decision memorandum that

coverage is available for gender assignment our gerowhich deterinmed able and heters and not otherwise excluded by any other relevant statutory requirements by the MAC on a case-by-case basis. "The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule." (78 Fed. Reg. 48165 (August 7, 2013)).

**Comment**: Some commenters cautioned that CMS' choice to not issue a NCD at this time must not be interpreted as a national non-coverage determination or used in any way to inappropriately restrict access to coverage for transgender Medicare beneficiaries or other transgender individuals. Multiple commenters indicated their disappointment that CMS did not propose a National Coverage Determination (NCD) and, instead, chose to continue to have local MACs make the coverage decisions on a case-by-case basis. Commenters stated this could result in variability in coverage.

**Response**: We appreciate the comments. We are not issuing a NCD at this time because the available evidence for gender reassignment surgery provides limited data on specific health outcomes and the characteristics of specific patient populations that might benefit from surgery. In the absence of a NCD, the MAC's use the same statutory authority as NCDs, section 1862(a)(1)(A) of the Social Security Act (the Act). Under section 1862(a)(1)(A) an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. While CMS did not have enough evidence to issue a NCD, we believe the MACs will be able to make appropriate coverage decisions on a case-by-case basis taking into account individual characteristics of the Medicare beneficiary.

**Comment:** Some commenters sought a NCD that would establish guidelines for coverage and include elements such as a prescribed set of surgeries and a shared decision making element.

**Response:** For the reasons stated above, we are not issuing a NCD at this time and, therefore, are not establishing specific gender reassignment surgery coverage guidelines for the Medicare program. We generally agree that shared decision-making is a fundamental approach to patient-centered health care decisions and strongly encourage providers to use these types of evidence based decision aids. We have not found a shared decision aid on GRS and encourage the development of this necessary element to conduct formal shared-decision making.

**Comment**: Some commenters expressed concern that there is a misunderstanding of transgender individuals as having a disorder or being abnormal. Some commenters indicated a history of bias and discrimination within society as a whole that has occurred when transgender individuals have sought health care services from the medical community. Some commenters are concerned that the decision not to make a NCD will subject individuals seeking these services to corporate bias by Medicare contractors.

**Response**: Weakhow we

**Comment**: Commenters mentioned the cost of gender reassignment surgery could influence MAC decision making.

**Response**: The decisions on whether to cover gender reassignment surgery in a particular case are made on the basis of the statutory language in section 1862 of the Social Security Act that establish exclusions from coverage and would not depend on the cost of the procedure.

#### 2. Coverage with Evidence Development and Research

**Comment**: In our proposed decision memorandum, we specifically invited comments on whether a study could be developed that would support coverage with evidence development (CED). One organization commented, "We strongly caution against instituting a CED protocol." Commenters were opposed to coverage limited in clinical trials, suggesting that such coverage would restrict access to care. Several commenters provided suggested topics for clinical research studies for the transgender population. For example, one commenter suggested a study of non-surgical treatment for transgender children prior to puberty.

**Response**: While we appreciate the comments supporting further research, in general, for gender reassignment surgery, we agree that CED is not the appropriate coverage pathway at this time. While CED is an important mechanism to support research and has the potential to be used to help address gaps in the current evidence, we are not aware of any available, appropriate studies, ongoing or in development, on gender reassignment surgery for individuals with gender dysphoria that could be used to support a CED decision.

#### 3. Gender Reassignment Surgery as Treatment

**Comment**: One group of commences of the standard for the

**Response**: We acknowledge that GRS may be a reasonable and necessary service for certain beneficiaries with gender dysphoria. The current scientific information is not complete for CMS to make a NCD that identifies the precise patient population for whom the service would be reasonable and necessary.

#### 4. Physician Recommendations

**Comment**: Several commenters stated that gender reassignment surgery should be covered as long as it was determined to be necessary, or medically necessary by a beneficiary's physician.

**Response**: Physician recommendation is one of many potential factors that the local MAC may consider when determining whether the documentation is sufficient to pay a claim.

#### 5. WPATH Standards of Care

**Comment**: Several commenters suggested that CMS should recommend the WPATH Standards of Care (WPATH) as the controlling guideline for gender reassignment surgery. They asserted it could satisfy Medicare's reasonable and necessary criteria for determining coverage on a case-by-case basis.

**Response**: Based on our review of the evidence and conversations with the experts and patient advocates, we are aware some providers consult the WPATH Standards of Care, while others have created their own criteria and requirements for surgery, which they think best suit the needs of their patients. As such, and given that WPATH acknowledges the guidelines should be flexible, we are not in the position to endorse exclusive use of WPATH for coverage. The MACs, Medicare Advantage plans, and Medicare providers can use clinical guidelines they determine useful to inform their determination of whether an item or service is reasonable and necessary. When making this determination, local MACs may take into account physician's recommendations, the individual's clinical characteristics, and available clinical evidence relevant to that individual.

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**6. Scope of the NCA Request** 

**Comment**: One commenter stated that CMS did not address the full scope of the NCA request.

**Response**: The formal request for a NCD is publicly available on our tracking sheet. (<u>https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf</u>) The letter did not explicitly seek a national coverage determination related to counseling or hormone therapies, but focused on surgical remedies. CMS is aware that beneficiaries with gender dysphoria use a variety of therapies.

**Comment**: Other commenters stated the scope of the proposed decision is unnecessarily broad because it discussed therapies other than surgery. They suggested this discussion could lead to the unintended consequence of restricting access to those services for transgender Medicare beneficiaries and other transgender individuals.

**Response**: As we noted in our proposed decision, our decision focused only on gender reassignment surgery. In the course of reviewing studies related to those surgeries, occasionally authors discussed other therapies that were mentioned in our summaries of the evidence. To the extent possible, we have modified our decision to eliminate the discussion of other therapies which were not fully evaluated in this NCA.

7. NCA Question

**Comment**: Some commenters expressed concern about the phrasing of the question in this NCA.

**Response**: The phrasing of the research question is consistent with most NCAs and we believe it is appropriate.

**Comment**: Several commenters disagreed with our summary of the clinical evidence and analysis. A few commenters contended that the overall tone of the review was not neutral and seemed biased or flawed. One commenter noted that the Barrett publication was available on the Internet.

**Response**: We appreciate the comments that identified technical errors, and we made the necessary revisions to this document. However, we disagree with the contention that our evidence review was not neutral and seemed biased or flawed. We believe that the summary and analysis of the clinical evidence are objective. As with previous NCAs, our review of the evidence was rigorous and methodical. Additionally, we reviewed the Barrett publication, but it did not meet our inclusion criteria to be included in the Evidence section.

#### 9. Evidence Review with Transgender Experts

**Comment**: Several commenters requested that CMS re-review the clinical evidence discussed in the proposed decision memorandum with outside experts in the field of transgender health and transition/gender reassignment -related surgeries. Several offered the expertise within their organization to assist in this effort.

**Response**: We appreciate these comments and the transgender health community's willingness to participate. For this NCA we discussed gender reassignment surgery protocols with experts, primarily in coordinated care settings. Additionally, the public comment periods provide opportunities for expert stakeholder input. According to our process for all NCAs, we do not jointly review evidence with external stakeholders but have carefully reviewed the very detailed comments submitted by a number of outside experts in transgender health care.

#### **10.** Previous Non-Coverage NCD

**Comment**: One commenter noted that they thought research studies for gender reassignment surgery could not take place when the old NCD that prohibited coverage for gender reassignment surgery was in effect.

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**Response**: CMS does not directly conduct clinical studies or pay for research grants. Some medical services are non-covered by Medicare; however, national non-coverage does not preclude research via a number of avenues and other funding entities such as the National Institutes of Health. In this instance, the previous NCD did not preclude interested parties from funding research for gender reassignment surgery that could have been generalizable to the Medicare population.

# **11.** How the Medicare Population Differs from the General Population

**Comment**: One commenter questioned how the Medicare population differed from the general population, and why any differences would be important in our decision-making.

**Response**: The Medicare population is different from the general population in age (65 years and older) and/or disability as defined by the Social Security Administration. Due to the biology of aging, older adults may respond to health care treatments differently than younger adults. These differences can be due to, for example, multiple health conditions or co-morbidities, longer duration needed for healing, metabolic variances, and impact of reduced mobility. All of these factors can impact health outcomes. The disabled Medicare population, who are younger than age 65, is different from the general population and typical study populations due to the presence of the causes of disability such as psychiatric disorders, musculoskeletal health issues, and cardiovascular issues.

# 12. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

**Comment**: One commenter suggested CMS should have convened a MEDCAC for this topic.

**Response**: We appreciate the comment. Given the limited evidence, we did not believe a MEDCAC was warranted according to our guidance document entitled "Factors CMS Considers in Referring Topics to the Medicare Evidence Development & Coverage Advisory Committee" (<u>https://www.cms.gov/Regulations-and-Guidance/FACA/MEDCAC.html</u>).

# 13. §1557 of the Affordable Care Act (ACA)

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**Comment**: Some commenters asserted that by not explicitly covering gender reassignment surgery at the national level, CMS was discriminating against transgender beneficiaries in conflict with Section 1557 of the Accountable Care Act (ACA).

**Response**: This decision does not affect the independent obligation of covered entities, including the Medicare program and MACs, to comply with Section 1557 in making individual coverage decisions. In accordance with Section 1557, MACs will apply neutral nondiscriminatory criteria when making case-by-case coverage determinations related to gender reassignment surgery.

#### 14. Medicaid

**Comment**: Some commenters observed that some states cover gender reassignment surgery through Medicaid or require commercial insurers operating in the state to cover the surgery.

**Response**: We appreciate the information about Medicaid and state requirements; however, State decisions are separate from Medicare coverage determinations. We make evidence-based determinations based on our statutory standards and processes.

#### **15.** Commercial Insurers

**Comment**: In several instances, commenters told us that the healthcare industry looks to CMS coverage determinations to guide commercial policy coverage.

**Response**: CMS makes evidence-based national coverage determinations based on our statutory standards and processes as defined in the Social Security Act, which may not be the same standards that are used in commercial insurance policies or by other health care programs. In addition as noted above, the Medicare population is different (e.g., Medicare covers 95% of adults 65 and older) than the typical population under Printed on 5/31/2018. Page 58 of 150

commercial insufers: We do ynddissde woverage dealsion # to dai ve bolicy for sther health began zations' coverage in one way or the other.

#### 16. Healthcare for Transgender Individuals

**Comment**: Numerous professional associations wrote to CMS to explain their support for access to healthcare for transgender individuals.

**Response**: CMS recognizes that transgender beneficiaries have specific healthcare needs. Many health care treatments are available. We encourage all beneficiaries to utilize their Medicare benefits to help them achieve their best health.

#### **17. Intended Use of the Decision Memorandum**

**Comment**: Several commenters expressed concern that the analysis provided in the proposed and final decision memorandums may be used by individuals, entities, or payers for purposes unrelated to Medicare such as denial of coverage for transgender-related surgeries.

**Response**: The purpose of the decision memoranda is to memorialize CMS' analysis of the evidence, provide responses to the public comments received, and to make available the clinical evidence and other data used in making our decision consistent with our obligations under the § 1862 of the Act. The NCD process is open and transparent and our decisions are publicly available. Congress requires that we provide a clear statement of the basis for our determinations. The decision memoranda are an important part of the record of the NCD. Our focus is the Medicare population which, as noted above, is different than the general population in a number of ways. Other entities may conduct separate evidence reviews and analyses that are suited for their specific populations.

#### **18. Cost Barriers to Care and Effects**

**Comment**: A few son inters stated what with out meditar boost of sold and the may be a risk of negative consequences for the individual. One commenter suggested that CMS should consider priorauthorization for these surgeries.

**Response**: CMS is aware that paying out-of-pocket for medical care is a strain on a beneficiary's finances. We are also aware of beneficiaries' hesitancy to undergo surgery prior to knowing whether or not Medicare will pay the claim. Gender reassignment surgeries are not the only procedures whereby payment is not determined until after the provider submits the claim to Medicare. Importantly, documentation for the claims need to be explicit about what procedures were performed and include the appropriate information in the documentation to justify using the code or codes for surgery. Of note, CMS has claims data that indicate Medicare has paid for gender reassignment surgeries in the recent past. Determining which services are designated for prior-authorization is outside of the scope of the NCA process.

# **19. Surgical Risks and Benefits**

**Comment**: A number of commenters conveyed the benefits of gender reassignment surgery, while other commenters expressed concern that gender reassignment surgery was harmful.

**Response**: We appreciate these comments.

#### **20. Expenditure of Federal Funds**

**Comment**: Some commenters opposed spending Medicare program funds on gender reassignment surgery for a variety of reasons. For example, some commenters believe it is an "elective" procedure. Other commenters suggested that funds should first be spent on other priorities such as durable medical equipment (DME) or mobility items such as power chairs; increasing reimbursement to providers; or that spending should be limited to the proportion to the transgender adult population in the Medicare program.

**Response**: The purpose of this NCA is to determine whether or not CMS should issue a NCD to cover surgery for patients who have gender dysphoria. NCAs do not establish payment amounts or spending priorities and, therefore, these comments are outside the scope of this consideration. Printed on 5/31/2018. Page 60 of 150

# VIII. CMS Analysis

National coverage determinations are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under § 1862(I)(6) of the Act. In general, in order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B and must not be otherwise excluded from coverage.

Moreover, in most circumstances, the item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A)). The Supreme Court has recognized that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." Heckler v. Ringer, 466 U.S. 602, 617 (1984). See also, 78 Fed. Reg. 48,164, 48,165 (August 7, 2013)

When making national coverage determinations, we consider whether the evidence is relevant to the Medicare beneficiary population. In considering the generalizability of the results of the body of evidence to the Medicare population, we carefully consider the demographic characteristics and comorbidities of study participants as well as the provider training and experience. This section provides an analysis of the evidence, which included the published medical literature and guidelines pertaining to gender dysphoria, that we considered during our review to answer the question:

*Is there sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria?* 

CMS carefully considered all the studies listed in this decision memorandum to determine whether they answered the question posed in this NCA. While there appears to be many publications regarding gender reassignment surgery, it became clear that many of the publications did not meet our inclusion/exclusion criteria as explained earlier in the decision memorandum.

Thirty-three papers were eligible based on our inclusion/exclusion criteria for the subsequent review (Figure 1). All studies reviewed had potential methodological flaws which we describe below.

Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up (Appendices C and F). The impact of a specific therapeutic intervention can be difficult to determine when there are multiple serial treatments such as psychotherapy, hormone treatment and surgery. To reduce confounding, outcome assessment just prior to and after surgery such as in a longitudinal study would be helpful. The objective endpoints included psychiatric treatment, attempted suicide, requests for surgical reversal, morbidity (direct and indirect adverse events), and mortality (Appendix F). CMS agrees with the utility of these objective endpoints. Quality of life, while important, is more difficult to measure objectively (Appendix E).

Of the 33 studies reviewed, published results were conflicting – some were positive; others were negative. Collectively, the evidence is inconclusive for the Medicare population. The majority of studies were nonlongitudinal, exploratory type studies (i.e., in a preliminary state of investigation or hypothesis generating), or did not include concurrent controls or testing prior to and after surgery. Several reported positive results but the potential issues noted above reduced strength and confidence. After careful assessment, we identified six studies that could provide useful information (Figure 1). Of these, the four best designed and conducted studies that assessed quality of life before and after surgery using validated (albeit non-specific) psychometric studies did not demonstrate clinically significant changes or differences in psychometric test results after GRS. (Heylens et al., 2014; Ruppin, Pfafflin, 2015; Smith et al., 2005; Udeze et al., 2008) (Appendix C Panel A and Appendix G.)

Two studies (three articles) assessed functional endpoints (request for surgical reassignment reversal and morbidity/mortality) (Dhejne et al., 2011; Dhejne et al., 2014 along with Landén et al., 1998) (Figure 1 and Appendix C, Panel A and Appendix G). Although the data are observational, they are robust because the Swedish national database is comprehensive (including all patients for which the government had paid for surgical services) and is notable for uniform criteria to qualify for treatment and financial coverage by the government. Dhejne et al. (2014) and Landén et al. (1998) reported cumulative rates of requests for surgical reassignment reversal or change in legal status of 3.3% while Dhejne et al. (2014) reported 2.2%. The authors indicated that the later updated calculation had the potential to be an underestimate because the most recent surgical cohorts were larger in size and had shorter periods of follow-up.

Dhejne et al., (2011) tracked all patients who had undergone reassignment surgery (mean age 35.1 years) over a 30 year interval and compared them to 6,480 matched controls. The study identified increased mortality and psychiatric hospitalization compared to the matched controls. The mortality was primarily due to completed suicides (19.1-fold greater than in control Swedes), but death due to neoplasm and cardiovascular disease was increased 2 to 2.5 times as well. We note, mortality from this patient population did not become apparent until after 10 years. The risk for psychiatric hospitalization was 2.8 times greater than in controls even after adjustment for prior psychiatric disease (18%). The risk for attempted suicide was greater in male-to-female patients regardless of the gender of the control. Further, we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality. The study, however, was not constructed to assess the impact of gender reassignment surgery *per se.* 

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We believe at minimum study designs should have a pre-test/post-test longitudinal design accompanied by characterization of all patients lost to follow-up over the entire treatment series as well as those patients who did not complete questionnaires, and the use of psychometric quality-of-life tools which are well validated with linkage to "hard" (objective) patient outcomes in this particular patient population (Trentacosti 2007, PRO 2009) (Appendices C and D).

#### **Patient Care**

Clinical evidentiary questions regarding the care of patients with gender dysphoria remain. Many of the publications focused on aspects of surgical technique as opposed to long-term patient outcomes. The specific type(s) of gender/sex reassignment surgery (e.g., genital, non-genital) that could improve health outcomes in adults remain(s) uncertain because most studies included patients who had undertaken one or more of a spectrum of surgical procedures or did not define the specific types of surgical procedures under study. Furthermore, surgical techniques have changed significantly over the last 60 years and may not reflect current practice (Bjerrome Ahlin et al., 2014; Doornaert, 2011; Green, 1998; Pauly, 1968; Selvaggi et al., 2007; Selvaggi, Bellringer, 2011; Tugnet et al., 2007; Doornaert, 2011).

The WPATH care recommendations present a general framework and guidance on the care of the transgender individual. The standards of care are often cited by entities that perform gender reassignment surgery. WPATH notes, "More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria." Appendix D in the WPATH Standards of Care briefly describes their evidence base and acknowledges the historical problems with evidentiary standards, the preponderance of retrospective data, and the confounding impact of multiple interventions, specifically distinguishing the impact of hormone therapy from surgical intervention.

Additionally, CMS met with several stakeholders and conducted several interviews with centers that focus on healthcare for transgender individuals in the U.S. Primary care rather than gender reassignment surgery was often the main focus. Few of the U.S.-based reassignment surgeons we could identify work as part of an integrated practice, and few provide the most complex procedures.

#### **Psychometric Tools**

CMS reviewed psychometric endpoints because gender dysphoria (inclusive of prior nomenclature) describes an incongruence between the gender assigned at birth and the gender(s) with which the person identifies.

The psychometric tools used to assess outcomes have limitations. Most instruments that were specific for gender dysphoria were designed by the investigators themselves or by other investigators within the field using limited populations and lacked well documented test characterization. (Appendices E and F) By contrast, test instruments with validation in large populations were non-specific and lacked validation in the gender dysphoric patient populations. (Appendices E and F). In addition, the presentation of psychometric results must be accompanied by enough information about the test itself to permit adequate interpretation of test results. The relevant diagnostic cut-points for scores and changes in scores that are clinically significant should also be scientifically delineated for interpretation.

#### Generalizability

It is difficult to generalize these study results to the current Medicare population. Many of the studies are old given they were conducted more than 10 years ago. Most of these studies were conducted outside of the U.S. in very different medical systems for treatment and follow-up. Many of the programs were single-site centers without replication elsewhere. The study populations were young and without significant physical or psychiatric co-morbidity (Appendix D). As noted earlier, psychiatric co-morbidity may portend poor outcomes (Asscheman et al., 2011; Landén et al., 1998).

#### Knowledge Gaps

This patient population faces complex and unique challenges. The medical science in this area is evolving. This review has identified gaps in the evidentiary base as well as recommendations for good study designs. The Institute of Medicine, the National Institutes of Health, and others also identified many of the gaps in the data. (Boehmer, 2002; HHS-HP, 2011; IOM, 2011; Kreukels-ENIGI, 2012; Lancet, 2011; Murad et al., 2010; NIH-LGBT, 2013) The current or completed studies listed in ClinicalTrials.gov are not structured to assess these gaps. These gaps have been delineated as they represent areas in which patient care can be optimized and are opportunities for much needed research.

#### **B. Health Disparities**

Four studies included information on racial or ethnic background. The participants in the three U.S. based studies were predominantly Caucasian (Beatrice, 1985; Meyer, Reter, 1979; Newfield et al., 2006). All of the participants

in the single Asian study were analy the of the seven to a program and the single Asian study were and the seven to a program and the se

#### C. Summary

Based on an extensive assessment of the clinical evidence as described above, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.

The knowledge on gender reassignment surgery for individuals with gender dysphoria is evolving. Much of the available research has been conducted in highly vetted patients at select care programs integrating psychotherapy, endocrinology, and various surgical disciplines. Additional research of contemporary practice is needed. To assess long-term quality of life and other psychometric outcomes, it will be necessary to develop and validate standardized psychometric tools in patients with gender dysphoria. Further, patient preference is an important aspect of any treatment. As study designs are completed, it is important to include patient-centered outcomes.

Because CMS is mindful of the unique and complex needs of this patient population and because CMS seeks sound data to guide proper care of the Medicare subset of this patient population, CMS strongly encourages robust clinical studies with adequate patient protections that will fill the evidence gaps delineated in this decision memorandum. As the Institute of Medicine (IOM, 2011) importantly noted: "Best practices for research on the health status of LGBT populations include scientific rigor and respectful involvement of individuals who represent the target population. Scientific rigor includes incorporating and monitoring culturally competent study designs, such as the use of appropriate measures to identify participants and implementation processes adapted to the unique characteristics of the target population. Respectful involvement refers to the involvement of LGBT individuals and those who represent the larger LGBT community in the research process, from design through data collection to dissemination."

# IX. Decision

Currently, the local Medicare Administrative Contractors (MACs) determine coverage of gender reassignment surgery on a case-by-case basis. We have a received a complete, formal request to make a national coverage determination on surgical remedies for gender identity disorder (GID), now known as gender dysphoria. The Centers for Medicare & Medicaid Services (CMS) is not issuing a National Coverage Determination (NCD) at this time on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence is inconclusive for the Medicare population.

Consistent with the request CMS received, the focus of this National Coverage Analysis (NCA) was gender reassignment surgery. Specific types of surgeries were not individually assessed. We did not analyze the clinical evidence for counseling or hormone therapy treatments for gender dysphoria. As requested by several public commenters, we have modified our final decision memorandum to remove language that was beyond the scope of the specific request. We are not making a national coverage determination relating to counseling, hormone therapy treatment for gender dysphoria.

While we are not issuing a NCD, CMS encourages robust clinical studies that will fill the evidence gaps and help inform which patients are most likely to achieve improved health outcomes with gender reassignment surgery, which types of surgery are most appropriate, and what types of physician criteria and care setting(s) are needed to ensure that patients achieve improved health outcomes.

# A. Appendix A

# Diagnostic & Statistical Manual of Mental Disorders (DSM) Criteria for Disorders of Gender Identity since 1980

<b>DSM Version</b>	<b>Condition Name</b>	Criteria	Criteria	Comments
DSM III 1980 <i>Chapter:</i> <i>Psychosexual</i> <i>Disorders</i>	<b>Trans-sexualism</b> 302.5x [Gender Identity Disorder of Child-hood (302.6)]	Required A (cross- gender identification) and B (aversion to one's natal gender) criteria Dx excluded by physical intersex condition Dx excluded by another mental disorder, e.g., schizophrenia	Sense of discomfort and inappropriateness about one's anatomic sex. Wish to be rid of one's own genitals and to live as a member of the other sex. The disturbance has been continuous (not limited to periods of stress) for at least 2 years.	Further characterization by sexual orientation Distinguished from Atypical Gender Identity Disorder 302.85

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DSM Version	Condition Name	-wmc Criteria	104 Filed: 06/08/18 Page 1	59 of Comments
<b>DSM III- Revised</b> <b>1987</b> <i>TS classified as</i> <i>an Axis II dx</i> (personality disorders and mental retardation) in a different chapter. GID included under Disorders Usually First Evident in Infancy, Childhood, Adolescence	<b>Trans-sexualism</b> (TS) (302.50) [GID of C]	Required A and B criteria	Persistent discomfort and sense of inappropriateness about one's assigned sex. Persistent preoccupation for at least 2 years with getting rid of one's 1° and 2° sex characteristics and acquiring the sex characteristics of the other sex. Has reached puberty	Further characterization by sexual orientation Distinguished from Gender Identity Disorder of Adolescence or Adulthood, Non-trans- sexual Type •e.g., cross-dressing not for the purposes of sexual excitement Gender Identity Disorder Not Otherwise Specified 302.6 •e.g., intersex conditions Gender Identity Disorder Not Otherwise Specified 302.85 •e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
	<b>GID of</b> <b>adulthood</b> , non- trans-sexual type, added			
<b>DSM IV 1994</b> Chapter: Sexual & Gender Identity Disorders	<b>Gender Identity</b> <b>Disorder</b> in Adolescents and Adults (302.85) (Separate criteria & code for children, but same name)	criteria Dx excluded by physical intersex condition	Cross-gender identification •e.g., Stated desire to be another sex •e.g., Desire to live or be treated as a member of the other sex •e.g., conviction that he/she has the typical feelings and reactions of the other sex •e.g., frequent passing as the other sex Persistent discomfort with his/her sex or sense of inappropriateness in the gender role of that sex. •e.g., belief the he/she was born the wrong sex •e.g., preoccupation with getting rid of 1° and 2° sex characteristics &/or acquiring sexual traits of the other sex •Clinically significant distress or impairment in social, occupational, or other important areas of functioning	Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6 •e.g., intersex conditions •e.g., stress related cross-dressing •e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex
<b>DSM IV-</b> <b>Revised</b> <b>2000</b> <i>Chapter:</i> <i>Sexual &amp;</i> <i>Gender Identity</i> <i>Disorders</i> Printed on 5/31/2	<b>Gender Identity</b> <b>Disorder</b> (Term trans- sexual-ism eliminated) 2018. Page 67 of 15	Required A & B criteria Dx excluded by physical intersex condition	<ul> <li>Cross-gender identification</li> <li>e.g., stated desire to be the other sex</li> <li>e.g., desire to live or be treated as the other sex</li> <li>e.g., conviction that he/she has the typical feelings &amp; reactions of the other sex</li> </ul>	Outcome may depend on time of onset Further characterization by sexual orientation Distinguished from Gender Identity Disorder Not Otherwise

DSM Version	Condition Name	-wmc Document #: 1	04 Filed: 06/08/18 Page 1	60 of 242 Comments
			<ul> <li>e.g., frequent passing as the other sex</li> <li>Persistent discomfort with his or her sex OR sense of inappropriateness in the gender role of that sex</li> <li>e.g., belief the he/she was born the wrong sex</li> <li>e.g., preoccupation with getting rid of 1° and 2° sex characteristics &amp;/or acquiring sexual traits of the other sex</li> <li>Clinically significant distress or impairment in social, occupational, or other important areas of functioning</li> </ul>	<ul> <li>e.g., intersex conditions</li> <li>e.g., stress related cross-dressing</li> <li>e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex</li> </ul>
DSM V 2013 Separate Chapter from Sexual Dysfunctions & Paraphilic Disorders	<b>Gender</b> <b>Dysphoria</b> (302.85) 2018. Page 68 of 15	Gender nonconformity itself not considered to be a mental disorder The dysphoria associated with the gender incongruence is Eliminates A & B criteria Considers gender incongruence to be a spectrum Considers intersex/ "disorders of sex development" to be a subsidiary and not exclusionary to dx of GD	<ul> <li>•Marked discordance between natal 1° and 2° sex characteristics* and experienced/expressed gender</li> <li>•Conviction that he/she has the typical feelings &amp; reactions of the other sex (or some alternative gender)</li> <li>•Marked desire to be the other sex (or some alternative gender)</li> <li>•Marked desire to desire be treated as the other sex (or some alternative gender)</li> <li>•Marked desire to be rid of natal 1° and 2° sex characteristics**</li> <li>•Marked desire to acquire 1° and 2° sex characteristics of the other sex (or some alternative gender)</li> <li>Clinically significant distress or impairment in social, occupational, or other important areas of functioning</li> <li>* or in young adolescents, the anticipated 2° sex characteristics</li> <li>** or in young adolescents, the anticipated 2° sex characteristics</li> <li>≥ 6 month marked discordance between natal gender &amp; experienced/expressed gender as demonstrated by ≥ 6 criteria:</li> <li>•Strong desire to be of the other gender or an insistence that one is of another gender.</li> </ul>	Includes diagnosis for post transition state to permit continued treatment access Includes disorders of sexual development such as congenital hyperplasia and androgen insensitivity syndromes

SM Version	Condition Name	nc Document #: 104 Filed: 06/08/18 Page 161 of 242 Criteria
		<ul> <li>Strong preference for cross -gender roles in make- believe play.</li> <li>Strong preference for the toys, games, or activities of the other gender.</li> <li>Strong preference for playmates of the other gender.</li> <li>In boys, strong preference for cross-dressing; in girls, strong preference for wearing masculine clothing</li> <li>In boys, rejection of masculine toys, games, activities, avoidance of rough and tumble play; in girls, rejection of feminine toys, games, and activities.</li> </ul>
	Unspecified Gender Dysphoria (302.6) (F64.9)	This category applies to presentations in which sx c/w gender dysphoria that cause clinically significant distress or impairment, but do not meet the full criteria for gender dysphoria & the reason for not meeting the criteria is not provided.
	Specified Gender Dysphoria 302.6 (F64.8)	If the reason that the presentation does not meet the full criteria is provided then this dx should be used

C/W=consistent with Dx=diagnosis GD=gender dysphoria Sx=symptoms TS=transsexual 1°=primary 2°=secondary

# **B. Appendix B**

# 1. General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the Printed on 5/31/2018. Page 69 of 150

generalizability and high from a strange on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

# **Assessing Individual Studies**

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were
  assigned (intervention or control). This is important especially in subjective outcomes, such as pain or
  quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by
  either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rahangs at resear 2026 sign ave been pased and the signify of Cadds strong design dates ory to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials Non-randomized controlled trials Prospective cohort studies Retrospective case control studies Cross-sectional studies Surveillance studies (e.g., using registries or surveys) Consecutive case series Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

#### Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

#### Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

**Appendix C** 

Patient Population: Enrolled & Treated with Sex Reassignment Surgery Loss of Patients & Missing Data

#### Panel A (Controlled Studies)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Dhejne 2011	Longitudinal Controlled	804 w GD	324	324 (100%)	-
Dhejne 2014 Landén	Longitudinal for test variable Controlled	767 applied for SRS 25 applications denied. 61 not granted full legal status 15 formal applications for surgical reversal	681	681 (100%)	NA: Clinical data extracted retrospectively in earlier paper
Heylens	Longitudinal Controlled	90 applicants for SRS 33 excluded 11 later excluded had not yet received SRS by study close.	57 (46)	46 (80.7%) Only those w SRS evaluated	Psycho-social survey missing data for 3 at baseline & 4 after SRS. SCL90 not completed by 1 at baseline, 10 after hormone tx, & 4 after SRS missing data for another 1.1% to 11.1%.
Kockott	Longitudinal Controlled	80 applicants for SRS 21 excluded	59	32 (54.2%) went to surgery	1 preoperative patient was later excluded b/c lived completely in aspired gender w/o SRS. Questions on financial sufficiency not answered by 1 surgical pt.

Author	Case: 3:17-cy-002 Study Type	<sup>64</sup> Recruitment Pool <sup>#: 1</sup>	Enrolled	06/08/18 GRSge 16	<sup>6 01</sup> Completion
					Questions on sexual satisfaction & gender contentment not answered by 1 & 2 patients awaiting surgery respectively.
Mate-Kole 1990	Longitudinal Controlled	40 sequential patients of accepted patients. The number in the available patient pool was not specified.	40	20 (50%) went to surgery	-
Meyer	Longitudinal Controlled	Recruitment pool: 100 50 were excluded.	50	15 (30%) had undergone surgery 14 (28%) underwent surgery later	The assessments of all were complete
Rakic	Longitudinal Controlled	92 were evaluated 54 were excluded from surgery 2 post SRS were lost to follow-up 2 post SRS were excluded for being in the peri-operative period	32	32 (100%)	Questionnaire completed by all.
Ruppin	Longitudinal Controlled	The number in the available patient pool was not specified. 140 received recruitment letters. 69 were excluded	71	69 (97.2%)	The SCL-90, BSRI, FPI-R, & IPP tests were not completed by 9, 34, 13, &16 respectively. Questions about romantic relationships, sexual relationships, & family relationships were not answered by 1, 3, 2, & 23 respectively. Questions regarding gender security & regret & were not answered by 1& 2 respectively.
Smith	Longitudinal Controlled	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. 103 were excluded from additional tx	162	162 (100%)	36 to 61 (22.2%- 37.6% of those adults w pre-SRS data) did not complete various post-SRS tests.
Udeze Megeri	Longitudinal Controlled	International patient w GD 546 & post SRS 318. 40 M to F subjects were prospectively selected.	40	40 (100%)	-
Ainsworth	Internet/convention Survey Cross-sectional Controlled	Number of incomplete questionnaires not reported	247	72 (29.1%) 75 (30.6%) facial 147 (59.5%) had received neither facial nor reassignment surgery	-

Author	Case: 3:17-cy-002 Study Type	64-Wecruitment Pool#: 1	<sup>04</sup> Enrolled	06/08/18 GRSge 16	<sup>7 of 242</sup> Completion
	Controlled	14 excluded for demographic matching reasons			The assessments were completed by all
Haraldsen	Cross-sectional Controlled	Recruitment pool: 99	86	59 (68.6%)	-
Kraemer	Cross-sectional Controlled	The number in the available patient pool was not specified.	45	22 (48.9%)	-
Kuhn	Cross-sectional Controlled	The number in the available patient pool was not specified.	75	55 (73.3%)	-
Mate-Kole 1988	Cross-sectional Controlled	150 in 3 cohorts. Matched on select traits. The number in the available patient pool was not specified.	150	50 (66.7%)	-
Wolfradt	Cross-sectional Controlled	The number in the available patient pool was not specified.	90	30 (33.3%)	-

# Panel B (Surgical Series: No Concurrent Controls)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Blanchard et al.	Cross-sectional Control: Normative test data	294 clinic patients w GD had completed study questionnaire 116 authorized for GRS. 103 completed GRS & 1 yr post-operative. 24 excluded	79	79(100%)	-
Weyers et al.	Cross-sectional Control: Normative test data	<ul> <li>&gt;300 M to F patients had undergone GRS</li> <li>70 eligible patients recruited</li> <li>20 excluded</li> </ul>	50	50 (100%)	SF-26 not completed by 1
Wierckx et al.	Cross-sectional except for recall questions Control: Normative test data	<ul> <li>79 F to M patients had undergone GRS &amp; were recruited.</li> <li>3 additional non-clinic patients were recruited by other patients.</li> <li>32 excluded initially; 1 later.</li> </ul>	49	49 (100%)	SF-36 test not completed by 2. Questions regarding sexual re -lationship, sex function, & surgical satisfaction were answered by as few as 27, 28, 32 respectively.
Eldh et al.	Cross-sectional except for 1 variable Control: Self for 1 variable-employ-ment	136 were identified. 46 excluded	90	90 (100%)	Questions regarding gender iden-tity, sex life, acceptance, & overall satisfaction were not answered by 13, 14, 14 & 16 respectively. Employment data missing for 11.
Hess et al.	Cross-sectional		119	119 (100%)	

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Author	Case: 3:17-cv-0026 <sup>2</sup> Study Type	<sup>1-wm</sup> Recruitment #- 104	Filed: 06/08/	18 %aga 168	of 242 Completion
	No control	254 consecutive eligible patients post GRS identified & sent surveys. 135 excluded.			Questions regarding the esthetics, functional, and social outcomes of GRS were not answered by 16 to 28 patients.
Lawrence	Cross-sectional No control	727 eligible patients were recruited. 495 were excluded	232	232 (100%)	-
Salvador et al.	Cross-sectional No control	<ul> <li>243 had enrolled in the clinic</li> <li>82 completed GRS</li> <li>69 eligible patients were identified.</li> <li>17 excluded.</li> </ul>	52	52 (100%)	-
Tsoi	Cross-sectional No control	The number in the available patient pool was not specified.	81	81 (100%)	-

## Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Study Type	Recruitment Pool	Enrolled	% GRS	Completion
Gómez-Gil et al. 2012	Cross-sectional No direct control: Analysis of variance	200 consecutive patients were recruited. 13 declined participation or were excluded for incomplete questionnaires.	187	79 (42.2%)	See prior box.
	Cross-sectional No direct control: Analysis of variance	The number in the available patient pool was not specified.	31	7 (22.6%)	HADS test not completed by 1
al.	Cross-sectional No direct control: Analysis of variance & regression	255 with GD were identified. 77 were excluded.	148 (140)	Not clearly stated. At least 103 underwent some form of GRS.	8 later excluded for incomplete SF -36 tests. 37 w recent GRS or hormone initiation were excluded from analysis of SF-36 results103.
Newfield et al.	Internet survey Cross-sectional No direct control: Analysis of variance	Number of incomplete questionnaires not reported 446 respondents; 384 U.S respondents 62 non-U.S. respondents excluded from SF-36 test results 8 U.S. respondents excluded	376 (U.S.)	139 to 150 (37.0- 39.9%) in U.S.	-
	Cross-sectional No direct control: Analysis w regression	The number in the available patient pool was not specified. 277 were recruited. 25 excluded	252(193)	80 (41.4%) non- genital surgery	59 were excluded for incomplete questionnaires. See prior box.
Asscherman	Longitudinal		1331	1177 (88.4%)	-

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Author	Study Type	0264 Recruitment Pool #: 102	Eiled: 06/08	3/18 Bage 169 of	<sup>24</sup> Completion
	No analysis by tx status	The number in the available patient pool was not specified.			
Johansson et al.	Cross-sectional except for 1 variable No analysis by tx status except for 1 question	60 eligible patients 18 excluded.	42	32 (76.2% of enrolled & 53.3% of eligible) (genital surgery)	-
Leinung et al.	Cross-sectional No analysis by tx status	242 total clinic patients	242	91 (37.6%)	Employment status data missing for 81 of all patients

\*Data obtained via a survey on a website and distributed at a conference B/C=because BSRI=Bem Sex Role Inventory F=Female FP-R=Freiberg Personality Inventory GD=Gender dysphoria GID=Gender identity disorder HADS=Hospital Anxiety & Depression Scale IPP=Inventory of Interpersonal Problems M=Male NA=Not applicable SCL-90=Symptom Checklist-90 SF-36=Short Form 36 GRS=Sex reassignment surgery Tx=Treatment W/o=without

#### Appendix D

## **Demographic Features of Study Populations**

## Panel A (Controlled Studies)

Author	Age (years; mean, S.D., range)	Gender	Race
Ainsworth	Only reassignment surgery:50 (no S.D.) Only facial surgery: 51 (no S.D.) Both types of surgery: 49 (no S.D.) Neither surgery: 46 (no S.D.)	247 M to F	-
Beatrice	Pre-SRS M to F: 32.5 (27-42), Post-SRS: 35.1 (30-43)	20 M to F plus 20 M controls	100% Caucasian

Author	Case: 3:1/-cv-00264-wmc Document # Age (years; mean, S.D., range)	104 Filed: 06/08/18 Page 170 of 242	Race
Dehjne 2011	Post-SRS: all 35.1±9.7 (20-69), F to M 33.3+8.7 (20-62), M to F 36.3+ 10.1(21-69)	133 (41.0%) F to M, 191 (59.0%) M to F; ratio 1:1.4	-
Dhejne 2014 Landén	F to M SRS cohort: median age 27 M to F SRS cohort: median age 32 F to M applicants for reversal: median age 22 M to F applicants for reversal: median age 35	252 (37.0%) F to M, 429 (63.0%) M to F; ratio 1:1.7 15 applicants for reversal	-
		5 (33.3%) F to M, 10 (66.7%) M to F; ratio 1:2	
Haraldsen	Pre-SRS & Post-SRS: F to M 34±9.5, F to M 33.3±10.0 Post-SRS cohort reportedly older. No direct data provided.	Pre & Post SRS 35 (40.7%) F to M, 51 (59.3%) M to F; ratio 1:1.5	-
Heylens	-	11 (19.3% of 57) F to M, 46 (80.7%); ratio 1:4.2 (80.7% underwent surgery)	-
Kockott	Pre-SRS (continued wish for surgery): 31.7±10.2 Post-SRS: 35.5±13.1	Pre-SRS (continued wish for surgery) 3 (25%) F to M, 9 (75%) M to F; ratio 1:3 Post SRS: 14 (43.8%) F to M, 18 (56.2%) M to F; ratio 1:1.3	-
Kraemer	Pre-SRS: 33.0±11.3, Post-SRS: 38.2±9.0	Pre-SRS 7 F to M (30.4%), 16 M to F (69.6%); ratio 1:2.3 Post-SRS 8 F to M (36.4%), 14 M to F (63.6%); ratio 1:1.8	-
Kuhn	All post SRS: median (range): 51 ( 39-62) (long-term follow-up)	3 (5.4%) F to M, 52 (94.5%) M to F; ratio 1:17.3.	-
Mate-Kole 1988	Initial evaluation: 34, Pre-SRS: 35, Post-SRS: 37	150 M to F	-
Mate-Kole 1990	Early & Usual wait SRS: 32.5 years (21- 53)	40 M to F	-
Meyer	Pre-SRS: 26.7 Delayed, but completed SRS: 30.9 Post-SRS: 30.1	Pre-SRS: 5 (23.8%) F to M, 16 (76.2%) M to F; ratio 1:3.2 Delayed, but completed SRS: 1 (7.1%) F to M, 13 (92.9%) M to F; ratio 1:13 Post-SRS: 4 (26.7%) F to M, 11 (73.3%) M to F; ratio 1:2.8	86% Caucasian
Rakic	All: $26.8\pm6.9$ (median 25.5, range 19- 47), F to M: $27.8\pm5.2$ (median 27, range 23- 37), M to F: $26.4\pm7.8$ (median 24, range 19-47).	10 (31.2%) F to M, 22 (68.8%) M to F; ratio 1:2.2	-
Ruppin	All: $47.0\pm10.42$ (but 2 w/o SRS) (13.8±2.8 yrs post legal name change) (long-term follow-up) F to M: $41.2\pm5.78$ , M to F $52.9\pm10.82$	36 (50.7%) F to M, 35 (49.3%) M to F; ratio 1:0.97	-
Smith	Time of surgical request for post-SRS: 30.9 (range 17.7-68.1) Time of follow-up for post-SRS: 35.2 (range 21.3-71.9)	Pre-SRS: 162: 58 (35.8%) F to M, 104 [64.2%] M to F; ratio 1:1.8 Post-SRS: 126: 49 (38.9%) F to M, 77 (61.1%) M to F; ratio 1:1.6	-
Jdeze Megeri	M to F: 47.33±13.26 (range 25-80).	40 M to F	-
Wolfradt	Patients & controls: 43 (range 29-67).	30 M to F plus 30 F controls plus 30 M controls.	-

\*Data obtained via a survey on a website and distributed at a conference SD=Standard deviation

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Blanchard et al.	F to M: 32.6, M to F w M partner preference: 33.2, F to M w F partner preference: 47.7 years	Post-GRS: 47 (45.6%) F to M, 56 (54.4%) M to F; ratio 1:1.19. In study: 38 (48.1%) F to M, 32 (40.5%) M to F w M partner preference, 9 (11.4%) M to F w F partner preference; ratio 1:0.8: 0.2	-
Weyers et al.	Post-GRS M to F: 43.1 ±10.4 (long- term follow-up)	50 M to F	-
Wierckx et al.	Time of GRS: $30\pm8.2$ years (range 16 to 49) Time of follow-up: $37.1\pm8.2.4$ years (range 22 to 54)	49 M to F	-
Eldh et al.	-	50 (55.6%) F to M, 40 (44.4%) M to F; ratio 1:0.8 There is 1 inconsistency in the text suggesting that these should be reversed.	-
Hess et al.	-	119 M to F	-
Lawrence	Time of GRS: $44\pm9$ (range 18-70)	232 M to F	-
Salvador et al.	Time of follow-up for post-GRS: 36.28±8.94 (range 18-58) (Duration of follow-up: 3.8±1.7 [2-7])	52 M to F	-
Tsoi	Time of initial visit: All: $24.0\pm4.5$ , F to M: $25.4\pm4.4$ (14-36), M to F: $22.9\pm4.6$ (14-36). Time of GRS: All: $25.9\pm4.14$ , F to M: $27.4\pm4.0$ (20-36), M to F: $24.7+4.3$ (20-36).	36 (44.4%) F to M, 45 (55.6%) M to F; ratio 1:1.25	0% 100% Asian

# Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	Age (years; mean, S.D., range)	Gender	Caucasian
Gómez-Gil et al. 2012	W & W/O GRS: All: 29.87±9.15 (range 15-61), W/O hormone tx: 25.9±7.5, W current hormone tx: 33.6±9.1. (At hormone initiation: 24.6±8.1).	W/O hormone tx: 38 (56.7%) F to M, 29 (43.3%) M to F; ratio 1:0.8. W hormone tx: 36 (30.0%) F to M, 84 (70.0%) M to F; ratio 1:2.3. Post-GRS: 29 (36.7%) F to M, 50 (63.3%) M to F; ratio 1:1.7.	-
Hepp et al.	W & W/O GRS: 32.2±10.3	W & W/O GRS: 11 (35.5%) F to M; 20 (64.5%) M to F; ratio 1:1.8.	-
Motmans et al.	W & W/O GRS: All (n=140) : 39.9±10.2, F to M: 37.0±8.5, M to F: 42.3±10.4	W & W/O GRS: N=140 63(45.0%) F to M, 77 (55.0%) M to F; ratio 1:1.2 N=103 49 (47.6%) F to M; 54 (52.4%) M toF; ratio 1:1.1	-
Newfield et al.	W & W/O GRS: U.S.+ non-U.S. : 32.8±11.2, U.S. 32.6±10.8	W & W/O GRS: U.S.+ non-U.S.: F to M, 438, U.S.: F to M: 376	89% of 336 respondents Caucasian
	W & W/O Non-genital GRS: 31.2±9.9 (range 16-67).		-

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Author	Age (years; mean, S.D., range)	ent #: 104 Filed: 06/08/18 Page	<sup>172</sup> Caucasian
		W & W/O Non-genital GRS: 74 (38.3%) F to M, 119 (61.7%) M to F; ratio1:1.6.	
Asscherman	Time of hormone tx: F to M: 26.1±7.6 (16–56), M to F: 31.4±11.4 (16–76)	Met hormone tx requirements: 365 (27.4%) F to M, 966 (72.6%) M to F; ratio 1:2.6. Post-GRS: 343 (29.1%) F to M, 834 (70.9%) M to F; ratio 1:2.4.	-
Johanssen	Time of initial evaluation: F toM: 27.8 (18-46), M to F 37.3 (21-60). Time of GRS: F to M: 31.4 (22-49), M to F 38.2 (22-57). Time of follow- up for post-GRS: F to M: 38.9 (28- 53), M to F 46.0 (25-69) (Long-term follow-up)	Approved for GRS: 21 (35%) F to M, 39 (65%) M to F; ratio 1:1.9) Post GRS: 14 (43.8%) F to M; 18 (56.2%) M to F; ratio 1:1.3)	-
Leinung et al.	Time of hormone initiation : F to M: 27.5, M to F 35.5	W & W/O GRS: 50 (20.7%) F to M, 192 M to F (79.3%); ratio 1:3.8. Post-GRS: 32 F to M (35.2%); 59 (64.8%) M to F; ratio 1:1.8.	-

## Appendix E

# **Psychometric and Satisfaction Survey Instruments**

Instrument Name and Developer	Development and Validation Information
APGAR Family Adaptability, Partner-ship Growth, Affection, and Resolve Smilkstein	Published in 1978 Initial data: 152 families in the U.S. A "friends" component was added in 1983. Utility has challenged by many including Gardner 2001
<b>Beck Depression Inventory</b> <i>Beck, Ward, Mendelson, Mock, &amp;</i> <i>Erbaugh</i>	Published initially in 1961 with subsequent revisions It was initially evaluated in psychiatric patients in the U.S.A. Salkind (1969) evaluated its use in 80 general outpatients in the UK. Itis copyrighted and requires a fee for use
<b>Bem Sex Role Inventory</b> Bem	Published 1974 Initial data: 100 Stanford Undergraduates 1973 update: male 444; female 279 1978 update: 470; female 340
Body Image Questionnaire Clement & Lowe	Validity study published 1996 (German) Population: 405 psychosomatic patients, 141 medical students, 208 sports students
<b>Body Image Scale</b> <i>Lindgren &amp; Pauly</i> <i>(Kuiper, Dutch adaptation 1991)</i>	1975 Initial data: 16 male and 16 female transsexual patients in Oregon
<b>Crown Crisp Experiential Index</b> (formerly Middlesex Hospital Questionnaire)	Developed circa 1966 Manual published 1970

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Instrument Name and Developer	wmc Document #: 104 Filed: 06/08/18 Pa Development and Validation Information
Crown & Crisp	Initial data: 52 nursing students while in class in the UK
<b>(2<sup>nd</sup>) European Quality of Life Survey</b> Anderson, Mikuliç, Vermeylen, Lyly-Yrjanainen, & Zigante,	Published in 2007 The pilot survey was tested in the UK and Holland with 200 interviews. The survey was revised especially for non-response questions. Another version was tested in 25 persons of each of the 31 countries to be surveyed. Sampling methods were devised. 35,634 Europeans were ultimately surveyed. Additional updates
<b>Female Sexual Function Index</b> <i>Rosen, Brown, Heiman, Leiblum,</i> <i>Meston, Shabsigh, Ferguson,</i> <i>D'Agostino</i> <i>Wiegel, Meston, &amp; Rosen</i>	Published in 2000 Initial data: 131 normal controls & 128 age- matched subjects with female sexual arousal disorder from 5 U.S. research centers. Updated 2005: the addition of those with hypoactive sexual desire disorder, female sexual orgasm disorder, dyspareunia/vaginismus, & multiple sexual dysfunctions (n=568), plus more controls (n=261).
Fragebogen zur Beurteilung des eigenen Korpers Strauss	Published 1996 (German)
Freiberg Personality Inventory Fahrenberg, Hampel, & Selg	7 <sup>th</sup> edition published 2001, 8 <sup>th</sup> edition in 2009 (Not in PubMed) German equivalent of MMPI
<b>"gender identity disorder in childhood"</b> Smith, van Goozen, Kuiper, & Cohen-Kettenis	11 items derived from the Biographical Questionnaire for Trans-sexuals (Verschoor Poortinga 1988) (Modified by authors of the Smith study)
Gender Identity Trait Scale Altstotter-Gleich	Published 1989 (German)
<b>General Health Questionnaire</b> Goldberg & Blackwell (initial study) Goldberg & Williams (manual)	Initial publication 1970 Manual published ?1978, 1988 (Not in PubMed) Initial data: 553 consecutive adult patients in a single UK primary care practice were assessed. Sample of 200 underwent standardized psychiatric interview. Developed to screen for hidden psychological morbidity. Proprietary test. Now 4 versions.
Hospital Anxiety & Depression Scale Zigmond & Snaith	Published in 1983 Initial data: Patients between 16 & 65 in outpatient clinics in the UK >100 patients; 2 refusals. 1 <sup>st</sup> 50 compared to 2 <sup>nd</sup> 50.
<b>Inventory of Interpersonal</b> <b>Problems</b> <i>Horowitz</i>	Published 1988 Initial data: 103 patients about to undergo psychotherapy; some patients post psycho- therapy (Kaiser Permanente-San Francisco) Proprietary test
<b>King's Health Questionnaire</b> Kelleher, Cardozo, Khullar, & Salvatore	1997 Initial data: 293 consecutive women referred for urinary incontinence evaluation in London Comparison to SF-36
Minnesota Multi-phasic Personality Inventory Hathaway & McKinley	Published in 1941 Updated in 1989 with new, larger, more diverse sample.

Instrument Name and Developer	wmc Document #: 104 Filed: 06/08/18 Pa Development and Validation Information
Butcher, Dahlstrom, Graham, & Tellegen	MMPI-2: 1,138 men & 462 women from diverse communities & several geographic regions in the U.S.A. The test is copyrighted.
Modified Androphia-Gynephilia Index	Neither the underlying version or the Blanchard modified version could be located in PubMed (Designed by the author of the Blanchard et al. study)
"post-operative functioning 13 items" Doorn, Kuiper, Verschoor, Cohen- Kettenis	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
"post-operative functioning 21 items" Doorn, Kuiper, Verschoor, Cohen- Kettenis	Published 1996 (Dutch) (Not in PubMed) (Designed by 1 of the authors of the Smith study)
Scale for Depersonalization Experiences Wolfradt	Unpublished manuscript 1998 (University of Halle) (Designed by 1 of the authors of the Wolfradt study)
<b>"sex trait function"</b> Cohen-Kettenis & van Goozen	Published 1997 Assessed in 22 adolescents (Designed by 1 of the authors of the Smith Study)
<b>Self-Esteem Scale</b> Rosenberg	Published 1965 (Not in PubMed) Initial data: 5,024 high-school juniors & seniors from 10 randomly selected New York schools
<b>Short-Form 36</b> RAND Ware & Sherbourne1992 McHorney, Ware, & Raczek 1993	Originally derived from the Rand Medical Outcomes Study (n=2471 in version 1; 6742 in version 2 1989). The earliest test version is free. Alternative scoring has been developed. There is a commercial version with a manual.
Social Anxiety & Distress Scale Watson & Friend	Initial publication in1969 Requires permission for use
<b>Social Support Scale</b> Van Tilburg 1988	Published 1988 (Dutch) (Not in PubMed)
<b>Spielberger State &amp; Trait Anxiety Questionnaire</b> Spielberger, Gorsuch, Lushene, Vagg, & Jacobs	Current format published in 1983 Proprietary test
<b>Symptom Checklist-90</b> Derogatis, Lipman, Covi Derogatis & Cleary	Published in 1973 & 1977 Reportedly with normative data for psychiatric patients (in- & out-patient) & normal subjects in the U.S. Has undergone a revision Requires qualification for use
<b>Tennessee Self-Concept Scale</b> <i>Fitts &amp; Warren</i>	In use prior to 1988 publication. Initial data: 131 psychiatric day care patients. Updated manual published 1996. Update population >3000 with age stratification. No other innformation available. Requires qualification for use
<b>Utrecht Gender Dysphoria Scale</b> <i>Cohen-Kettenis &amp; van Goozen</i>	Published in 1997 Initial population: 22 transgender adolescents who underwent reassignment surgery. (Designed by 1 of the authors of the Smith study)

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Instrument Name and Developer	wmc Document #: 104 Filed: 06/08/18 Pag Development and Validation Information	ge 175 of 242
<b>WHO-Quality of Life</b> (abbreviated version) <i>Harper for WHO group</i>	Field trial version released 1996 Tested in multiple countries. The Seattle site consisted of 192 of the 8294 subjects tested). Population not otherwise described. The minimal clinically important difference has not been determined. Permission required	

Althof et al., 1983; Greenberg, Frank, 1965; Gurtman, 1996; Lang, Vernon, 1977; Paap et al., 2012; Salkind et al., 1969; Vacchiano, Strauss, 1968.

### Appendix F

Endpoint Data Types and Sources

### Panel A (Controlled Studies)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Substan- tive &/or Accessible Normative Data	Investigator-designed	Other	Other
Dhejne 2011	Yes	-	-	-	-	Mortality (Suicide, Cardiovascular Disease [possible adverse events from Hormone Tx], Cancer), Psych hx & hospitalization, Suicide attempts
Dhejne Landén	Yes	-	-	-	Includes demographics*	Education, Employment, Formal application for reversal of status, Psych dx & tx, Substance abuse** More elements in earlier paper
Beatrice	-	MMPI form R, TSCS	-	-	Demographic	Education, Income, Relationships
Haraldsen	-	SCL-90/90R	-	-	Demographic	

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	Case:	Instrument	w/o Substan-	t #: 104 Filed: 06/08/18	Page 176 of	242
Author	Data Substal Norma	Substantive Normative Data	tive &/or Accessible Normative Data	Investigator-designed	Other	Other
						DSM Axis 1, II, V (GAF), Substance abuse
Heylens	-	SCL-90	-	Yes-2	Demographic	Employment, Relationships, Substance abuse, Suicide attempts
Ainsworth	-	Likely SF- 36v2*	-	Yes-1	Demographic	-
Ruppin	-	SCL-90R	BSRI, FPI-R, IIP	Yes-2	Demographic	Adverse events from surgery, Employment, Psych tx, Relationships, Substance abuse
Smith	-	MMPI-short, SCL-90?R	BIS, UGDS, ? Cohen- Kettenis', Doorn's x2, (Gid- c, SSS)	Yes-1 or 2	Demographic	Adverse events from surgery, Employment, Relationships
Udeze Megeri	-	SCL-90R	BDI, GHQ, HADS,STAI-X1, STAI-X2	-	-	Psych eval & ICD-10 dx
Kuhn	-	-	KHQ	Yes-1	Demographic	Relationships
Mate-Kole 1990	-	-	BSRI, CCEI	Yes-1	Demographic	Employment (relative change), Psych hx, Suicide hx
Wolfradt	-	-	BIQ, GITS, SDE, SES	Yes-1	-	-
Kraemer	-	-	FBeK	-	Demographic	-
Mate-Kole 1988	-	-	BSRI, CCEI	-	Demographic	Employment, Psych hx, Suicide hx,
Kockott	-	-	-	Yes-1	Demographic	Employment, Income, Relationships, Suicide attempts
Meyer	-	-	-	Yes-1	Demographic	Education, Employment, Income, Psych tx, Phallus removal request
Rakic	-	-	-	Yes-1	Demographic	Employment, Relationships

## Panel B (Surgical Series: No Concurrent Controls)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Sub- stantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Weyers	-	SF-36	FSFI	Yes-2	Demographic	Hormone levels, Adverse events from surgery, Relationships
Blanchard	-	SCL-90R	(AG)	Yes-1	Demographic	Education, Employment, Income, Relationships, Suicide (Incidental finding)
Wierckx	-	SF-36	-	Yes-3	Demographic	Hormone levels, Adverse events from surgery, Relationships
Eldh	-	-	-	Yes-1	-	Adverse events from surgery, Employment, Relationships, Suicide attempts
Hess	-	-	-	Yes-1	-	-
Lawrence	-	-	-	Yes-4	Demographic	Adverse events from surgery
Salvador	-	-	-	Yes-1	Demographic	Relationships
Tsoi	-	-	-	Yes-1	Demographic	Education, Employment, Relationships (relative change)

## Panel C (Mixed Treatment Series: No Direct Control Groups)

Author	National Data	Instrument w Substantive Normative Data	Instrument w/o Sub- stantive &/or Accessible Normative Data	Investigator-designed	Other	Other
Asscheman et al.	Yes	-	-	-	Demographic	

Author	National Data	Instrument w Substantive Normative Data	w/o Sub- stantive &/or Accessible Normative Data	Investigator-designed	Other	Other
						Mortality (HIV, Possible adverse events from Hormone Tx, Substance abuse, Suicide)
Motmans et al.	-	SF36 EQOLS (2 <sup>nd</sup> )	-	-	Demographic	Education, Employment, Income, Relationships
Newfield et al.	-	SF-36v2	-	-	Demographic	Income
Gómez-Gil et al. 2014	_	WHOQOL-BREF	APGAR	Yes-1	Demographic	Education, Employment, Relationships
Gómez-Gil et al. 2012	-	-	HADS, SADS	-	Demographic	Education, Employment, Living arrangements
Hepp et al.	-	-	HADS	-	Demographic	DSM Axis 1& II Psych dx
Johansson et al.	-	-	-	Yes-1	Demographic	Axis V change (Pt & Clinician) Employment (relative change) Relationship (relative change)
Leinung et al.	-	-	-	-	Demographic	Employment, Disability, DVT, HIV status, Psych dx
** From med AG=Androph APGAR=Fam BDI=Beck De BIQ=Body In BIS=Body In BSRI=Bem S CCEI=Crown Cohen-Kettel Dorn's x2= F Post-oper EQOLS (2nd) FBeK=Fragel FPI-R=A vers	dical charts ilia-Gyneph ily Adaptab epression I nage Quest nage Scale Sex Role Inv Crisp Expense crisp Expense ost-operat rative funct e=2nd Euro pogen zur E sion of the	bility, Partnership nventory cionnaire ventory eriential Index rait function (An a	author helped de growth, Affection author helped de items (An author An author helped ife Survey igenen Korpers	1985) (used more for clas n, and Resolve esign) or helped design)	sification)	

FSFI+Female Sexual Function Index GHQ=General Health Questionnaire Gid-c=Gender identity disorder in childhood (used more for predictors) (An author helped design) GITS=Gender Identity Trait Scale HADS=Hospital Anxiety Depression Scale

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IIP=Inventory GRANE Performance Document #: 104 Filed: 06/08/18 Page 179 of 242 KHQ=King's Health Questionnaire MMPI=Minnesota Multi-phasic Personality Inventory SADS=Social Anxiety & Distress Scale SCL-90 (±R)=A version of the Symptom Checklist 90 SDE=Scale for Depersonalized Experiences (An author designed) SES=Self-Esteem Scale SF-36 (v2)=Short Form-36(version2) SSS=Social Support Scale (used more for predictors) STAI-X1, STAI-X2=Spielberger State and Trait Anxiety Questionnaire TSCS=Tennessee Self-Concept Scale UGDS=Utrecht Gender Dysphoria Scale (An author helped design) WHOQOL-BREF=World Health Organization-Quality of Life (abbreviated version)

#### Appendix G.

# Longitudinal Studies Which Used Patients as Their Own Controls and Which Used Psychometric Tests with Extensive Normative Data or Longitudinal Studies Which Used National Data Sets

Author	Test	Patient and Data Loss	Results				
	Psychometric Test						
Heylens et al. Belgium 2014	SCL-90R	<ul> <li>90 applicants for SRS were recruited.</li> <li>•8 (8.9%) declined participation.</li> <li>•12 (13.3%) excluded b/c GID-NOS dx.</li> <li>•12 (13.3%) did not complete the treatment sequence b/c of psychiatric/physical comorbidity, personal decision for no tx, or personal decision for only hormone tx.</li> <li>•1 (1.1%) committed suicide during follow-up.</li> <li>57 (63.3% of recruited) entered the study.</li> <li>•1 (12.2% of initial recruits) had not yet received SRS by study close.</li> <li><b>46 (51.1% of recruited) underwent serial evaluation</b></li> <li>•The test was not completed by 1 at t=0, 10 at t=1 (after hormone tx), &amp; 4 at t=2 (after SRS) missing data for another 1.1% to 11.1%.</li> </ul>	At t=0, the mean global "psychoneuroticism" SCL- 90R score, along with scores of 7 of 8 subscales, were statistically more pathologic than the general population. After hormone tx, the mean score for global "psychoneuroticism" normalized & remained normal after reassignment surgery.				
Ruppin,Pfafflin Germany 2015	, SCL-90R	The number in the available patient pool was not specified.					

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		<ul> <li>140 received recruitment letters.</li> <li>2 (1.4% of those with recruitment letters) had died.</li> <li>1 (0.7%) was institutionalized.</li> <li>5 (3.6%) were ill.</li> <li>8 (5.7%) did not have time.</li> <li>8 (5.7%) stated that GD was no longer an issue.</li> <li>8 (5.7%) provided no reason.</li> <li>28 (20.0%) declined further contact.</li> <li>9 (6.4%) were lost to follow-up.</li> <li>71 (50.7%) agreed to participate.</li> <li>2 (1.4%) had not undergone SRS</li> <li>The test was not completed by 9.</li> <li>missing data for another 6.4%.</li> </ul>	At t=0, the "global severity index "SCL-90R score was $0.53\pm0.49$ . At post-SRS follow-up the score had decreased to $0.28\pm0.36$ . The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 0-4. In the same way, all of the subscale scores were statistically different, but the effect size was reported as large only for "interpersonal sensitivity": $0.70\pm0.67$ at t=0 and $0.26\pm0.34$ post- SRS.
Smith et al. Holland 2005	MMPI SCL-90	The number in the available adult patient pool was not specified. 325 adult & adolescent applicants for SRS were recruited. •103 (31.7%) were not eligible to start hormone tx & real-life experience. •34 (10.7%) discontinued hormone tx 162 (an unknown percentage of the initial recruitment) provided pre -SRS test data. •36 to 61 (22.2%- 37.6% of those adults w pre-SRS data) did not complete post-SRS testing.	143.0 $\pm$ 40.7. At post SRS-follow-up, the score had decreased to 120.3 $\pm$ 31.4.
Udeze, et al. 2008 Megeri, Khoosal 2007 UK	SCL-90R	The number in the available patient pool was not specified. 40 subjects were prospectively selected. •Post-operative testing was conducted within 6 months to minimize previously determined loss rates.	At t=0, the mean raw global score was 48.33. At post-SRS follow-up, the mean score was 49.15.

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			There were no statistically significant changes in the global score or for any of the subscales.	
	National Da	tabases		
Dehjne Sweden 2011	Swedish National Records	<ul> <li>804 with GID in Sweden 1973 to 2003 were identified.</li> <li>480 (59.7%) did not apply or were not approved for SRS 324 (40.3%) underwent SRS.</li> <li>All were followed.</li> <li>3240 controls of the natal sex and 3240 controls of the reassigned gender were randomly selected from national records</li> </ul>	All cause mortality was higher (n=27[8%]) than in controls (H.R 2.8 [1.8- 4.3]) even after adjustment for covariants. Divergence in survival curves was observed after 10 years. The major contributor was completed suicide (n=10 [3%]; adjusted H.R. 19.1 [5.8-62.9]). Suicide attempts were more common (n= 29 [9%]) than in controls (adjusted H.R. 4.9 [2.9-8.5]). Hospitalizations for psychiatric conditions (not related to gender dysphoria) were more common n= 64 [20%] than in controls (H.R. 2.8 [2.0-3.9]) even after adjusting for prior psychiatric morbidity.	
Dhejne et al. 2014 Landén et al. 1998 Sweden	Swedish National Registry	<ul> <li>767 applied for SRS/legal status (1960-2010)</li> <li>•25 (3.3%) applications denied.</li> <li>•61 (8.0%) not granted full legal status</li> <li>681 (88.7%) underwent SRS.</li> <li>•All were followed.</li> </ul>	15 formal applications for reversal to natal/original gender (2.2% of the SRS population) were identified thus far (preliminary number). (Does not reflect other manifestations of regret such as suicide.)	

GID-NOS=Gender Identity Disorder-Not Otherwise Specified HR=Hazard Ratio SRS=Sex reassignment surgery Tx=Treatment Back to Top

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# EXPERT REPORT OF JOAN C. BARRETT AND ELAINE T. CORROUGH SUBMITTED ON BEHALF OF THE PLAINTIFFS

Alina Boyden and Shannon Andrews, Plaintiffs v. State of Wisconsin Department of Employee Trust Funds et al., Defendants

CASE NO. 17-CV-264 in the United States District Court for the Western District of Wisconsin

May 31, 2018

Presented by: Joan C. Barrett, FSA, MAAA Senior Consulting Actuary Axene Health Partners, LLC

Elaine Corrough, FSA, FCA, MAAA Partner and Consulting Actuary Axene Health Partners, LLC

This report has been prepared solely for the use of the American Civil Liberties Union of Wisconsin Foundation and the American Civil Liberties Union Foundation (the ACLU) for the purpose of providing expert information and analysis for the above mentioned lawsuit.



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# **Executive Summary**

The American Civil Liberties Union of Wisconsin Foundation and the American Civil Liberties Union Foundation (the ACLU), on behalf of Alina Boyden and Shannon Andrews, plaintiffs, engaged Axene Health Partners, LLC (AHP) to provide an expert report in rebuttal to the expert report of David V. Williams submitted on behalf of the State defendants in Case No. 17-CV-264 in the United States District Court for the Western District of Wisconsin. In addition to this report, AHP has agreed to provide expert testimony in depositions and at trial as necessary.

In preparation for this report, AHP reviewed the expert report of David V. Williams ("the Williams Report"), submitted on behalf of the defendants and the supporting information referenced in the Williams Report as well as other related sources of information. We did not attempt to duplicate the calculations described in the Williams report due to time constraints. We do reserve the right to perform that analysis at a later date, however. We did test the calculations and assumptions Mr. Williams describes for reasonability and consistency with standard actuarial principles. Similarly, we did not attempt to provide an independent estimate of the costs. As part of our review, however, we did compare Mr. Williams' estimate to independent sources of cost estimates.

The purpose of the Williams Report was to estimate the healthcare costs associated with removing the exclusion (the "Exclusion") in the Wisconsin State Employees Benefit Plan (the "State Plan") that excludes coverage for "surgical procedures, services and supplies related to surgery and hormone therapy associated with gender reassignment." Mr. Williams' work was done in support of the State defendants in the civil rights case of Boyden, et al., v. State of Wisconsin Group Ins. Board, et al., No. 17-CV-264 (United States District Court for the Western District of Wisconsin).

# Conclusions

In our expert opinion, the methods used by Mr. Williams are generally appropriate, but his estimate of a cost of \$0.15 per member per month (PMPM) is on the high end of the range we would consider reasonable. Although it was not explicitly stated, we assume that this estimate represents the cost in 2016 based on Mr. Williams' description of his work. Based on that estimate, however, it is our opinion that the cost to cover this benefit is immaterial. Based on the information described in the Interrogatories, we estimate that the average 2016 cost for covered services under the state plan is \$495 PMPM, which would make the cost of removing the exclusion 0.03 % of total costs. In our expert opinion, any benefit that is less than 0.1% of total cost is considered immaterial, since it amounts to a rounding error.

# **Professional Qualifications**

This report has been prepared by Joan C. Barrett, FSA, MAAA and peer-reviewed by Elaine T. Corrough, FSA, FCA, MAAA in accordance with the following Standards of



Practice as promulgated by the Actuarial Standards Board of the American Academy of Actuaries:

- Actuarial Standards of Practice No. 1, "Introductory Standard of Practice"
- Actuarial Standards of Practice No. 5, "Incurred Health and Disability Claims"
- Actuarial Standards of Practice No. 17, "Expert Testimony by Actuaries"
- Actuarial Standards of Practice No. 23, "Data Quality"
- Actuarial Standards of Practice No. 25, "Credibility Procedures Applicable to Accident and Health, Group Term Life, and Property/Casualty Coverages"
- Actuarial Standards of Practice No. 41, "Actuarial Communication"

# Compensation

The billing rates for Ms. Barrett and Ms. Corrough are \$400 per hour and \$445 per hour respectively. The compensation is not dependent on the outcome of the case or on the opinions contained in this report.

# Personal Qualifications

Both Ms. Barrett and Ms. Corrough are Fellows of the Society of Actuaries (FSA) and Members of the American Academy of Actuaries (MAAA) in good standing and are qualified to perform this work.

Before joining AHP, Ms. Barrett led the National Accounts Actuarial area for UnitedHealth Care. In that role Ms. Barrett and her team provided pricing and benefit strategy work for large self-insured groups, including developing the complex actuarial systems underlying this work. As part of that work, she often estimated the cost of specific benefits like transgender surgery.

Ms. Corrough provided similar support during her tenure at Aon/Aon Hewitt. In that position, she frequently reviewed the work of other actuaries. Since joining AHP, Ms. Corrough has provided expert witness services and developed a measurement system for a targeted condition management program.

Brief biographies and curricula vitae, which include a list of publications in the past ten years, are included in the appendix of this report. Neither Ms. Barrett nor Ms. Corrough has provided expert testimony.

# Background

We relied on our knowledge of actuarial pricing principles in reviewing the Williams Report. In this section we describe those principles and their application to the circumstances of this case.



We reviewed the following documents in performing this review: the second amended complaint; the Defendants' Responses to Plaintiffs' First Set of Requests to Admit, Interrogatories and Requests for Production ("Interrogatories"); the Williams Report; the expert report of Stephanie Budge, Ph.D.; two reports by Segal Consulting on the costs of providing surgical and related services for treatment of gender dysphoria; the Terms and Conditions for Comprehensive Medical Plan Participation in the State of Wisconsin Group Health Benefit Program and Uniform Benefits for the 2016 Benefit Year; the World Professional Association for Transgender Health (WPATH) Standards of Care; and each of the references listed in Mr.Williams' bibliography, with the exception of the Diagnostic and Statistical Manual of the American Psychiatric Association. In addition to the sources included in the discovery process, we reviewed the Behavioral Risk Factor Surveillance System website <a href="https://www.cdc.gov/brfss">https://www.cdc.gov/brfss</a>) and the American Society of Plastic Surgeons website (<a href="https://www.plasticsurgery.org">https://www.plasticsurgery.org</a>).

## The Estimation Process

The general formula for calculating the estimated net cost of adding a benefit to a plan or removing an exclusion reflects:

- The direct costs associated with adding the benefit
- The incremental costs in currently covered benefits due to the new benefit
- Savings in currently covered benefits as a result of adding the benefit
- A risk premium

A few comments on this concept:

- Costs are based on a specific time period, usually a calendar year.
- Costs are typically calculated on a per member per month (PMPM) basis, where the definition of a member includes employees and dependents.
- The formula for calculating a PMPM = [expected number of claims during the year] x [average cost per claim]÷[average number of members covered]÷12.
- Cost of a benefit may also be expressed as a percent of total costs, in which case both the numerator and denominator need to be consistent in terms of time period and applicable population.
- The estimate should reflect typical clinical treatment patterns and accepted standards of care for the procedure or underlying condition in question.
- Similarly, the estimate should reflect the plan provisions regarding which services are covered, which services are excluded as well as any limitations or exceptions to those services.
- Whenever possible, the starting point for the estimate should be the plan's own historical experience. To the extent that is not possible, the experience of similar plans may be used, with appropriate adjustments.
- Other sources of information, like published papers and data, should be used to test the reasonableness of the estimate.
- The determination of the risk premium depends on the purpose of the estimate. If the purpose of the estimate is to provide a best estimate, then the value of the risk premium should be zero. If the purpose of the estimate is to reflect some



measure of risk, then the risk premium should be greater than zero. Typically, the risk premium does not reflect the "worst case" scenario. Instead, it is calculated assuming that there is about an 80% to 90% chance that the actual costs will not exceed the estimate.

• The final value of the risk premium should reflect potential overstatements and understatements in the best estimate calculation.

There are always uncertainties in estimating the cost of a new benefit, so approximations are necessary. In reviewing the Williams Report we consistently looked to see if the general principles described above were followed, if the approximations were reasonable and the potential impact on the risk premium.

# **Clinical Considerations**

Clinical care for transgender individuals may include:

- Counseling and therapy before reassignment surgery, after the surgery or instead of the surgery
- Hormone replacement therapy
- Surgical procedures to feminize or masculinize the chest and genitals
- Other gender confirmation surgeries to alter the body to feminize or masculinize the patient's physical appearance

The World Professional Association for Transgender Health (WPATH) has established standards of care which include both eligibility and readiness requirements. The transition process may take multiple years to complete.

## The State Plan

The State Plan currently excludes "procedures, services and supplies related to surgery and sex hormones associated with gender reassignment". In addition to this exclusion, the plan excludes cosmetic and experimental procedures, but covers other medically necessary surgeries. Our interpretation of this language is that the State Plan currently covers surgeries like mastectomies, hysterectomies, breast reconstruction and similar procedures unless there is a diagnosis code or other indicator that implies that the procedure is related to gender confirmation. We have no way to validate that with the information available but that interpretation is consistent with our knowledge of typical claims-payment policies and procedures.

If the Exclusion is removed, then the State plan may attempt to specify whether or not members under age 18 are eligible for coverage and whether or not related procedures to masculinize or feminize appearance are covered. For purposes of this analysis, we assume that there will be coverage for members under age 18 and that all gender confirmation surgeries will be covered.



## Baseline Numbers

In our review we assumed that all numbers relate to calendar year 2016 unless otherwise noted. Using the answers to Questions 6 and 7 in the Interrogatories, we further assumed:

- The number of employees with individual coverage in 2016 was 26,168 and the number with family coverage was family coverage was 43,054 for a total of 69,222.
- Assuming 1 member per employee for individual coverage and 3.2 for family coverage, we estimated that there were 165,000 members in total.
- The total cost for the employer portion of the plan was \$979,741,313.30, which results in a PMPM cost of \$495.

# **Claims-Based Analysis**

In preparing his report, Mr. Williams relied primarily on a claims-based analysis described in this section. AHP reviewed Mr. Williams' description of the steps that he used to calculate his estimate and we compared these steps to the general principles described above.

## Methodology

The specific steps he described are:

- <u>Define the benefit</u>. Mr. Williams states that he used a broad approach in defining the benefit for his initial estimate. Specifically, he included individuals with a diagnosis of gender dysphoria and services that may be related to gender reassignment surgery, both in preparation for surgery and for post-surgical treatment as a starting point for his analysis. Later in his analysis, he adjusted the initial estimate to account for a potential overstatement.
- <u>Define criteria for identifying individuals with relevant claims</u>. The first step in Mr. Williams' analysis was to determine which individuals submitted a gender dysphoria claim. To do that, he compiled a list of diagnostic and procedure codes that indicate a potential diagnosis of gender dysphoria. To compile the list, Mr. Williams relied on the Blue Cross and Blue Shield of Massachusetts (BCBSMA) medical policy for gender dysphoria since that policy included extensive information about coding procedures. He then compared the substance of that policy to the policies used by the State Plan third-party administrators, Dean Health Plan and WPS. He concluded that the policies were similar enough that he could rely on the BCBSMA coding procedures for his analysis.
- <u>Gather data</u>. Using the criteria described above, Mr. Williams identified 8,200 individuals with a diagnosis of gender dysphoria using the 2016 Truven MarketScan commercial data base. Based on his description of the process, it appears that this process was HIPAA-compliant. He then assumed that the groups associated with those 8,200 individuals and only those groups covered



transgender surgery benefits. Using that assumption, he calculated the total number of members for those groups (20,037,382) and the corresponding gender dysphoria claims.

While we are familiar with the Truven data at a high level, we relied on Mr. Williams' work regarding the quality of the data and the accuracy of his calculations. We did not attempt to duplicate his work, but we do reserve the right to do so at a later date.

## Findings

The following table summarizes the findings in Tables 1A and 1B of the Williams Report.

		Individuals	Total Costs	% of Costs	Cost Per Person	PMPN
Non-Surgical Patients	Counseling	4,260	\$ 7,411,724	51% \$	1,740	\$ 0.03
	Hormone Therapy	4,072	\$ 2,717,390	19% \$	667	\$ 0.01
	Other	6,515	\$ 4,332,024	30% \$	665	\$ 0.02
	Sub-total	7,731	\$ 14,400,221	100% \$	1,863	\$ 0.06
Surgical Patients	Counseling	259	\$ 424,909	4% \$	1,641	\$ 0.00
	Hormone Therapy	417	\$ 229,705	2% \$	551	\$ 0.00
	Reassignment Surgery	469	\$ 7,318,440	73% \$	15,604	\$ 0.03
	Other	458	\$ 2,017,564	20% \$	4,405	\$ 0.01
	Sub-total	469	\$ 9,990,618	100% \$	21,302	\$ 0.04
All Patients	Counseling	4,519	\$ 7,836,633	32% \$	1,734	\$ 0.03
	Hormone Therapy	4,489	\$ 2,947,095	12% \$	657	\$ 0.01
	Reassignment Surgery	469	\$ 7,257,523	30% \$	15,474	\$ 0.03
	Other	6,973	\$ 6,349,588	26% \$	911	\$ 0.03
	Total	8,200	\$ 24,390,839	100% \$	2,974	\$ 0.10

From this table, the total cost of covering all gender dysphoria benefits is \$0.10, with \$0.04 being the direct cost for gender reassignment surgeries and \$0.06 for all other gender dysphoria claims, even if those claims are currently covered under the terms of the State Plan. Translating these numbers to the State Plan, the total cost would be approximately \$200,000 for 68 individuals. The direct cost of the surgery would be about \$85,000 for 4 surgical patients.

Mr. Williams used the midpoint of the \$0.04 to \$0.10 range (\$0.07) as his best estimate before adding the risk premium as discussed below. In effect, his final estimate reflects a \$0.04 PMPM for gender reassignment surgical services and a net increase of \$0.03 for gender dysphoria services not currently covered under the Uniform Benefits provision of the State Plan. The difference between the \$0.10 originally calculated for all gender dysphoria claims and the \$0.07 represents the net effect of accounting for services already covered under the State Plan and the potential clinical savings associated with fewer claims for services that would be rendered unnecessary if the patients' gender dysphoria is effectively treated by hormones or surgical procedures.



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## Review

Overall, Mr. Williams followed sound actuarial principles and made appropriate use of the available data. That said, we have a few observations:

- Mr. Williams stated that his determinations might have overstated the average number of members which would have understated the costs. While that may be true, it is also likely that some groups with coverage had no claims, which would have resulted in an understatement in the number of members and an overstatement of the costs per member.
- It appears Mr. Williams' analysis corresponds to our assumptions about coverage described earlier.
- We reviewed several published sources, including those listed in the Williams Report, and did not find a source that helped us to quantify the potential savings associated with removing the Exclusion or the percent of gender dysphoria claims already being covered. That said, based on the expert witness testimony of Dr. Budge, transition-related care is considered cost-effective because "denial of care is associated with increased disparities in depression, drug abuse, HIV and additional conditions that are costly to treat." Based on that, we assume savings exist, even though they cannot be quantified precisely.
- In theory, the \$0.03 difference between the \$0.10 and the \$0.07 mentioned above represents the net impact of potential savings and the overstatement from services already covered.

In addition to the review described above, we looked at the January 17, 2017 estimate provided to Lisa Ellinger by Segal consultants, Kirsten R. Schlatten, ASA, MAAA and Kenneth C. Vieira, FSA, MAAA. They estimated the impact to be in the \$0.05 to \$0.13 range. In addition, in a letter to Ann Timmons dated March 3, 2014, Segal consultants estimated the cost to be between 0.02% and 0.03% of total costs. Both estimates are consistent with Mr. Williams' estimate.

Given all the considerations described above, we agree that Mr. Williams' best estimate of \$0.07 is an appropriate starting point. Under that scenario, the net impact to the State Plan would be \$140,000 or 0.01% of total costs.

# **Final Estimate and Materiality**

Although we agree that Mr. Williams' best estimate is appropriate, we believe his risk premium represents a "worst case" scenario as opposed to a more reasonable scenario.



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## **Risk Premium and Final Estimate**

Mr. Williams' final estimate was \$0.15 PMPM. For the State Plan this translates to a total cost of 0.03% of total costs. He derived this estimate by including a risk premium of 50% for utilization and 50% for costs. In effect, he doubled the best estimate.

To put that in perspective, the difference between the best estimate and the final estimate is \$160,000 (\$300,000 - \$140,000). This could happen under scenarios like:

- An additional single reassignment surgery at a cost of \$160,000. This would be almost 8 times the average cost of such surgeries.
- 8 additional reassignment surgeries at an average cost of \$20,000. This would triple the expected number of surgeries.
- 80 additional non-surgical patients at an average cost of \$2,000. This would more than double the number of patients.

Given that the probability of any claim for services is close to zero, each of these scenarios is highly unlikely. Our recommendation would be to use a 25% margin, resulting in a \$0.09 PMPM. This would support a scenario where there was one additional reassignment surgery and 16 additional non-surgical patients. The net impact to the State Plan would be \$175,000 or 0.02% of total costs.

There were two factors supporting our recommended margin. First, according to the American Society of Plastic Surgeons, there were only 3,200 gender confirmation surgeries of all types performed in 2016 even though the surgical techniques have been around since the 1950's. We expect to see a steady growth over time, but not a doubling of the number of surgeries in the near future. Second, in our experience there is a natural tendency to overstate the cost of a benefit when it is relatively new since there is so little known about costs and utilization initially. Employers have been offering this benefit for over a decade now, so there is no need to be overly cautious.

## Materiality

Even at Mr. Williams' estimate of \$0.15, the removal of the Exclusion rounds to 0.0%, so it is clearly immaterial. It is standard actuarial practice to assume that any benefit that is 0.1% of total costs or less is immaterial for several reasons, but mostly because it is considered a rounding error. In our experience, no employer has made a benefits decision based on cost for a benefit that costs less than 0.1%. Regardless, there would be no way to validate the the accuracy of a projection of a cost at or below this threshold after the fact, because normal variance for a group the size of the State Plan is between 3% and 5% based on our experience.

For the State Plan, this 0.1% materiality level translates to a 2016 PMPM of \$0.50, or more than triple Mr. Williams' final estimate of \$0.15, more than 5 times our final estimate of \$0.09 and more than 7 times our mutual best estimate of \$0.07.



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# **Actuarial Disclosures**

## Reliance on Data Supplied by Others

In preparing this report, I have relied on data and reports supplied by the ACLU of Wisconsin including the Williams Report. While we have reviewed the information in detail to determine reasonability, we have not audited the data and report, and do not attest herein to their accuracy.

#### **Responsible Actuary**

Unless otherwise noted, I am responsible for the assumptions and methodologies presented in this report. Questions regarding this report should be directed to my attention.

## Qualifications

I, Joan Barrett, am a Fellow of the Society of Actuaries and a Member of the American Academy of Actuaries in good standing, and am qualified to complete this work.

Respectfully submitted,

par &. Banet

Joan Barrett, FSA, MAAA Senior Consulting Actuary Axene Health Partners, LLC May 31, 2018



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# CURRICULUM VITAE

# JOAN C. BARRETT, FSA, MAAA

Axene Health Partners, LLC O: 860.858.5654 | C: 860.463.9484 | joan.barrett@axenehp.com

#### SUMMARY

Seasoned health actuary with over 35 years of professional experience, recognized for technical experience, leadership, communication skills and professional integrity.

#### **CURRENT POSITION**

## Advisor to Insurers and Employers

Senior Consulting Actuary, Axene Health Partners, LLC, June 2015 – Present Role: Consulting with health insurers and employers on a variety of actuarial assignments. Recent projects:

- Rate-making procedures and strategies
- Rate fling support
- Employee benefits pricing and strategy

#### PREVIOUS WORK EXPERIENCE

#### **National Accounts Actuary**

Vice President, National Accounts, UnitedHealthcare. February 1993 – June 2015 Roles: Providing actuarial support to senior management and employers

- 1. Actuarial support and risk management for senior management
- 2. Benefit design and strategic consulting for Fortune 500 employers
- 3. Consumerism and actuarial research
- 4. Small and large group rate filings and pricing
- 5. Actuarial support for union negotiations
- 6. Analysis of self-funded network reimbursement methodologies
- 7. Rate-filings and pricing

#### QUALIFICATIONS AND DESIGNATIONS

- FSA Fellow of the Society of Actuaries (SOA)
- MAAA Member of the American Academy of Actuaries (AAA)

#### **EDUCATION**

- Bachelor of Arts, Frederick College, Portsmouth Virginia (Mathematics)
- Master of Arts, Miami University, Oxford, Ohio (Mathemetics)

## PUBLICATIONS IN THE LAST 10 YEARS

- <u>Barrett, Joan</u>. (2018) Time to Update Your Trend Process?. *HealthWatch* (Society of Actuaries).
- <u>Barrett, Joan (2017)</u>. Evolution of the Health Actuary: A Health Section Strategic Initiative. *HealthWatch*.
- <u>Barrett, Joan.</u> (2017) Accountability: Rates. *Inspire Accountability Series*. (Axene Health Partners)
- <u>Barrett, Joan.</u> (2017) The Chronic Disease Burden. *Inspire Series on the U.S. Healthcare Sytem*. (Axene Health Partners)
- <u>Barrett, Joan</u>. (2016). Making Predictive Analytics Our Own. *Predictive Analytics and Futurism* (Society of Actuaries)
- <u>Barrett, Joan.</u> (2016). Ch. 34: Medical Claims Cost Trend Analysis. *Group Insurance*, Skwire, Daniel D., 7<sup>th</sup> Edition.
- <u>Barrett, Joan and Kessler, Emily.</u> (2015) New Directions: The SOA in China. *The Actuary* (Society of Actuaries.
- Barrett, Joan. (2010) Chairperson's Corner. Expanding Horizons. (Society of Actuaries)
- <u>Barrett, Joan.</u> (2009) Chairperson's Corner. *Expanding Horizons.* (Society of Actuaries)
- Barrett, Joan. (2008) Timing's Everything: The Impact of Benefit Rush (Society of Actuaries)

## EXPERT WITNESS EXPERIENCE

None

## CURRENT AND RECENT SOCIETY OF ACTUARIES (SOA) ENGAGEMENTS, ACTIVITIES AND ACCOMPLISHMENTS

- Vice-President, 2015 to 2017
  - Chair, Value of the Credential Task Force
  - Member, Issues Advisory Committee
  - Member, Policy and Governance Committee
  - Member, Cultivating Opportunities Team
- Elected Board Member, 2011 to 2014
  - o Chair, International Committee
    - Chair, Audit Committee
    - Member, Business Analytics Team
    - o Academic Partner
- Initiative 18/11: What Can We Do About the Cost of Health Care
  - o Planning Committee member
  - o Participant
- Section Experience
  - o Chair, Education and Research Section Council
  - o Board Partner, Health Section Council
  - o Board Partner, Predictive Analytics and Futurism Section Council
  - Chair, Evolution of the Health Actuary Task Force, chartered by the Health Section Council
  - Member, Health Section Council
- Basic Education Experience
  - o General Officer, General Insurance Curriculum
  - General Officer, Group and Health

- Continuing Professional Development Experience
  - Chair, Health Meeting
  - o Board Partner, Continuing Professional Development Committee
  - Frequent speaker
- Research
  - Chair, Project Oversight Group, "Enterprise Risk Management Practice as Applied to Health Insurers, Self-Insured Plans and Health Financial Professionals"
  - o Chair, Project Oversight Group, "Risk and Mitigation for Health Insurance Companies"
  - Chair, Project Oversight Group, "Measurement of Healthcare Quality and Efficiency: Resources for Healthcare Professionals"

# **BRIEF BIOGRAPHY**

# JOAN C. BARRETT, FSA, MAAA

Axene Health Partners, LLC O: 860.858.5654 | C: 860.463.9484 | joan.barrett@axenehp.com

Joan Barrett is a Senior Consulting Actuary with Axene Health Partners, LLC. She is a well-known and well-respected actuary. Joan brings great value to AHP clients with a knack for developing strong systems for analyzing network value and core actuarial functions, such as trends and pricing. Joan joined AHP following a successful career at UnitedHealth Group, where she led the National Accounts Actuarial area for many years. In that role, she was instrumental in developing several innovative concepts in risk analysis and consumer analytics.

In 2017 she completed her service as a Society of Actuaries Vice-President. During her terms on the Board of Directors, she chaired both the International Committee and the Audit Committee. In 2011 she was named one of the Top Ten Volunteers for the Society of Actuaries. In part, this was because of her work as Chair of the Group and Health Curriculum Committee, the group that defines what every aspiring health actuary needs to know.

Joan recently chaired the Evolution of the Health Actuary Task Force which was been charged with defining the needs of health actuaries in the years to come and recommending a path to meet these needs. She is also a frequent speaker and author.

Joan received her Bachelor of Arts in mathematics from Frederick College and her Master of Arts in mathematics from Miami University. She is a Fellow of the Society of Actuaries and a Member of the American Academy of Actuaries.

Joan lives in Tolland, Connecticut near her children and grand-children.

# CURRICULUM VITAE

# Elaine Corrough, FSA, FCA, MAAA

Axene Health Partners, LLC O: 503.272.6036 | C: 847.271.1470 | elaine.corrough@axenehp.com

#### SUMMARY

Seasoned health actuary with over 20 years of professional experience, recognized for technical experience, communication skills and professional integrity.

#### **CURRENT POSITION**

## Advisor to Health Systems, Insurers, and Related Organizations.

Partner & Consulting Actuary, Axene Health Partners, LLC, January 2016 – Present Senior Consulting Actuary, Axene Health Partners, LLC, March 2012 – December 2016 Role: Consulting with health systems and health insurers on Medicaid, Medicare, and commercial blocks of business on a variety of actuarial assignments.

Recent projects:

- Expert witness services regarding health actuarial practice and provider payment levels
- Contract review and analysis, cost model development, reimbursement schemes, and risk-based rate analysis
- Actuarial support for provider-payor contract negotiations and network development
- Analysis of self-funded rates for trusts and self-funded employers
- Strategies and structures for alternative payment models
- Evaluation of operational expenses for health plan, including negotiated MSO rates
- Cost analysis for setting network provider reimbursement rates on fee-for-service and risk (capitation) bases
- Claims analysis and payment model development for health systems
- Evaluation of risk readiness for health systems
- Measurement model for targeted condition management program

## PREVIOUS WORK EXPERIENCE

## **Employee Benefits Actuary.**

Vice President, Aon/Aon Hewitt, January 2009–December 2011. Employee benefits consulting. Actuary/Consultant, Hewitt Associates, October 1995–December 2006 and December 2007–December 2008

Role: Consulting with employers on all aspects of their health and welfare benefits.

- Analysis of self-funded network reimbursements and overall health plan performance
- Claims analytics and reserves calculations
- Benefit design and strategic consulting
- Various national roles at Hewitt including national development leader and manager of actuarial operations for the health practice

## Staff Fellow.

Health Staff Fellow, Society of Actuaries, January 2007 – November 2007. Role: Unique national position focusing on the educational and research needs of practicing health actuaries.

## QUALIFICATIONS AND DESIGNATIONS

- FSA Fellow of the Society of Actuaries (SOA)
- MAAA Member of the American Academy of Actuaries (AAA)
- FCA Fellow of the Conference of Consulting Actuaries (CCA)

## **EDUCATION**

• Bachelor of Arts 1992, Washington University in St. Louis, Classics (Languages)

## EXPERT WITNESS WORK

None

## PUBLICATIONS IN THE LAST 10 YEARS

- Corrough, Elaine. (2017) Data Intermediaries: Pulling Insights from Confidential Data. *Inspire* Series (Axene Health Partners)
- Corrough, Elaine. (2016). Chairperson's Corner. HealthWatch. (Society of Actuaries)
- Elaine, Corrough. (2016) Ch. 18: The Affordable Care Act. *Group Insurance*, 7<sup>th</sup> Edition (Skwire)

## CURRENT AND RECENT PROFESSIONAL ENGAGEMENTS, ACTIVITIES AND ACCOMPLISHMENTS

- Project Oversight Group member (Society of Actuaries Research MACRA), 2018
- Merit Reviewer (multiple grant applications improving healthcare systems), PCORI, 2018
- SOA Nominating Committee 2017-18
- Merit Reviewer (multiple grant applications dissemination & implementation), PCORI, 2017
- Project Oversight Group member (Society of Actuaries Research Healthcare Fraud), 2017
- Presenter (Health Research), 2016 SOA Annual Meeting Outstanding Session Award
- Presenter (ACA co-op failures), September 2016 Portland Actuarial Club
- Presenter (ACA marketplace sustainability), 2016 State of Reform-Portland
- Panelist (Actuarial Standards of Practice), 2016 SOA Spring Health Meeting
- Editorial Board member, *HealthWatch*, 2016
- SOA Health Section Council 2015-16 Chair (elected position)
- Contributing author, *Group Insurance* (textbook, 7<sup>th</sup> edition)
- Presenter (provider reimbursement models), 2016 State of Reform-Seattle
- Presenter (actuarial communications and writing), 2015 SOA Spring Health Meeting
- Panelist (clinical measures for payment models), 2015 SOA Spring Health Meeting
- Presenter (provider reimbursement models), 2015 State of Reform-Los Angeles
- Moderator (options for small groups under ACA), SOA Webcast, July 2015
- SOA Health Section Council 2014-15 Vice-Chair (elected position)
- SOA Health Research Committee 2014-17 member
- SOA Health Research Oversight Committee 2016-17 member
- CCA 2015 Health Reform Meeting planning committee member

- Actuarial Standards Board (ASB) MV/AV Task Force and related Actuarial Standard of Practice (ASOP) – task force member
- Joint Discipline Panel 2016 member
- Panel moderator, 2014 CCA Health Reform Meeting, State Perspectives on Rate Filing Reviews
- SOA Public Relations 2013-2014 media interviews
  - "Is This the Hardest Job in America?" Wall Street Journal, 5/1/2014
  - Commentary on ACA and rate development interviews with media outlets including CNN (11/2013), BloombergBusinessWeek (11/2013), Politico (12/2013), Modern Healthcare (4/2014), Vox.com (4/2014), Kaiser Health News (4/2014), MarketWatch (4/14), Associated Press (4/2014)
- CCA 2014 Health Reform Meeting planning committee member
- SOA Basic Education 2013 volunteer, General Insurance track
- Panel moderator, 2013 SOA Annual Meeting & Exhibit, Healthcare Cost Trends
- Scorecard committee member, Healthcare Cost Institute, April 2012
- Public testimony, Joint Legislation Audit & Review Subcommittee (State of Washington), February 2011
- SOA Basic Education 2007-08 volunteer, Health track (wrote original content)

**BRIEF BIOGRAPHY** 

# Elaine Corrough, FSA, FCA, MAAA

Axene Health Partners, LLC O: 503.272.6036 | C: 847.271.1470 | elaine.corrough@axenehp.com

Elaine is a Partner and Consulting Actuary with Axene Health Partners, and has recently opened our new office in Portland, Oregon after working in the Murrieta headquarters for several years. With over 20 years of health actuarial experience, Elaine's recent work has focused on actuarial analysis, cost modeling, and formal certifications for carriers and health systems, including state ACA rate filings; actuarial reviews for the Round 2 Centers for Medicare and Medicaid Innovation (CMMI) Health Care Innovations Awards; and strategic and tactical support for health systems taking on risk. Elaine especially enjoys projects linking regulatory and contractual requirements with actuarial methods.

Prior to joining AHP, Elaine consulted on all aspects of health and welfare benefits for plan sponsors ranging from small public entities to Fortune 100 companies. In addition to traditional consulting activities such as pricing, discount analysis, and claims analysis for self-funded employer plans, her expertise includes actuarial analysis of legislative and regulatory developments; ROI assessments; health risk migration and mapping; and complex model design and development. She was also the national measurement leader for the healthcare consulting practice of a large consulting firm. In addition, Elaine is a past Staff Fellow in health for the Society of Actuaries.

Elaine has presented at multiple industry conferences on a variety of topics. She is a Fellow of the Society of Actuaries, a Fellow of the Conference of Consulting Actuaries, and a Member of the American Academy of Actuaries. In addition to serving on multiple committees for these organizations, she was a member of the Actuarial Standards Board Health Committee's Task Force focused on developing an actuarial standard of practice for determining minimum value and actuarial value under the Affordable Care Act. She was the 2015-16 chairperson of the SOA Health Section Council (elected position), and is also a member of the SOA's Health Research Advisory Committee.

Elaine earned a Bachelor of Arts degree in Classics (with an emphasis on languages) from Washington University in St. Louis.

CURRENT STAFF BILLING RATES

# Elaine Corrough, FSA, FCA, MAAA

Axene Health Partners, LLC 503.272.6036 | elaine.corrough@axenehp.com

As of March 2018, hourly billing rates are as follows:

Elaine Corrough, FSA, FCA, MAAA - \$445 Project Lead and Lead Actuary

Other team members: Peer Review - \$405-\$545 Medical Director/Clinical Consultant - \$435-\$475 Senior Consulting Actuary - \$310-\$415 Consulting Actuary - \$295-\$345 Actuary - \$170-\$300