The Honorable Marsha J. Pechman

**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF WASHINGTON AT SEATTLE**

RYAN KARNOSKI, et al.,

*Plaintiffs*,

v.

DONALD J. TRUMP, in his official capacity as President of the United States, et al.,

*Defendants*.

Case No. 2-17-cv-01297-MJP

**DECLARATION OF GEORGE R. BROWN, M.D., D.F.A.P.A. IN SUPPORT OF PLAINTIFFS' OPPOSITION TO MOTION TO STAY PRELIMINARY INJUNCTION PENDING APPEAL**

I, George R. Brown, M.D., DFAPA, declare as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. My professional background and qualifications are set forth in my previous declaration, filed on January 25, 2018. *See* ECF No. 143. A copy of that declaration is attached as Exhibit A.

3. The purpose of this supplemental declaration is to offer my expert opinion on the "Department of Defense Report and Recommendations of Military Service By Transgender Persons," which I refer to in this declaration as the "Implementation Report." A copy of the Implementation Report is attached as Exhibit B.

4. I have knowledge of the matters stated in this declaration and have collected and cite to relevant literature concerning the issues that arise in this litigation.



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5. As noted in my previous declaration, I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour for work that does not involve depositions or court testimony (e.g., review of materials, emails, preparing reports); $500 per hour for depositions (there is a half-day fee for depositions); $600 per hour for in-court testimony; and $4,000 per full day spent out of the office for depositions and $4,800 per full day out of the office for trial testimony. Travels days necessary for work are billed at half the "work day" rate plus expenses. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

**THE IMPLEMENTATION REPORT REJECTS THE OVERWHELMING MEDICAL CONSENSUS REGARDING TRANSGENDER IDENTITY AND TREATMENT FOR GENDER DYSPHORIA**

6. Although the Implementation Report refers to a study conducted by a "Panel of Experts," the referenced panel does not appear to have included any experts in treating gender dysphoria or any medical experts at all. The Implementation Report indicates that the panel consulted with such experts, but the Implementation Report appears to have consistently disregarded what those experts say. *See* Ex. B, Implementation Report at 17.

7. As a result, the Implementation Report relies on notions of gender dysphoria and transgender identity that have no basis in fact, science, or medicine and that have been rejected by the mainstream medical community.

8. In my previous declaration, I explained that arguments that the mental health of transgender persons could justify prohibiting such individuals from serving in the military are wholly unfounded and unsupported in medical science. *See* Ex. A, Jan. 25, 2018 Brown Decl. ¶¶ 69–73. Being transgender—and living in accordance with one's gender identity—is not a mental defect or disorder. To the extent the misalignment between gender identity and assigned birth sex creates clinically significant distress (gender dysphoria), that distress is curable through appropriate medical care that allows the individual to live consistently with their gender identity.

9. Only a subset of transgender people have gender dysphoria. If a transgender person is able to live in accordance with their gender identity from an early age, they may never

develop gender dysphoria as an adult. If a transgender person develops gender dysphoria, they can receive appropriate transition-related care that resolves the clinically significant distress. For transgender people who have resolved symptoms of gender dysphoria, the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (2013) ("DSM-5") provides a separate "post-transition" diagnostic subtype to reflect that the gender dysphoria is in remission and that the person may only need a maintenance dose of cross-sex hormones.

10. The Implementation Report turns this understanding on its head by requiring transgender people to live in accordance with the sex assigned to them at birth.

11. The Implementation Report directly contradicts the medical consensus about the nature of gender dysphoria by treating every transgender person who lives according to the person's gender as having a disabling mental health condition even when the person no longer experiences gender dysphoria. The medical community has definitively rejected that view. In response to the Implementation Report, the American Psychological Association stated that it "is alarmed by the administration's misuse of psychological science to stigmatize transgender Americans and justify limiting their ability to serve in uniform and access medically necessary health care." *See* Ex. C, APA Statement Regarding Transgender Individuals Serving in Military. The American Medical Association released a similar statement reaffirming that "there is no medically valid reason—including a diagnosis of gender dysphoria—to exclude transgender individuals from military service" and expressing concern that the Implementation Report "mischaracterized and rejected the wide body of peer-reviewed research on the effectiveness of transgender medical care." *See* Ex. D, AMA Letter to Secretary James Mattis. The American Psychiatric Association also released a statement denouncing the Implementation Report and reiterating that "[t]ransgender people do not have a mental disorder; thus, they suffer no impairment whatsoever in their judgment or ability to work." *See* Ex. E, APA Statement.

12. Decades of research have demonstrated that attempting to treat gender dysphoria by forcing transgender people to live in accordance with their sex assigned at birth—to "convert"

them out of being transgender—is ineffective, unethical, and dangerous. The mainstream medical community overwhelmingly condemns this "conversion therapy."

13. The Implementation Report appears to dispute the consensus of the mainstream medical community that gender dysphoria is amenable to treatment through social and medical transition. As noted in my previous declaration, the American Medical Association, the Endocrine Society, the American Psychiatric Association, and the American Psychological Association all agree that medical treatment for gender dysphoria is medically necessary and effective. *See* American Medical Association, Resolution 122 (A-08) (2008); American Psychiatric Association, Position Statement on Discrimination Against Transgender & Gender Variant Individuals (2012); Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2017); American Psychological Association Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination (2009). *See* Ex. A, Jan. 25, 2018 Brown Decl. ¶ 33.

14. Sixty years of clinical experience and data have demonstrated the efficacy of treatment for the distress resulting from gender dysphoria (*see*, for example, the recently published multi-country, long-term follow up study: Tim C. van de Grift et al., *Effects of Medical Interventions on Gender Dysphoria and Body Image: A Follow-Up Study*, 79 Psychosomatic Med. 815 (Sept. 2017)). The Implementation Report asserts that this evidence is unreliable because there are no "double-blind" scientific studies regarding the efficacy of surgical care for gender dysphoria. But medical standards of care are not determined solely by double-blind studies, especially in the context of surgery. Double-blind studies with "sham" surgeries are often impossible or unethical to conduct.

15. If the military limited all medical care to surgical procedures supported by prospective, controlled, double-blind studies, then only a very few medical conditions would ever be treated. For example, one of the most common surgical procedures performed in the United States is tonsillectomy, with over 530,000 cases completed a year, using one of multiple, competing surgical techniques. However, a review of the evidence base for this very common

procedure, including when to apply it and the best surgical techniques to utilize, is not supported by "double blind" controlled studies in spite of the common use of this treatment over centuries. *See* Reginald F. Baugh et al., *Clinical Practice Guideline: Tonsillectomy in Children*, 144 Otolaryngology–Head and Neck Surgery S1 (2011)). Baugh and coauthors noted: "While there is a body of literature from which the guidelines were drawn, significant gaps remain in knowledge about preoperative, intraoperative, and postoperative care in children who undergo tonsillectomy." *Id.* at S22.

16. Similarly, appendicitis is one of the most common causes of acute abdominal pain in the United States. However, it remains unclear whether the common approach of appendectomy is superior to nonsurgical treatment with antibiotics in many patients. A recent Cochrane review was inconclusive: "We could not conclude whether antibiotic treatment is or is not inferior to appendectomy. Because of the low to moderate quality of the trials, appendectomy remains the standard treatment for acute appendicitis." *See* Ingrid M. H.A. Wilms et al., *Appendectomy Versus Antibiotic Treatment for Acute Appendicitis*, Cochrane Database of Systematic Rev. (2011).

17. By insisting that treatment for gender dysphoria—unlike treatment for virtually every other medical condition—be supported by "double blind" studies, the Implementation Report holds the robust medical consensus surrounding treatment for gender dysphoria to an impossible standard—and a standard that few if any medical conditions currently treated by DoD are required to meet.

18. The Implementation Report also mischaracterizes a recent decision by the U.S. Department of Health & Human Services Center for Medicare and Medicaid Services ("CMS"). *See* Ex. B, Implementation Report at 24–26. 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* Ex. F, NCD 140.3, Transsexual Surgery. The decision specifically noted that, regardless of whether the studies were randomized double-blind 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.

19. In the document referenced by the Implementation Report, CMS decided to continue covering surgery based on patients' individual needs and refrain from issuing national standards regarding how to determine medical necessity in individualized cases. *See* Ex. G, CMS Report. The Implementation Report incorrectly states that CMS "found insufficient scientific evidence to conclude that such surgeries improve health outcomes for persons with gender dysphoria." Ex. B, Implementation Report at 24 n.82. In fact, 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." Ex. G, CMS Report at 54 (emphasis added). In particular, CMS expressed concern that the Medicare population includes "older adults [who] may respond to health care treatments differently than younger adults." *Id.* at 57. 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." *Id.* 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.

## INDIVIDUALS WHO HAVE UNDERGONE GENDER TRANSITION ARE MEDICALLY FIT TO ENLIST

20. To justify prohibiting transgender people from serving even if they have resolved the distress associated with gender dysphoria, the Implementation Report attempts to use a

transgender person's history of gender dysphoria as a proxy for *other* mental health conditions such as anxiety, depression, and suicidal behavior.

21. Statistically, transgender people as a group are at greater risk of experiencing those conditions as a result of the stressors inherent in being prevented from transitioning or obtaining medical care throughout all, or much, of their lives. Some studies have documented that these health disparities can persist even after transition-related treatment because of the continuing effects of discrimination and the reality that gender dysphoria-specific treatments are not panaceas for all problems that a person may experience in their life (nor were these treatments designed to be). *See, e.g.*, Ex B, Implementation Report at 25 (citing Cecilia Dhejne et al., *Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PloS One, 6 (2011)). But there is no evidence to support the notion that every individual transgender person is at risk of developing one of these conditions, particularly for those who have been treated early in their lives, as opposed to those who never received treatment or who may have come to treatment much later in life, such as the transgender veterans studied by my research group and cited in the Implementation Report at 21 n.60 (citing George R. Brown & Kenneth T. Jones, *Mental Health and Medical Health Disparities in 5135 Transgender Veterans Receiving Healthcare in the Veterans Health Administration: A Case-Control Study*, 3 LGBT Health 128 (2016)).

22. Under the Open Service policy, all prospective military service members must undergo a rigorous examination to identify any pre-existing mental health diagnoses that would preclude enlistment. There is no reason to use a person's transgender status as a proxy for depression, anxiety, or suicidal ideation because the military directly screens for those conditions. Anyone with a history of suicidal behavior—whether transgender or not—is categorically barred from enlisting. *See* DoDI 6130.03, Enclosure 4 § 29(n).[1] Anyone with a

[1] On March 30, 2018, DoD issued new regulations, which will go into effect on May 6, 2018. The U.S. Military Entrance Processing Command has not yet issued guidance applying the new regulations.

history of anxiety or depression—whether transgender or not—is barred from enlisting unless, *inter alia*, they have been stable and without medical treatment for 24 consecutive months or 36 consecutive months respectively. *See id.* §§ 29(f), (p). As a result, any transgender individual who actually has one of those conditions is already screened out without a need for a categorical ban.

23. There is no medical basis for using a transgender person's history of gender dysphoria as a proxy for other medical conditions that the person does not actually have. This approach is akin to assuming non-transgender female applicants are, or should be considered, clinically depressed, as it is well known that depressive disorders are about twice as common in non-transgender females than in non-transgender males. *See* Paul R. Albert, *Why Is Depression More Prevalent in Women?* 40 J. of Psychiatry & Neuroscience 219–21 (2015)). If a transgender individual who seeks to enlist in the military has already transitioned, no longer experiences gender dysphoria, and has been screened for other mental health conditions (including depression, anxiety, and suicidal ideation) there is no reason to conclude that individual is at elevated risk of developing one of these comorbidities in the future.

24. The Implementation Report distorts my own work by citing a recent study in which I documented that some transgender veterans who have received treatment after years of living in the shadows continue to have health disparities even after their gender dysphoria is resolved through treatment. *See* Ex. B, Implementation Report at 21 n.60. The veterans in my study were untreated veterans for a long period of time and survived—but did not thrive—while living an inauthentic life in the shadows while serving on active duty. Many of the transgender veterans included in this large study had never received treatment for gender dysphoria at any time in their lives. Clearly, the population group of transgender individuals in that study is not comparable to the population group of people who have already received medical care, resolved their gender dysphoria, and are coming to the military openly stating they are transgender.

25. The Implementation Report also states that data regarding existing service members has called into question assumptions about the mental health of transgender service

members. *See* Ex. B, Implementation Report 21. I have reviewed USDOE 2633-2664, which appears to be a slide-show presentation of the data on which the Implementation Report relies. *See* Exhibit H, USDOE 2633-2664 (also filed as Docket No. 139-27 in the related matter of *Stone, et al. v. Trump, et al.*, No. 17-CV-02459-MJG (D. Md.)). It should be noted that my career as an academic research psychiatrist, including conducting extensive research within the Department of Defense and the Department of Veterans Affairs for many years on a full time basis, enables me to critically assess research design, methodology, and outcomes.

26. As an initial matter, none of the data relates to service members who have completed transition and are enlisting for the first time—the group of people who meet the Open Service standards and began the process of enlisting on or after January 1, 2018. The data are exclusively from service members who were diagnosed with gender dysphoria while already serving, in some cases well before any guidance was provided by DoD for treatment or transition. Again, this means that the data reflects a group of people who were serving in the shadows potentially for years before they were allowed to serve openly.

27. Even with respect to these service members, the data is fundamentally flawed and presented in a grossly misleading manner. The study period for the data was for the 22-month period from October 1, 2015 to July 26, 2017. But Secretary Carter's Open Service Directive was not issued until June 30, 2016, and the military did not issue force-wide treatment protocols for gender dysphoria until October 1, 2016. As a result, for 12 out of the 22 months included in the study, the service members were, with few exceptions, not serving openly and not receiving DoD-sanctioned treatments for gender dysphoria.

28. If the purpose of the study is to draw conclusions about the health of transgender service members under the Open Service policy, it is fundamentally illegitimate to include data from before that policy went into effect and before those service members were allowed to receive health care under DoD guidelines to treat their gender dysphoria.

29. For example, the Implementation Report cites data from the study for the proposition that transgender service members had an average of 28.1 mental health encounters

over a 22-month period. *See* Ex. B, Implementation Report at 24; Ex. H, USDOE 2633-2664 at 8. But it is impossible to determine whether these mental health encounters occurred before or after the Open Service policy went into effect. If the utilization rate dropped once service members started receiving care for gender dysphoria, then the data would actually support the efficacy of the Open Service policy.

30. The Implementation Report also ignores the critical fact that service members were *required* to meet with mental health providers numerous times to document their gender dysphoria as a precondition for receiving health care for gender dysphoria, and for continued access to cross-sex hormones. It is not stated how many of these visits were mandated/required, as opposed to visits voluntarily requested by service members for mental health care. As a result, without more specific data, there is no reason to conclude that mental health visits by transgender service members who are initiating transition-related care are a sign of co-morbid mental health conditions. The report is quite misleading is this regard, as it implies that all mental health visits by transgender service members were initiated for the treatment of mental illnesses, when this is far from the truth.

31. Similarly, the Implementation Report cites data from the study for the proposition that service members with gender dysphoria are "eight times more likely to attempt suicide than Service members as a whole." Ex. B, Implementation Report at 12. In fact, the underlying data refers to "suicidal ideation," not actual suicide attempts. Ex. H, USDOE 2633-2664 at 9. Moreover, with respect to suicidal ideation, the data does not reveal whether the suicidal ideation was reported before or after the service member was allowed to serve openly and receive treatment. Given the fundamental flaws with the study methodology and the low number of observed events, the data presented on this, and other, mental health questions are not interpretable in any meaningful way.

32. In short, transgender individuals should be screened and evaluated for mental health conditions the same way every other person is screened and evaluated. There is no

medical basis for using a transgender individual's history of gender dysphoria as a proxy for other mental health conditions that they do not have.

## TRANSGENDER SERVICE MEMBERS WHO HAVE TRANSITIONED ARE PHYSICALLY FIT TO ENLIST AND DEPLOY

33. As I explained in my previous declaration, the argument that cross-sex hormone treatment should be a bar to service for transgender individuals is not supported by medical science or current military medical protocols. Experts in the endocrine treatment of transgender people have previously advised military medical providers that cross-sex hormone treatments can be accomplished without difficulty, both before accession and after service has begun. *See* WPATH Timeline Guide for United States Armed Service Members Going Through Transgender Hormonal or Surgical Transition (Jan. 2017), https://www.wpath.org/newsroom/policies (attached as Ex. I).

34. The military allows people with a history of other medical conditions to enlist even when the condition is currently being managed by medication. Individuals with abnormal menstruation, dysmenorrhea, and endometriosis may enlist if their conditions are adequately managed through hormone medication. *See* DoDI 6130.03, Enclosure 4 §§ 14(a), (d), (e).[2] Individuals with Gastro-Esophageal Reflux Disease or high cholesterol may enlist if they are taking medication with no relevant side effects. *Id.* §§ 13(a), 25(i).

35. The Implementation Report asserts that transgender service members receiving cross-sex hormone therapy would risk having their treatment disrupted if they are deployed. But the same concerns about interruptions apply to every service member who is deployed while taking medication. These concerns have not been a barrier to deployment for service members who require hormones for other medical conditions or who require medications for other mental health conditions that allow for deployment.

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[2] As noted previously noted, DoD issued new regulations on March 30, 2018, which will go into effect on May 6, 2018. *See supra* n.1. The U.S. Military Entrance Processing Command has not yet issued guidance applying the new regulations.



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36. Military policy also allows service members to take a range of medications, including hormones, while deployed in combat settings. Access to medication is predictable, as "[t]he Military Health Service maintains a sophisticated and effective system for distributing prescription medications to deployed service members worldwide." *See* M. Joycelyn Elders et al., *Medical Aspects of Transgender Military Service*, 41 Armed Forces & Soc'y 199, 207 (Aug. 2014) (the "Elders Commission Report").

37. Hormone therapy is neither too risky nor too complicated for military medical personnel to administer and monitor. The risks associated with use of cross-sex hormone therapy to treat gender dysphoria are low and not any higher than for the hormones that many non-transgender active duty military personnel currently take. The medications do not have to be refrigerated, and alternatives to injectables are readily available, further simplifying treatment plans. Clinical monitoring for risks and effects is not complicated and, with training and/or access to consultations, can be performed by a variety of medical personnel in the DoD, just as is the case in the VHA. This is the military services' current practice in support of the limited medical needs of their transgender troops in CONUS (Continental United States) and in deployment stations worldwide. Guidance on this issue was provided in January 2017 to military medical providers who care for transgender service members and shows that stable, transitioned troops require only yearly laboratory monitoring for cross-sex hormone treatment (which is consistent with the yearly, routine laboratory health screenings that *all* active duty troops receive). *See* Ex. I, WPATH Timeline Guide.

38. Transgender service members—including service members who receive hormone medication—are just as capable of deploying as service members who are not transgender. DoD rules expressly permit deployment, without need for a waiver, for a number of medical conditions that present a much more significant degree of risk in a harsh environment than simply being transgender. For example, hypertension is not disqualifying if controlled by medication, despite the inherent risks in becoming dehydrated in desert deployment situations. Heart attacks experienced while on active duty or treatment of active duty troops with coronary

artery bypass grafts are also not disqualifying, if they occur more than a year preceding deployment. These are very serious, life-threatening medical conditions with a high rate of recurrence, yet these service members with cardiovascular disease are nonetheless allowed to stay on active duty and deploy under prescribed conditions.

39. Under the Department of Defense's generally applicable policies, service members may deploy with certain psychiatric conditions, if they demonstrate stability under treatment for at least three months. *See* DoDI 6490.07, Enclosure 3 § h(2); Dep't of Defense, Clinical Practice Guidance for Deployment-Limiting Mental Disorders and Psychotropic Medications (2013). Army regulations specifically provide that "[a] psychiatric condition controlled by medication should not automatically lead to non-deployment." *See* AR 40-501 § 5-14(8)(a).

40. Instead of discussing these medical conditions, the Implementation Report compares cross-sex hormone therapy for gender dysphoria with other medical conditions that are plainly not comparable. For example, the Implementation Report states that "[a]ny DSM-5 psychiatric disorder with residual symptoms or medication side effects, which impair social or occupational performance, require a waiver for the Service member to deploy." Ex. B, Implementation Report at 34. As I previously explained, gender dysphoria is a treatable and curable condition. With medically appropriate care, it is possible for transgender service members to resolve the clinically significant gender dysphoria without any residual symptoms or impairment. Comparisons made to schizophrenia and bipolar disorder in the Implementation Report are inappropriate, as these two conditions constitute serious mental illnesses for which treatments are often ineffective and for which the notion of "cure" is nonsensical.

## SERVICE MEMBERS WHO TRANSITION WHILE IN SERVICE CAN MEET THE SAME RETENTION STANDARDS THAT APPLY TO NON-TRANSGENDER SERVICE MEMBERS

41. As I explained in my previous declaration, service members who are diagnosed with gender dysphoria after already enlisting can transition while in service and still meet the same retention standards that apply to non-transgender service members. The military has

generally applicable standards for determining whether a service member may continue to serve despite periods of limited nondeployability. If a transgender service member's limited period of nondeployability complies with those generally applicable standards, there is no reason why the service member should be automatically discharged simply because they were receiving surgery for gender dysphoria as opposed to a different medical condition. A determination of nondeployability must be based on the status of the individual and not on arbitrary, non-evidence based determinations. There is some evidence that the latter is occurring, based on the widely disparate between-service data reported on days of limited duty for service members receiving treatment for gender dysphoria as reported by the various services. *See* Ex. H, USDOE 2633-2664 at 17. This DoD data strongly suggests that non-medical factors are playing an outsized role in determination of days spent in other than full-duty capacities for transgender service members on service-level treatment plans. These data are then being used by DoD in a misleading way to state that transitioning troops are missing from full duty for unacceptably long periods of time.

42. Although the Implementation Report states that one commander predicted that transgender service members beginning a course of hormone therapy will be nondeployable for as long as two-and-a-half years, the Implementation Report does not cite any data to support that assertion. Ex. B, Implementation Report at 33–34. To the contrary, the presentation of the data states that service members initiating hormone therapy were nondeployable for 3–6 months in the Navy and for an average of 5–6 months in the Army and Air Force. Ex. H, USDOE 2633-2664 at 17. There is no medical basis for the Implementation Reports suggestion that cross-sex hormone therapy could render a transgender service member nondeployable for a full twelve months. Ex. B, Implementation Report at 23. In fact, expert guidance on this very issue was provided to military medical providers by WPATH in January 2017, as previously noted.

43. There is also no basis to presume that surgical care for gender dysphoria will render transgender service members nondeployable for extended periods of time. The recovery

time for non-genital surgeries, which are the most common procedures performed, is only 2–8 weeks. Ex. H, USDOE 2633-2664 at 19.

44. Moreover, transgender service members can schedule medical procedures to ensure that they do not interfere with deployment. This approach is routinely done for other medically necessary procedures, such as orthopedic surgeries that allow for flexibility in the timing of the surgery. As the Implementation Report acknowledges, "[t]his conclusion was echoed by some experts in endocrinology who found no harm in stopping or adjusting hormone therapy treatment to accommodate deployment during the first year of hormone use." Ex. B, Implementation Report at 34.

45. To be sure, there may be some transgender service members whose individualized medical needs make it impossible to transition while satisfying the military's generally applicable standards for deployment and retention. But those determinations can and should be made on a case-by-case basis depending on the individual's fitness to serve, as is done with other treatable conditions. There is no medical basis to conclude that all, or even most, service members undergoing treatment for gender dysphoria are categorically unfit to serve.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 2, 2018.

George R. Brown, M.D., DFAPA



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**CERTIFICATE OF SERVICE**

The undersigned certifies under penalty of perjury under the laws of the United States of America and the laws of the State of Washington that all participants in the case are registered CM/ECF users and that service of the foregoing documents will be accomplished by the CM/ECF system on May 14, 2018.

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# Exhibit A

The Honorable Marsha J. Pechman

**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF WASHINGTON AT SEATTLE**

RYAN KARNOSKI, et al.,

*Plaintiffs*,

v.

DONALD J. TRUMP, in his official capacity as President of the United States, et al.,

*Defendants*.

Case No. 2-17-cv-01297-MJP

**DECLARATION OF GEORGE R. BROWN, M.D., D.F.A.P.A. IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

I, George R. Brown, M.D., D.F.A.P.A., declare as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. The purpose of this declaration is to offer my expert opinion on: (1) the medical condition known as gender dysphoria; (2) the prevailing treatment protocols for gender dysphoria; (3) the United States military's pre-2016 ban on the enlistment and retention of men and women who are transgender; (4) the subsequent lifting of that ban; and (5) the unfounded medical justifications for banning individuals who are transgender from serving in the United States military.

3. I have knowledge of the matters stated in this declaration and have collected and cite to relevant literature concerning the issues that arise in this litigation.



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**PROFESSIONAL BACKGROUND**

4. I am a Professor of Psychiatry and the Associate Chairman for Veterans Affairs in the Department of Psychiatry at the East Tennessee State University, Quillen College of Medicine. My responsibilities include advising the Chairman; contributing to the administrative, teaching, and research missions of the Department of Psychiatry; consulting on clinical cases at the University and at Mountain Home Veterans Health Administration ("VHA") Medical Center, where I also hold an appointment; and acting as a liaison between the VHA Medical Center and the East Tennessee State University Department of Psychiatry. The majority of my work involves researching, teaching, and consulting about health care in military and civilian transgender populations.

5. I also hold a teaching appointment related to my expertise with health care for transgender individuals and research at the University of North Texas Health Services Center ("UNTHSC"). My responsibilities include teaching and consultation with UNTHSC and the Federal Bureau of Prisons staff regarding health issues for transgender individuals.

6. In 1979, I graduated *Summa Cum Laude* with a double major in biology and geology from the University of Rochester in Rochester, New York. I earned my Doctor of Medicine degree with Honors from the University of Rochester School of Medicine in 1983. From 1983-1984, I served as an intern at the United States Air Force Medical Center at Wright-Patterson Air Force Base in Ohio. From 1984-1987, I worked in and completed the United States Air Force Integrated Residency Program in Psychiatry at Wright State University and Wright-Patterson Air Force Base in Dayton, Ohio. A true and correct copy of my Curriculum Vitae is attached hereto as Exhibit A.

7. I first began seeing patients in 1983. I have been a practicing psychiatrist since 1987, when I completed my residency. From 1987-1991, I served as one of the few U.S. Air Force teaching psychiatrists. In this capacity, I performed more than 200 military disability evaluations and served as an officer on medical evaluation boards at the largest hospital in the Air Force.

8. During the last 33 years, I have evaluated, treated, and/or conducted research in person with 600-1,000 individuals with gender disorders, and during the course of research, conducted chart reviews of more than 5,100 additional patients with gender dysphoria. The vast majority of the patients I have worked with have been active duty military personnel or veterans.

9. For three decades, my research and clinical practice has included extensive study of the health care for transgender individuals, including three of the largest studies focused on the health care needs of transgender service members and veterans. Throughout that time, I have done research with, taught on, and published peer-reviewed professional publications specifically addressing the needs of transgender military service members. *See* Brown Ex. A (CV).

10. I have authored or coauthored 40 papers in peer-reviewed journals and 19 book chapters on topics related to gender dysphoria and health care for transgender individuals, including the chapter concerning gender dysphoria in Treatments of Psychiatric Disorders (3d ed. 2001), a definitive medical text published by the American Psychiatric Association.

11. In 2014, I coauthored a study along with former Surgeon General Joycelyn Elders and other military health experts, including a retired General and a retired Admiral. The study was entitled "Medical Aspects of Transgender Military Service." *See* Elders J, Brown GR, Coleman E, Kolditz TA, *Medical Aspects of Transgender Military Service*. ARMED FORCES AND SOCIETY, 41(2): 199-220, 2015; published online ahead of print, DOI: 10.1177/0095327X1454 5625 (Aug. 2014) (the "Elders Commission Report"). The military peer-reviewed journal, Armed Forces and Society, published the Elders Commission Report. A true and correct copy of that report is attached hereto as Exhibit B.

12. I have served for more than 15 years on the Board of Directors of the World Professional Association for Transgender Health ("WPATH"), the leading international organization focused on health care for transgender individuals. WPATH has more than 2,000 members throughout the world and is comprised of physicians, psychiatrists, psychologists, social workers, surgeons, and other health professionals who specialize in the diagnosis and treatment of gender dysphoria.

13. I was a member of the WPATH committee that authored and published in 2011 the current version of the WPATH Standards of Care ("SoC") (Version 7). The SoC are the operative collection of evidence-based treatment protocols for addressing the health care needs of transgender individuals. I also serve as a chapter Co-Lead on the WPATH committee that will author and publish the next edition of the Standards of Care (Version 8).

14. Without interruption, I have been an active member of WPATH since 1987. Over the past three decades, I have frequently presented original research work on topics relating to gender dysphoria and the clinical treatment of transgender people at the national and international levels.

15. I have testified or otherwise served as an expert on the health issues of transgender individuals in numerous cases heard by several federal district and tax courts. A true and correct list of federal court cases in which I have served as an expert is contained in the "Forensic Psychiatry Activities" section of my Curriculum Vitae, which is attached hereto as Exhibit A.

16. I have conducted and continue to provide trainings on transgender health issues for the VHA as well as throughout the Department of Defense ("DoD"). After the DoD announced the policy that allowed for transgender individuals to serve openly in the Armed Forces in 2016, I conducted the initial two large military trainings on the provision of health care to transgender service members. The first training in Spring 2016 was for the Marine Corps. The second training in Fall 2016 was for a tri-service (Army, Navy, and Air Force) meeting of several hundred active duty military clinicians, commanders, and Flag officers.

17. Since the issuance of DoD Instruction ("DoDI") 1300.28 in October 2016, I have led trainings for a national group of military examiners (MEPCOM) in San Antonio, Texas (May, 2017) and for Army clinicians at Fort Knox, Kentucky (July, 2017). Among other things, DoDI 1300.28 implemented the policies and procedures in Directive-type

Memorandum 16-005, established a construct by which transgender service members may transition gender while serving, and required certain trainings for the military.

18. I have been centrally involved in the development, writing, and review of all national directives in the VHA relating to the provision of health care for transgender veterans. I also coauthored the national formulary that lists the medications provided by the VHA for the treatment of gender dysphoria in veterans. Finally, I regularly consult with VHA leadership regarding the training of VHA clinicians on transgender clinical care of veterans nationally.

**GENDER DYSPHORIA**

19. The term "transgender" is used to describe someone who experiences any significant degree of misalignment between their gender identity and their assigned sex at birth.

20. Gender identity describes a person's internalized, inherent sense of who they are as a particular gender (*i.e.*, male or female). For most people, their gender identity is consistent with their assigned birth sex. Most individuals assigned female at birth grow up, develop, and manifest a gender identity typically associated with girls and women. Most individuals assigned male at birth grow up, develop, and manifest a gender identity typically associated with boys and men. For transgender people, that is not the case. Transgender women are individuals assigned male at birth who have a persistent female identity. Transgender men are individuals assigned female at birth who have a persistent male identity.

21. Experts agree that gender identity has a biological component, meaning that each person's gender identity (transgender and non-transgender individuals alike) is the result of biological factors, and not just social, cultural, and behavioral ones.

22. Regardless of the precise origins of a person's gender identity, there is a medical consensus that gender identity is deep-seated, set early in life, and impervious to external influences.

23. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (2013) ("DSM-5") is the current, authoritative handbook on the diagnosis of

mental disorders. Mental health professionals in the United States, Canada, and other countries throughout the world rely upon the DSM-5. The content of the DSM-5 reflects a science-based, peer-reviewed process by experts in the field.

24. Being transgender is not a mental disorder. *See* DSM-5. Men and women who are transgender have no impairment in judgment, stability, reliability, or general social or vocational capabilities solely because of their transgender status.

25. Gender dysphoria is the diagnostic term in the DSM-5 for the condition that can manifest when a person suffers from clinically significant distress or impairment associated with an incongruence or mismatch between a person's gender identity and their assigned sex at birth.

26. The clinically significant emotional distress experienced as a result of the incongruence of one's gender with their assigned sex and the physiological developments associated with that sex is the hallmark symptom associated with gender dysphoria.

27. Only the *subset* of transgender people who have clinically significant distress or impairment qualify for a diagnosis of gender dysphoria.

28. Individuals with gender dysphoria may live for a significant period of their lives in denial of these symptoms. Some transgender people may not initially understand the emotions associated with gender dysphoria and may not have the language or resources for their distress to find support until well into adulthood.

29. Particularly as societal acceptance towards transgender individuals grows and there are more examples of high-functioning, successful transgender individuals represented in media and public life, younger people in increasing numbers have access to medical and mental health resources that help them understand their experience and allow them to obtain medical support at an earlier age and resolve the clinical distress associated with gender dysphoria.

**TREATMENT FOR GENDER DYSPHORIA**

30. Gender dysphoria is a condition that is amenable to treatment. *See* WPATH SoC (Version 7); Elders Commission Report at 9-16; Agnes Gereben Schaefer et al., *Assessing the*

*Implications of Allowing Transgender Personnel to Serve Openly*, RAND Corporation (2016) at 7 ("RAND Report") (a true and correct copy of the report is attached hereto as Exhibit C).

31. With appropriate treatment, individuals with a gender dysphoria diagnosis can be fully cured of *all* symptoms.

32. Treatment of gender dysphoria has well-established community standards and is highly effective.

33. The American Medical Association ("AMA"), the Endocrine Society, the American Psychiatric Association, and the American Psychological Association all agree that medical treatment for gender dysphoria is medically necessary and effective. *See* American Medical Association (2008), Resolution 122 (A-08); American Psychiatric Association, Position Statement on Discrimination Against Transgender & Gender Variant Individuals (2012); Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2009); American Psychological Association Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination (2009). Additional organizations that have made similar statements include the American Academy of Child & Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Nursing, American College of Nurse Midwives, American College of Obstetrics and Gynecology, American College of Physicians, American Medical Student Association, American Nurses Association, American Public Health Association, National Association of Social Workers, and National Commission on Correctional Health Care.

34. The protocol for the treatment of gender dysphoria is set forth in the WPATH SoC and in the Endocrine Society Guidelines.[1] First developed in 1979 and currently in their seventh version, the WPATH SoC set forth the authoritative protocol for the evaluation and treatment of gender dysphoria. This approach is followed by clinicians caring for individuals with gender dysphoria, including veterans in the VHA. As stated above, I was a member of the

[1] *Available at* https://academic.oup.com/jcem/article/102/11/3869/4157558 .

WPATH committee that authored the SoC (Version 7), published in 2011. A true and correct copy of that document is attached hereto as Exhibit D.

35. Depending on the needs of the individual, a treatment plan for persons diagnosed with gender dysphoria may involve components that are psychotherapeutic (*i.e.*, counseling as well as social role transition – living in accordance with one's gender in name, dress, pronoun use); pharmacological (*i.e.*, hormone therapy); and surgical (*i.e.*, gender confirmation surgeries, like hysterectomy for those transitioning to the male gender and orchiectomy for those transitioning to the female gender). Under each patient's treatment plan, the goal is to enable the individual to live all aspects of one's life consistent with his or her gender identity, thereby eliminating the distress associated with the incongruence.

36. There is a wide range in the treatments sought by those suffering from gender dysphoria. For example, some patients need both hormone therapy and surgical intervention, while others need just one or neither. Generally, medical intervention is aimed at bringing a person's body into some degree of conformity with their gender identity.

37. As outlined further below, treatment protocols for gender dysphoria are comparable to those for other mental health and medical conditions, including those regularly treated within the United States military. *See* RAND Report at 8-9; Elders Commission Report at 13 ("the military consistently retains non-transgender men and women who have conditions that may require hormone replacement").

## PRE-2016 MILITARY POLICY

38. Prior to 2016, military policy treated transgender individuals with gender dysphoria differently than people with other curable conditions.

***Former Enlistment Policy***

39. DODI 6130.03 established the medical standards for accession/entry into military service. Enclosure 4 of the enlistment instruction contains an extensive list of physical and mental conditions that disqualify a person from enlisting in the military. For instance, persons with autism, schizophrenia, or delusional disorders (or a history of treatment for these

conditions) are excluded from enlistment. Prior to 2016, that list also contained "change of sex" and "transsexualism," which were outdated references to transgender individuals and individuals with gender dysphoria. *See* Elders Commission Report at 7.

40. The enlistment policy allows for the possibility of waivers for a variety of medical conditions. The instruction, however, specifies that entry waivers will not be granted for conditions that would disqualify an individual from the possibility of retention. As discussed further below, because certain conditions related to being transgender ("change of sex") were formerly grounds for discharge from the military, men and women who are transgender could not obtain medical waivers to enter the military. *Id.* at 7-8.

41. Under military instructions, the general purpose of disqualifying applicants based on certain physical and mental conditions is to ensure that service members are: (1) free of contagious diseases that endanger others, (2) free of conditions or defects that would result in excessive duty-time lost and would ultimately be likely to result in separation, (3) able to perform without aggravating existing conditions, and (4) capable of completing training and adapting to military life. *Id.* at 7.

42. Because gender dysphoria, as described above, is a treatable and curable condition, unlike other excluded conditions, its inclusion on the list of disqualifying conditions was inappropriate. Individuals with gender dysphoria (or under the language at the time – those who had a "change of sex") were disqualified from joining the military, despite having a completely treatable, or already treated, condition.

43. The enlistment policy treated transgender individuals in an inconsistent manner compared with how the military addressed persons with other curable medical conditions. The result of this inconsistency was that transgender personnel were excluded or singled out for disqualification from enlistment, even when they were mentally and physically healthy.

44. For example, persons with certain medical conditions, such as Attention Deficit Hyperactivity Disorder ("ADHD") and simple phobias, could be admitted when their conditions could be managed without imposing undue burdens on others. Individuals with ADHD are

prohibited from enlisting unless they meet five criteria, including documenting that they maintained a 2.0 grade point average after the age of 14. Similarly, individuals with simple phobias are banned from enlisting, unless they meet three criteria including documenting that they have not required medication for the past 24 continuous months.

45. In short, even though the DoD generally allowed those with manageable conditions to enlist, the former regulation barred transgender service without regard to the condition's treatability and the person's ability to serve.

***Former Separation Policy***

46. The medical standards for retiring or separating service members who have already enlisted are more accommodating and flexible than the standards for new enlistments.

47. Until recently, the medical standards for separation were set forth in DoDI 1332.38. On August 5, 2014, the DoD replaced DoDI 1332.38 with DoDI 1332.18, which permits greater flexibility for the service branches to provide detailed medical standards.

48. The separation instructions divide potentially disqualifying medical conditions into two different tracks. Service members with "medical conditions" are placed into the medical system for disability evaluation. Under this evaluation system, a medical evaluation board ("MEB") conducts an individualized inquiry to determine whether a particular medical condition renders a service member medically unfit for service. If a service member is determined to be medically unfit, the service member may receive benefits for medical separation or retirement, or may be placed on the Temporary Duty Retirement List with periodic reevaluations for fitness to return to duty. While in the U.S. Air Force, I served as an officer on at least two hundred of these MEBs.

49. Under the separation instruction, service members with genitourinary conditions, endocrine system conditions, and many mental health conditions are all evaluated through the medical disability system. *See* DoDI 1332.38 §§ E4.8, E4.11, E4.13; AR 40-501 §§ 2-8, 3-11, 3-17, 3-18, 3-31, 3-32; SECNAVIST 180.50_4E §§ 8008, 8011, 8013; U.S. Airforce Medical Standards Directory §§ J, M, Q.

50. By contrast, under the separation instructions, a small number of medical and psychiatric conditions are not evaluated through the medical evaluation process. Instead, these conditions are deemed to render service members "administratively unfit." Service members with "administratively unfit" conditions do not have the opportunity to demonstrate medical fitness for duty or eligibility for disability compensation.

51. Under DoDI 1332.38, the "administratively unfit" conditions were listed in Enclosure 5 of the instruction. Since August 5, 2014, when DoDI 1332.18 replaced 1332.38, the "administratively unfit" conditions are determined by the service branches, as set forth in AR 40-501 § 3-35; SECNAVIST § 2016; and AFI36-3208 § 5.11.

52. Enclosure 5 of DoDI 1332.38 included, among other conditions, bed-wetting, sleepwalking, learning disorders, stuttering, motion sickness, personality disorders, mental retardation, obesity, shaving infections, certain allergies, and repeated infections of venereal disease. It also included "Homosexuality" and "Sexual Gender and Identity Disorders, including Sexual Dysfunctions and Paraphilias." *See* Elders Commission Report at 8.

53. Similarly, the "administratively unfit" conditions in the service branches included "psychosexual conditions, transsexual, gender identity disorder to include major abnormalities or defects of the genitalia such as change of sex or a current attempt to change sex," AR 40-501 § 3-35(a); "Sexual Gender and Identity Disorders and Paraphilias," SECNAVIST § 2016(i)(7); and "Transsexualism or Gender Identity Disorder of Adolescence or Adulthood, Nontranssexual Type (GIDAANT)," AFI36-3208 § 5.11.9.5. The service branches retained these bars to service by transgender individuals after DoDI 1332.18 replaced DoDI 1332.38.

54. DoDI 1332.14 controlled administrative separations for enlisted persons. Under the instruction, a service member may be separated for the convenience of the government and at the discretion of a commander for "other designated physical or mental conditions." Before 2016, this particular separation category included "sexual gender and identity disorders." *Id.*

55. Because service members with gender dysphoria were deemed to be "administratively unfit," they were not evaluated by MEBs and had no opportunity to

demonstrate that their condition did not affect their fitness for duty. They were disqualified from remaining in the military despite having a completely treatable condition.

56. This was inconsistent with the treatment of persons with other curable medical conditions, who are given the opportunity to demonstrate medical fitness for duty or eligibility for disability compensation. For example, mood and anxiety disorders are not automatically disqualifying for retention in military service. Service members can receive medical treatment and obtain relief in accordance with best medical practices. Mood and anxiety disorders result in separation only if they significantly interfere with duty performance and remain resistant to treatment. In contrast, transgender individuals were categorically disqualified from further service without consideration of their clinical symptoms and any impact on their service.

57. The result of this inconsistency was that transgender personnel were singled out for separation, even when they were mentally and physically healthy, solely because they were transgender.

**OPEN SERVICE DIRECTIVE**

58. The DoD lifted the ban on open service by transgender military personnel following a June 30, 2016 announcement made by then-Secretary of Defense Ash Carter ("Open Service Directive").

59. Based on my extensive research and clinical experiences treating transgender individuals over decades, the Open Service Directive is consistent with medical science.

60. The Open Service Directive also aligns with the conclusions reached by the RAND National Defense Research Institute, the Elders Commission, and the AMA.

61. The RAND Report concluded that the military already provides health care comparable to the services needed to treat transgender individuals: "Both psychotherapy and hormone therapies are available and regularly provided through the military's direct care system, though providers would need some additional continuing education to develop clinical and cultural competence for the proper care of transgender patients. Surgical procedures quite similar

to those used for gender transition are already performed within the [Medical Health System] for other clinical indications." *See* RAND Report at 8.

62. The earlier Elders Commission, on which I served, concluded that "[t]ransgender medical care should be managed in terms of the same standards that apply to all medical care, and there is no medical reason to presume transgender individuals are unfit for duty. Their medical care is no more specialized or difficult than other sophisticated medical care the military system routinely provides." *See* Elders Commission Report at 4.

63. Additionally, in a unanimous resolution published on April 29, 2015, the AMA announced its support for lifting the ban on open transgender service in the military, based on the AMA's conclusion that there is no grounding in medical science for such a ban.[2]

***Enlistment Policy for Transgender Individuals***

64. The Open Service Directive's enlistment procedures are carefully designed to ensure that transgender individuals who enlist in the military do not have any medical needs that would make them medically unfit to serve or interfere with their deployment.

65. Under these standards, transgender individuals whose condition was stable for 18 months at the time of enlistment would be eligible to enlist, assuming a licensed medical provider certified that they met certain conditions. DTM-16-005 Memorandum and Attachment (June 30, 2016). For example, those seeking to enlist who had been treated with any counseling, cross-sex hormone therapy, or gender confirmation surgeries must have medical confirmation that they have been stable for the last 18 months. Similarly, those applicants taking maintenance cross-sex hormones as follow-up to their transition would also need certification that they had been stable on such hormones for 18 months.

***Retention Policy for Transgender Individuals***

66. Under the Open Service Directive, gender dysphoria is treated like other curable medical conditions. Individuals with gender dysphoria receive medically necessary care. Service

[2] *Available at* http://archive.palmcenter.org/files/A-15%20Resoultion%20011.pdf.

members who are transgender are subject to the same standards of medical and physical fitness as any other service member.[3]

67. The Open Service Directive also permits commanders to have substantial say in the timing of any future transition-related treatment for transgender service members. The needs of the military can also take precedence over an individual's need to transition, if the timing of that request interferes with critical military deployments or trainings.

## MEDICAL JUSTIFICATIONS FOR BANNING TRANSGENDER SERVICE MEMBERS ARE UNFOUNDED

68. Based upon: (1) my extensive research and experience treating transgender people, most of whom have served this country in uniform, (2) my involvement reviewing the medical implications of a ban on transgender service members, and (3) my participation in implementing the Open Service Directive allowing transgender individuals to serve openly, it is my opinion that any medical objections to open service by transgender service members are wholly unsubstantiated and inconsistent with medical science and the ways in which other medical conditions are successfully addressed within the military.

***Mental Health***

69. Arguments based on the mental health of transgender persons to justify prohibiting individuals from serving in the military are wholly unfounded and unsupported in medical science. Being transgender is not a mental defect or disorder. Scientists have long abandoned psychopathological understandings of transgender identity, and do not classify the incongruity between a person's gender identity and assigned sex at birth as a mental illness. To the extent the misalignment between gender identity and assigned birth sex creates clinically significant distress (gender dysphoria), that distress is curable through appropriate medical care.

70. Sixty years of clinical experience have demonstrated the efficacy of treatment of the distress resulting from gender dysphoria. *See* Elders Commission Report at 10 ("a significant

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[3] *Available at* https://www.defense.gov/Portals/1/features/2016/0616_policy/Guidance_for_Treatment_of_Gender_Dysphoria_Memo_FINAL_SIGNED.pdf.

body of evidence shows that treatment can alleviate symptoms among those who do experience distress"). Moreover, "empirical data suggest that many non-transgender service members continue to serve despite psychological conditions that may not be as amenable to treatment as gender dysphoria." *Id.* at 11.

71. The availability of a cure distinguishes gender dysphoria from other mental health conditions, such as autism, bipolar disorder, or schizophrenia, for which there are no cures. There is no reason to single out transgender personnel for separation, limitation of service, or bars to enlistment, based only on the diagnosis or treatment of gender dysphoria. Determinations can and should be made instead on a case-by-case basis depending on the individual's fitness to serve, as is done with other treatable conditions.

72. The military already provides mental health evaluation services and counseling, which is the first component of treatment for gender dysphoria. *See* RAND Report at 8.

73. Concerns about suicide and substance abuse rates among transgender individuals are also unfounded when it comes to military policy. At enlistment, all prospective military service members undergo a rigorous examination to identify any pre-existing mental health diagnoses that would preclude enlistment. Once someone is serving in the military, they must undergo an annual mental and physical health screen, which includes a drug screen. If such a screening indicates that a person suffers from a mental illness or substance abuse, then that would be the potential impediment to retention in the military. The mere fact that a person is transgender, however, does not mean that person has a mental health or substance abuse problem or is suicidal.

***Hormone Treatment***

74. The argument that cross-sex hormone treatment should be a bar to service for transgender individuals is not supported by medical science or current military medical protocols.

75. Hormone therapy is neither too risky nor too complicated for military medical personnel to administer and monitor. The risks associated with use of cross-sex hormone therapy

to treat gender dysphoria are low and not any higher than for the hormones that many non-transgender active duty military personnel currently take. There are active duty service members currently deployed in combat theaters who are receiving cross-sex hormonal treatment, following current DoD instructions, without reported negative impact upon readiness or lethality.

76. The military has vast experience with accessing, retaining, and treating non-transgender individuals who need hormone therapies or replacement, including for gynecological conditions (*e.g.*, dysmenorrhea, endometriosis, menopausal syndrome, chronic pelvic pain, male hypogonadism, hysterectomy, or oophorectomy) and genitourinary conditions (*e.g.*, renal or voiding dysfunctions). Certain of these conditions are referred for a fitness evaluation only when they affect duty performance. *See* Elders Commission at 13.

77. In addition, during service when service members develop hormonal conditions whose remedies are biologically similar to cross-sex hormone treatment, those members are not discharged and may not even be referred for a MEB. Examples include male hypogonadism, menstrual disorders, and current, or history of, pituitary dysfunction. *Id.*

78. Military policy also allows service members to take a range of medications, including hormones, while deployed in combat settings. *Id.* Under DoD policy only a "few medications are inherently disqualifying for deployment," and none of those medications are used to treat gender dysphoria. *Id.* (quoting Dept. of Defense, Policy Guidance for Deployment-Limiting Psychiatric Conditions and Medications, 2006 at para. 4.2.3). Similarly, Army regulations provide that "[a] psychiatric condition controlled by medication should not automatically lead to non-deployment." *See* AR 40-501 § 5-14(8)(a).

79. Access to medication is predictable, as "[t]he Medical Health Service maintains a sophisticated and effective system for distributing prescription medications to deployed service members worldwide." *See* Elders Commission at 13. At least as to cross-sex hormones, clinical monitoring for risks and effects is not complicated, and with training and/or access to consultations, can be performed by a variety of medical personnel in the DoD, just as is the case in the VHA. This is the military services' current practice in support of the limited medical needs

of their transgender troops in CONUS (Continental United States) and in deployment stations worldwide.

80. The RAND Corporation confirms the conclusions I draw from my experience with the military and the Elders Commission. Specifically, the RAND Report notes that the Medical Health System maintains and supports all of the medications used for treatment of gender dysphoria and has done so for treatment of non-transgender service members. In other words, all of the medications utilized by transgender service members for treatment of gender dysphoria are used by other service members for conditions unrelated to gender dysphoria. *See* RAND Report at 8 ("Both psychotherapy and hormone therapies are available and regularly provided through the military's direct care system, though providers would need some additional continuing education to develop clinical and cultural competence for the proper care of transgender patients"). Part of my role with the DoD over the past 18 months has been to provide this continuing education.

***Surgery***

81. There is no basis in science or medicine to support the argument that a transgender service member's potential need for surgical care to treat gender dysphoria presents risks or burdens to military readiness. The risks associated with gender-confirming surgery are low, and the military already provides similar types of surgeries to non-transgender service members. *See* Elders Commission Report at 14; RAND Report at 8-9.

82. For example, the military currently performs reconstructive breast/chest and genital surgeries on service members who have had cancer, been in vehicular and other accidents, or been wounded in combat. *See* RAND Report at 8. The military also permits service members to have elective cosmetic surgeries, like LeFort osteotomy and mandibular osteotomy, at military medical facilities. *See* Elders Commission Report at 14. The RAND Report notes that the "skills and competencies required to perform these procedures on transgender patients are often identical or overlapping. For instance, mastectomies are the same for breast cancer patients and female-to-male transgender patients." *See* RAND Report at 8.

83. There is no reason to provide such surgical care to treat some conditions and withhold identical care and discharge individuals needing such care when it is provided to treat gender dysphoria. Based on risk and deployability alone, there is no basis to exclude transgender individuals from serving just because in some cases they may require surgical treatment that is already provided to others.

84. The RAND Report also notes the benefit of military medical coverage of transgender-related surgeries because of the contribution it can make to surgical readiness and training. *Id.* ("performing these surgeries on transgender patients may help maintain a vitally important skill required of military surgeons to effectively treat combat injuries during a period in which fewer combat injuries are sustained").

85. The suggestion by some critics that when it comes to enlistment, individuals would join the military just to receive surgical care, is completely unfounded. The level of commitment and dedication to service makes it unlikely that someone would enlist and complete a years-long term of initial service simply to access health care services. Moreover, because medically-necessary care for gender dysphoria is now increasingly available in the civilian context, there would be limited need to join the military in order to obtain treatment.

***Deployability***

86. Critics have also cited non-deployability, medical readiness, and constraints on fitness for duty as reasons to categorically exclude transgender individuals from military service. Such arguments are unsubstantiated and illogical.

87. Transgender service members – including service members who receive hormone medication – are just as capable of deploying as service members who are not transgender. DoD rules expressly permit deployment, without need for a waiver, for a number of medical conditions that present a much more significant degree of risk in a harsh environment than being transgender. For example, hypertension is not disqualifying if controlled by medication, despite the inherent risks in becoming dehydrated in desert deployment situations. Heart attacks experienced while on active duty or treatment with coronary artery bypass grafts are also not

disqualifying, if they occur more than a year preceding deployment. Service members may deploy with psychiatric disorders, if they demonstrate stability under treatment for at least three months. *See* DoDI 6490.07, Enclosure 3.

88. Moreover, although a service member undergoing surgery may be temporarily non-deployable, that is not a situation unique to people who are transgender. Numerous non-transgender service members are temporarily or permanently non-deployable, including pregnant individuals, who are not separated as a result. *See* Elders Commission Report at 17.

89. Finally, the RAND Report ultimately concluded that the impact of open service of men and women who are transgender on combat readiness would be "negligible." *See* RAND Report at 70. Based on the available evidence of over 18 foreign militaries, RAND found that open service has had "no significant effect on cohesion, operational effectiveness, or readiness." *Id.* at 60. This includes the experience of Canada, which has permitted open service for over 20 years. *Id.* at 52.

## CONCLUSION

90. There is no evidence that being transgender alone affects military performance or readiness. There is no medical or psychiatric justification for the categorical exclusion of transgender individuals from the Armed Forces.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 23, 2018

George R. Brown, M.D., D.F.A.P.A.



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**CERTIFICATE OF SERVICE**

The undersigned certifies under penalty of perjury under the laws of the United States of America and the laws of the State of Washington that all participants in the case are registered CM/ECF users and that service of the foregoing documents will be accomplished by the CM/ECF system on January 25, 2018.

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# Exhibit A

# CURRICULUM VITAE

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Date of Preparation: August 29, 2017

**EDUCATION:**

Undergraduate: University of Rochester, Rochester, New York, 1975-1979;
Bachelor of Science with Highest Honors and Distinction in Research, Summa Cum Laude.
Double major, with BS in both biology and geology

Medical School: University of Rochester School of Medicine, Early Acceptance Program (Rochester Plan), 1979-1983; Doctor of Medicine with Honors; Health Professions Scholarship Program.

Internship: United States Air Force Medical Center, Wright-Patterson Air Force Base, Ohio, 1983-1984.

Residency: Wright State University - United States Air Force Integrated Residency in Psychiatry, Dayton, Ohio, 1984-1987.

**CREDENTIALS:**

FLEX, December, 1983 (Behavioral Sciences, 94%; Psychiatry, 93%).
Full licensure to practice medicine, State of Ohio, December, 1983 to April, 2017; license #50119; allowed to expire with no intent of practicing in Ohio.
Full licensure to practice medicine, State of Texas, August, 1989 to present; license #H5847
Full Licensure to practice medicine, Commonwealth of Kentucky, 1993 to 1995, #30100; allowed to expire with no intent of practicing in Kentucky.
Full licensure to practice medicine, State of Tennessee, 1994-present, license #25192

Psychiatry Resident In-Training Examinations;
1986: 98th percentile - all U.S. residents, psychiatry.
1985: 90th percentile - all U.S. residents, psychiatry.

1984: 98th percentile - all U.S. residents, psychiatry.
1983: 98th percentile - all U.S. residents, psychiatry.
American Board of Psychiatry and Neurology, Part I, April 1988 (92nd percentile); Part II, June 1989; ABPN Certificate #31377.
Electroconvulsive Therapy Administration Certification, 1985-1990.
Courtesy Staff Privileges, Charter Real Hospital, San Antonio, Texas, 1990-1994.
Courtesy Hospital Staff, Bexar County Hospital District, San Antonio, Texas, 1988-1994.
Full Admitting Privileges, Wilford Hall Medical Center, San Antonio, Texas, 1987-1993.
Full Admitting Privileges, James H. Quillen VAMC Hospital, Johnson City, TN, 1994-2016
Basic Life Support Certification, renewed March 2017

**PROFESSIONAL EXPERIENCE:**

Current Positions:

**Professor and Associate Chairman for Veterans Affairs, Department of Psychiatry and Behavioral Sciences, Quillen College of Medicine, East Tennessee State University**. 1995-present. Advisory duties to the Chairman, signature authority in absence of the Chair, contributing to administrative, teaching, and research missions of the Department, liaison between the VAMC and ETSU psychiatry administrations.

**Research, Teaching, and Resident supervision appointment, James H. Quillen VAMC.** February 1, 2016-present. Responsibilities include providing teaching, research services, clinical consultation, and resident supervision/mentoring in the Psychiatry Service.

**Clinical Professor of Psychiatry (Adjunct), University of North Texas Health Sciences Center.** 2017-present. Clinical privileges at Carswell Federal Correctional Institution in association with UNTHSC appointment. Responsibilities include teaching and consultation with UNTHSC and Federal Bureau of Prisons staff about transgender health issues.

Past Positions:

**Staff Psychiatrist, Mental Health Outpatient Clinic, James H. Quillen VAMC**. December, 2014-January 31, 2016. Responsibilities included treating veterans with chronic, persistent, mental illnesses in an outpatient setting and providing consultation services to junior staff and residents in psychiatry. Direct supervision of third year psychiatry residents in the Mental Health Clinic.

**Transgender Health Care Facility Lead, Mountain Home Health Care System.** 2014-January 31, 2016. Responsibilities included providing direct patient care for transgender veterans, providing national training for VHA health care providers learning how to provide transgender health care, direct supervision of other health care providers in teaching evaluation and treatment techniques, leading a multidisciplinary team of health care providers assigned to provide transgender health care in our 70,000 patient health care system.

**Program Officer, Health Care Outcomes, Office of Health Equity (10A6), VA Central Office, Washington, D.C.** December, 2012, to December, 2014. Responsibilities included researching medical and psychiatric health disparities in vulnerable populations of Veterans treated by the Veterans Health Administration, and assisting top officials in VHA in the development of policies that lead to elimination of health care outcome disparities in these subpopulations. Continued to see patients at Mountain Home VAMC throughout this appointment.

**Chief of Psychiatry, James H. Quillen VAMC**. November 22, 1995-December 16, 2012. Responsibilities included direct supervision of a staff of 34-42professional staff, including 24-28 psychiatrists, 2 Clinical Nurse Specialists, and 9-12 psychiatric nurse practitioners. Represented the Department in all meetings requiring the input of the Chief of Service. Attended executive meetings in the Medical Center and University. Contributed to long range planning of services in the Medical Center.

**Research Appointment (WOC), VHA Center of Excellence for Suicide Prevention,** Canandaigua, New York. 2011-2014. Responsibilities of this position included developing research protocols collaboratively with CoE staff that have national implications related to suicide in VHA.

**Director of Psychiatric Research**, **James H. Quillen VAMC Dept. of Psychiatry.** 1994-2012. Responsibilities included creating a research program de novo and leading a research team at the VAMC, teaching resident seminars, didactics, research electives, providing direct patient care for inpatients on research protocols (usually those with severe mental disorders), traveling to conferences to present research findings and providing Grand Rounds to other institutions and medical schools. Major focus of research activities has been working with stigmatized/disenfranchised populations and addressing mental health care aspects and disparities in care.

**Staff psychiatrist**, **Another Chance Recovery Program**, Morristown, Tennessee. March 1995-1996. This is an intensive outpatient drug and alcohol treatment program with a heavy emphasis on dual diagnosis patients, outpatient detoxification from chemical dependency, and a blend of the medical and 12-Step approaches to treatment of the chemically dependent patient. One evening clinic per week.

**Senior Research Scientist and Director of Psychiatric/Neuropsychiatric HIV Research**, Wilford Hall Medical Center, Henry M. Jackson Foundation for the Advancement of Military Medicine, San Antonio, Texas. 1 July 1991 to 1 October 93. Responsibilities included hiring and then directing a team of approximately 15 civilian and military psychiatric researchers conducting HIV-related psychiatric research; Principal Investigator on longitudinal psychiatric natural history study of early HIV infection (males and females), 1989-1993; preparing manuscripts, presenting research findings at national and international meetings; designing and implementing new protocols; interviewing and assisting in the hiring of personnel; managing administrative and personnel issues.

**Private practice** of adult psychiatry. 1991-November 1993. Part-time practice primarily focusing on sexuality and gender concerns, including endocrine care, and adult psychodynamic psychotherapy.

**Consulting Psychiatrist for Quality Assurance and Continuing Quality Improvement Programs**:
1) Charter Real Partial Hospitalization Program, San Antonio, Texas. 1990 to 12/93. Responsibilities of this part time position included designing and implementing a medical quality assurance program and assisting Utilization Review personnel with implementing efficient resource utilization procedures.
2) Colonial Hills Hospital Inpatient Services and Adult Partial Hospitalization Program, San Antonio, Texas. 1992. Responsibilities of this part time position included custom designing a four part program to address QA/CQI concerns on all inpatient units, coordinating the implementation of the program with hospital QA/UR personnel, and quantifying/ databasing physician charting performance to analyze trends.

**Staff Psychiatrist,** Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas:

1987-1989: Primary responsibility for inpatient ward of 25-33 patients, resident and medical student teaching, and professional presentations. 1040 admissions; average length of stay 13 days.

1989-1991: Outpatient Clinic service, responsible for evaluations and treatment of adult outpatients; supervision of PGY-3 residents in psychiatry and other staff working in the clinic (social workers, psychologists, and mental health technicians). Medical support for comprehensive Smoking Cessation Clinic.

1989-1991: Director of Psychiatric Research, half-time position; developed a research program primarily targeting psychiatric resident involvement with research and related activities, including presentations at regional and national professional meetings. Active in conducting research, reviewing and approving protocols, research design, editing publications submitted from the Department of Psychiatry, and organizing symposia; interviewing and selecting official for research personnel for multicenter collaborative HIV research grant.

**ACADEMIC APPOINTMENTS:**

Professor of Psychiatry (1998-present), East Tennessee State University, Quillen College of Medicine. VA Academic Faculty appointment.

Clinical Professor of Psychiatry (Adjunct), University of North Texas Health Sciences Center, Fort Worth, Texas (2017-present).

Adjunct Professor of Psychology, University of Tennessee at Knoxville (1997). Served on doctoral dissertation committee as supervisor and mentor for doctoral candidate in clinical psychology.

Associate Professor of Psychiatry (1994-1998), East Tennessee State University, Quillen College of Medicine. Full time geographic faculty appointment. Renewal of previously awarded academic ranking. Activities include serving on numerous committees (see below), teaching residents, providing electives, working collaboratively with staff to conduct new research projects, interviewing residency and faculty candidates.

Clinical Associate Professor of Psychiatry (1992-1994), University of Texas Health Science Center at San Antonio, San Antonio, Texas. 1987 to 1994. Primary responsibility of this position was teaching medical students and residents in individual, group, and lecture settings; provision of psychodynamic psychotherapy supervision. Lectures and seminars include core material on sexual dysfunction, treatment of paraphilias, gender identity disorders, homosexuality, and psychiatric aspects of HIV infection.

Clinical Associate Professor of Psychiatry (1992-1996), Uniformed Services University for the Health Sciences, School of Medicine, Bethesda, Maryland. Primary responsibility of this position was teaching medical students from the University who travel to San Antonio for clinical rotations in psychiatry and serving as a visiting lecturer for USUHS.

Full time faculty, Department of Psychiatry, Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas, 1987 to 1991. Adjunct clinical faculty, Department of Psychiatry, 1991 to 1993. Responsibilities included supervising psychiatric residents involved in research activities, sponsoring Distinguished Visiting Professors in conjunction with the Department, and teaching core didactic lectures and seminars.

Assistant Clinical Instructor, Wright State University School of Medicine, 1983-1987. Primary

responsibility of this position was teaching medical students during clinical rotation in psychiatry.

Chief Resident in Psychiatry, November, 1986 to March, 1987, with administrative, teaching, and research responsibilities.

**CONSULTATION EXPERIENCE:**

Psychiatric Liaison and Consultant to Oncology Unit, Good Samaritan Hospital, Dayton, Ohio, 1985.
Clinical Supervisor and Psychiatric Consultant to Montgomery County Juvenile Court Diversion Program, Dayton, Ohio, 1986-1987.
Consultation/Liaison Rotation, Keesler AFB, MS, 1986.
Psychiatric Consultant to the United States Air Force Child Abuse Task Force (convened by the Surgeon General of the Air Force), 1989-1991.
Lorain Correctional Institution, psychiatric consultant for inmate mental health evaluations and treatment, July-August 1993.
State of Tennessee Mental Health and Mental Retardation, appointed as consultant to develop Best Practice Guidelines for all State programs for Bipolar Disorder.
Health Ed, The Patient Education Agency: consultant for development of patient education materials for chronic mental illnesses, 2006-2007.
Consultant to Batavia Independent School District in assisting on-the-job gender transition for a transgender high school teacher, 2006.
Consultant to Port Ewan/Kingston BOCES School Program in assisting on-the-job transition for a transgender principal, 2007.
Consultant to the Federal Bureau of Prisons on policies relating to medical management of transgender inmates, 2009, 2014.
Consultant to Department of Defense on policy and medical issues related to transgender service members, 2016-present.
Faculty consultant to Carswell Federal Correctional Institution, Fort Worth, Texas, on transgender health issues, 2017-present.
Research Consultant to Michael Goodman, MD, Principal Investigator, PCORI Grant to study transgender health issues, Emory University, 2014-2016.
Department of Justice, National Institute of Corrections, 2017-present.
Department of Veterans Affairs, LGBT Veterans Program, Washington, DC, 2016-present.

**SPECIALIZED TRAINING EXPERIENCES:**

School of Aerospace Medicine, Course I, Brooks AFB, San Antonio, Texas, 1981.
Administrative Course for Chief Residents, Tarrytown, New York, June, 1985.
Combat Casualty Care Course, San Antonio, Texas, 1985.
Consultation and Liaison Psychiatry, Keesler AFB, Biloxi, Mississippi, 1986.
Center for the Treatment of Impotence, Case Western Reserve University, Cleveland, Ohio, July, 1986.
Forensic Psychiatry Course and associated clinical work, 6 months, 1986-87; ongoing case work in forensic psychiatry as expert witness and legal consultant, 1987-present.
Gender Identity Clinic, Case Western Reserve University, Cleveland, Ohio, July, 1986.
Paraphilias Clinic, Case Western Reserve University, Cleveland, Ohio, July, 1986.
Chemical Dependency Program, Samaritan Hall, Dayton, Ohio, August, 1986.
Advanced Study of Gender and Sexual Disorders, Institute of Living, Hartford, Connecticut, April, 1987.
Electroconvulsive Therapy Administration Training, Jan-June, 1985; June, 1987.
SCID training seminar, September, 1989.
American Board of Psychiatry and Neurology Examiner, 1991-present.

Administrative psychiatry and leadership training, James H. Quillen VAMC,1996 to 2012.
Physician Executive Training, American College of Physician Executives, (PIM-I Course, 31 hours; PIM-II Course, 31 hours, PIM-III Course, 31 hours), 1998-1999.
Masters and Johnson workshop on trauma, sexual compulsivity/addiction treatment, 11 hours, December, 2003.
Forensic Workshop on sex offenders, National Council on Sexual Addiction and Compulsivity, October, 2002
Forensic workshops, including PREA implementation, managing hunger strikes, mental health issues in prison, sponsored by National Commission on Correctional Health Care, 2010, 2012.
Forensic workshops, including 3 hours of training on medical and legal aspects of providing health care for transgender inmates, sponsored by National Commission on Correctional Health Care, 2015.

**COMMITTEE AND BOARD ACTIVITIES:**

Mohonasen Public School Board Member, Schenectady, New York, 1974-1975.
Social Chairman, Wright State University Psychiatry Residency, 1984.
Dayton Representative to the Member-in-Training Committee of the Ohio Psychiatric Association, 1984-1986.
Chairman, Member-in-Training Committee, Ohio Psychiatric Association, 1986-1987.
Chairman, Member-in-Training Committee, Dayton Psychiatric Society, 1985-1987.
Peer Review Committee, Ohio Psychiatric Association, 1986-1988.
Long Range Planning Committee, Ohio Psychiatric Association, 1986-1987.
American Psychiatric Association, Area IV Resident Caucus, Ohio Representative, 1987.
American Psychiatric Association, Committee of Residents of the Council on Medical Education and Career Development, Ohio Representative, 1986-1987.
Ohio Psychiatrist's Political Action Committee, Board of Directors, 1987.
Bexar County Psychiatric Society Committee on AIDS, 1990-1993.
World Professional Association for Transgender Health (WPATH) Committee to Revise the Standards of Care, 1990-present; Cochairman of Standards of Care Revision Committee, 2001-2005.
Psychiatric Consultant to the Board of Directors, Boulton and Park Society, San Antonio, Texas, 1988-1998.
President-elect, Society of Air Force Psychiatrists, 1990-1991.
Board of Directors, Alamo Area Resource Center (AIDS/HIV Service Organization), 1991-1992.
Board of Advisors, American Educational Gender Information Service (Atlanta, Georgia), 1992-1998.
Quality Assurance Committee, Texas Society of Psychiatric Physicians, 1992-1993.
Professional Standards Committee, Texas Society of Psychiatric Physicians, 1992-1993.
Board of Directors, Harry Benjamin International Gender Dysphoria Association (WPAth), 1993-1997; 2001-2007
Ethics Committee, Tennessee Psychiatric Association, 1994-present.
Advisory Committee on Publications and Advertising, Southern Medical Association, 1994-1996.
Councilor to the Executive Committee, Tennessee Psychiatric Association, East Tennessee Region, 1995-2005.
Vice-Chairman, Section on Neurology and Psychiatry, Southern Medical Association, 1995-1996.
President, New Health Foundation, 2001-2003.
Secretary of the Section on Neurology and Psychiatry, Southern Medical Association, 1997-2000.
American Psychiatric Association PKSAP and Medical Education Committees, appointed by Herb Sachs, M.D. and Harold Eist, M.D. (APA Presidents), 1997-2001.
Scientific Affairs Committee, Southern Medical Association, 1997-1999.

Consultant to the Joint Commission on Public Affairs, American Psychiatric Association, appointed by Rod Munoz, M.D. (APA President), 1998-1999.
Scientific Program Committee, Southern Psychiatric Association, 1999-2000.
Resident Award Committee, Southern Psychiatric Association, 1997-2009.
Ethics Committee; HIV Committee; Harry Benjamin International Gender Dysphoria Association, 1999-2005
Board of Directors, New Health Foundation, Chicago, IL, 2000-present.
Tennessee Department of Mental Health and Retardation Adult Committee on Best Practices (responsible for recommending guidelines for treatment of bipolar disorder), 2000-2003.
Associate Counselor for Tennessee, Southern Medical Association, 2000-2008.
Resident Award Committee, Southern Psychiatric Association, 2003-2009.
Board of Directors, James H. Quillen VAMC Research Corporation, 2003-2010.
HBIGDA Biennial Symposium Scientific Meeting Committee, 2006-2007.
Board of Regents, Southern Psychiatric Association, 2006.
Southern Medical Association, Section Secretary for Psychiatry and Neurology, 2004-2008.
Scientific Review Committee, World Professional Association for Transgender Health Symposium, 2007-2009; 2015-present.
Board of Regents, Second Year, Southern Psychiatric Association, 2007.
Chairman, Board of Regents, Southern Psychiatric Association, 2009.
WPATH Board of Directors, 3 terms totaling 13 years, with last term 2014 (mandatory rotation off the board).
Secretary-Treasurer, World Professional Association of Transgender Health, 2007-2009.
DSM-V workgroup on Gender Identity Disorders (WPATH advisory work group to American Psychiatric Association DSM-V GID task force), 2009.
World Health Organization advisory committee for ICD-11 (gender identity disorders), 2011-present.
Department of Veterans Affairs Transgender Directive Communication Plan Education Group, 2011-2012.
VHA Transgender Training Workgroup, Patient Care Services, 2012- present.
Numerous VA Central Office national workgroups and committees, including the workgroup to add birth sex and gender identity data fields to all VA medical records, 2012-present.
Commissioner, Palm Center Commission on Transgender Military Service, Appointed by Joycelyn Elders, MD, 2013 to 2014.

**PROFESSIONAL ORGANIZATIONS:**

American Psychiatric Association (1983-2015); #044933, Fellow, 1998; Distinguished Fellow, 2003
Association for the Advancement of Psychotherapy (1985-1993)
World Professional Association for Transgender Health (1986-present)
Ohio Psychiatric Association (1983-1987)
Texas Society of Psychiatric Physicians (1988-1994)
Tennessee Psychiatric Association (1994-2015)
American Medical Students Association (1977-1987)
American Medical Association (1983-1988; 2015-present)
Ohio State Medical Association (1983-1987)
Montgomery County Medical Society (1983-1987)
Dayton Psychiatric Society (1983-1987)
Society of United States Air Force Psychiatrists (1983-1991)
Bexar County, Texas, Psychiatric Society (1987-1990)
Southern Medical Association (1994-2010)
Southern Psychiatric Association (1997-2009)
New Health Foundation (advocacy organization for transgendered health care; 1996-present)

American Psychological Association Society for the Psychological Study of Men and Masculinity, Division 51, 1996-2000.

**AWARDS AND SPECIAL RECOGNITION:**

Valedictorian, Mohonasen High School, Schenectady, New York, 1975.
New York State Regents Scholarship, 1975-1979.
Bausch and Lomb Science Award and Scholarship, 1975-1979.
Phi Beta Kappa, junior year selection, 1977.
Donald Charles Memorial Award for Research in Biology, 1978.
Recognition for Highest Grade Point Average, Department of Biology-Geology, University of Rochester, 1979.
Dean's Letters of Commendation for Academic Achievement, University of Rochester, 1975-1983.
Letter of Commendation for Excellence in Pathology, University of Rochester, 1981.
Alpha Omega Alpha Medical Honor Society, University of Rochester, 1983.
Wright State University Department of Psychiatry selectee for fellowship in the Group for the Advancement of Psychiatry (GAP), 1984.
Wright State University Department of Psychiatry nominee for Laughlin Fellowship of the American College of Psychiatrists, 1985, 1986.
Physician's Recognition Award of the American Medical Association, 1986 to present.
President's Award of the Ohio Psychiatric Association for outstanding service to the organization, 1987.
Chairman's Recognition Award For Scholarship and Research, Wright State University Department of Psychiatry, 1987.
Air Force Training Ribbon, 1980.
Air Force Outstanding Unit Decoration, 1987; first oak leaf cluster additional award, 1990.
Air Force Expert Marksman Ribbon, 1988.
Air Force Achievement Medal for research accomplishments, 1990.
1990 American Academy of Psychosomatic Medicine Dlin Fischer Award for Significant Achievement in Clinical Research; corecipient.
Who's Who Among Human Services Professionals, 1990 to present.
West's Who's Who in Health and Medical Services, 1991 to present.
Marquis Who's Who of Board Certified Medical Specialists, 1992-present.
Bexar County Medical Society Certificate of Appreciation, 1991.
Air Force Meritorious Service Medal for distinguished clinical and research service to the Department of Psychiatry, Wilford Hall Medical Center, 1991.
Air Force National Defense Ribbon, Desert Storm Campaign, 1991.
Mohonasen High School Hall of Fame for Lifetime Achievement, 1992 inductee.
Health Care Professional of the Year Award, Boulton and Park Society, San Antonio, Texas, 1992-93.
Special Citation Award, Society of Behavioral Medicine, with Coyle C, et al., for presentation at 1993 Society of Behavioral Medicine Annual Meeting, 1993.
Institute for Legislative Action, 1995 Honor Role.
Sterling Who's Who of Health Care Professionals, 1995.
Southern Medical Association 1995 Award for Medical Excellence (Best Scientific Oral Presentation in Neurology and Psychiatry), $1,000 Scholarship prize, 1995.
Janssen Clinical Scholar, 1995.
Mountain Home VAMC Group Special Contribution Award, 1995, 1997.
Marquis Who's Who in the South and Southwest, 1996-1998.
Marquis Who's Who in Medicine and Healthcare, 1997-1998.
Certificate of Appreciation, ETSU Psychiatry Residents, 1997, 1998, 1999.
Fellow, American Psychiatric Association, 1998-2002.
Resident Special Recognition Award, June, 2000.
Distinguished Fellow, American Psychiatric Association, January, 2003

Special Group Contribution Award, VAMC, 2003
Secretary of Defense Certificate of Recognition, Cold War Military Service, 2003
VA Performance Award, 2005
First Annual Irma Bland Award for Excellence in Teaching Residents, presented by the American Psychiatric Association, May, 2005
Special Contribution Award, Mountain Home VAMC, for assisting in obtaining over 2.5 million in new program monies from VA Central Office RFP process, April 26, 2006
Top Psychiatrists of 2006, Consumer Research Council selectee
ETSU Resident Recognition Award for "dedication to the Resident's Journal Club", 2006
Fellow, Southern Psychiatric Association, 2006
ETSU Psychiatry Faculty Mentor of the Year Award, 2007
Cambridge Who's Who, Executive and Professional Registry, 2007
Southern Medical Association, Third Place Award for Scientific Poster Presentation, Dallas, Texas, December 5, 2009
Twenty-five year U.S. Government service award, January 10, 2010
Joint Commission recognition : “Top Performers on Key Quality Measures” (contributor), 2011
Robert W. Carey Quality Performance Excellence Award (contributor), 2011; Department of Veterans Affairs award using Baldrige criteria
James H. Quillen VAMC selected as VA to be featured in the Commonwealth Fund’s article on successful efforts to improve patient safety (contributor), 2011
Gender Identity Research and Education Society (GIRES) 2011 award to the 34 members of the Standards of Care Revision Committee for their work on the WPATH Standards of Care, 7th Version.
Robert W. Carey Quality Trophy Award, Mountain Home VAMC. This is the highest level of the Carey Award for those VAMC’s seeking performance excellence using the Baldrige Criteria. Awarded by the Secretary of the VA to the leadership team of which I was a Part, 2012.
Recognized by LGBT Health journal in March, 2016 as having first-authored the #1 and #3 most read articles in that journal since its inception.

**UNIVERSITY/VA COMMITTEE ACTIVITIES:**

Learning Resources Advisory Committee (ETSU), 1995-1996.
Psychiatric Residency Training Committee /Educational Policy Committee (ETSU), 1993-2017.
Peer Review Committee (VAMC), 1995-1996.
Chairman and Founder, Psychiatric Grand Rounds and Visiting Professor Program (ETSU), 1993-1997; 2003-2004.
Clinical Executive Board (VAMC), 1995-2012.
Research and Development Committee, Dean's Appointment (VAMC), 1996-1998.
Chairman, VAMC Research and Development Committee, 1999-2000.
Co-Chairman, Mental Health Council (VAMC), 1995-2009.
Academic Partnership Committee (ETSU), member, 1995-2012.
Facility Master Plan and Space Utilization Committee (VAMC), 1995-2010.
Professional Standards Board (VAMC), 1995-2012.
Safety Committee, Department of Psychiatry, Chairman (VAMC)
ETSU Psychiatry Promotion and Tenure Committee, 1998-present.
Resident Selection Committee, ETSU Psychiatry Program, 1998-2012.
Chairman, VAMC Research and Development Committee, 2001-2002.
Veterans Health Affairs, VISN 9, Budget and Finance Committee, 2002-2004.
Institutional Review Board (ETSU/VAMC), member, 1996-2003; served as acting chair as needed.
Cameron University Department of Psychology, Dissertation Committee Consultant for Beth Ryan, Masters Thesis, 2004-2005 (gender identity disorder research).
VISN 9 Mental Health Leadership Committee.
ETSU/VAMC Subcommittee on Graduate Medical Education, 2008-2012.

Vanderbilt University Department of Nursing, Dissertation Committee member and consultant for Gerald Meredith, 2009-2010.
VA Transgender Directive Education Workgroup; VACO workgroup to advise the Undersecretary, VHA, on how to educate and implement the 2011 and 2013 Directives on providing Healthcare to transgender and intersex Veterans, 2011-present.
Office of Health Equity (VACO), Health Equity Coalition, 2013-2014.
Numerous research committees and advisory panels for health equity research projects being conducted in VA, 2012-2015.
Chairman, Educational Policy Committee (Residency Training Committee), East Tennessee State University Department of Psychiatry, 2015-2016.
Self-Identified Gender Identity Data Field Training Workgroup (National VA work group to change electronic medical records data collection to include self-identified gender identity), 2012-present.
Research Committee, East Tennessee State University Department of Psychiatry, 2015-present.

**FORENSIC PSYCHIATRY ACTIVITIES:**

1. Military court proceedings, two occasions as expert witness at trial; U.S. Air Force, U.S. Army, c.1990-1992
2. Military Physical Evaluation Board Proceedings, expert testimony, 2/8/02
3. Farmer v. Hawk, United States District Court for the District of Columbia, expert opinion by affidavit on behalf of plaintiff, 1999
4. Yolanda Burt v. Federal Bureau of Prisons/Moritsugu, United States District Court for the District of Columbia, deposition testimony on behalf of plaintiff, 2000
5. Kosilek v. Maloney, 221 F.Supp 2d 156,186 (D.Mass. 2002), expert witness by trial testimony on behalf of plaintiff, 2001
6. Family Court expert witness trial testimony, Missouri, (custody issues for transgendered parent),1993
7. Thompson v. Idaho Department of Corrections (prison medical care Issues), consultant on behalf of plaintiff, 2002 (citation: Linda Patricia Thompson v. Dave Paskett, et al., Case No. CV00-388-S-BLW)
8. State of Missouri Medical Board, expert opinion by affidavit on behalf of physician, 10/2001
9. State of Tennessee Medical Board, expert opinion by affidavit on behalf of physician, 5/2002
10. Military Administrative Hearing, consultant, U.S. Army, December, 2002
11. Oiler v. Winn-Dixie Louisiana, Inc; USDC, Eastern District of Louisiana, No. 00-3114 “L” (3); consultant on behalf of defendant, 2001-2002
12. Moore v. State of Minnesota, consultant and deposition testimony on behalf of defendant, Attorney General's Office, State of Minnesota, 2003
13. Woods v. US Air Force, administrative discharge board, consultant, San Antonio, TX, 2003
14. Ophelia Azriel De’Lonta vs. Ronald Angelone and Prison Health Services, Inc. (Virginia Department of Corrections) United States District Court, Western District of Virginia, 330 F.3d 630,635 (4th Cir 2003) deposition testimony on behalf of plaintiff, 2003
15. Malpractice case, Tennessee, for defendant (primary care physician) consultant, 2004-2005
16. Josef v. Ontario Minister of Health, Attorney General of Ontario representing Her Majesty the Queen in Right of Ontario; Ontario Superior Court of Justice; expert opinion affidavit and consultant on behalf of plaintiff, 2004-2007.
17. Nubel v. New Jersey Board of Nursing, consultant and deposition testimony for defendant, 2004-2005
18. Malpractice case, Tennessee, consultant for defendant (psychiatrist), 2004-2005
19. Malpractice case, Kentucky, consultant for defendants (psychiatrists), 2005-2006
20. Kosilek v. Mass. Department of Corrections/ Kathleen Dennehy, expert witness by trial

testimony and consultant on behalf of plaintiff, 2005-2006 ( Kosilek v. Spencer, 889 F.Supp.2d 190 (D. Mass. Sept. 4, 2012); "Kosilek II."

21. Gammett v. Idaho Department of Corrections, expert opinion affidavit and consultant for plaintiff, 2005-2007 (Gammett v. Idaho State Bd. of Corrections, No. CV05-257-S-MHW, 2007 WL 2186896 (D. Idaho July 27, 2007)
22. Isaak v. Idaho Department of Corrections, consultant, and deposition testimony on behalf of plaintiff, 2006-2008
23. May v. State of Tennessee and multiple codefendants; consultant on behalf of defendant, Attorney General's Office, State of Tennessee, 2006
24. Fields/Sundstrom v. Wisconsin Department of Corrections, consultant and deposition testimony on behalf of plaintiff, 2007 ( Fields v. Smith, 653 F.3d 550 (7th Cir. 2011)
25. Palmer v. State of TN; malpractice case; consultant and deposition testimony for defendant, Attorney General's Office, State of Tennessee 2007
26. Spray v. Temp Agency, consultant and expert opinion affidavits on behalf of plaintiff, 2007
27. O'Donnabhain v. Internal Revenue Service/Department of the Treasury, expert witness by trial testimony on behalf of plaintiff, 2007 (O'Donnabhain v. Commissioner, 134 T.C. No. 4 (Feb. 2, 2010).
28. Battista v. Mass. Department of Corrections/Kathleen Dennehy, consultant and expert opinion affidavit for plaintiff, 2008-2011.
29. Plumley v. State of TN; malpractice case; consultant for defendant, 2009.
30. Kolestani v. State of Idaho, capital murder case, consultant and expert opinion affidavit for public defender's office, 2009.
31. Smith v. St. Mary's Medical Center, medical malpractice case, consultant for defendant, 2009-2011, expert witness by jury trial testimony, 2011.
32. Finch aka Destiny v. Idaho Department of Corrections, consultant for plaintiff, 2010-2011.
33. Soneeya v. Clarke, Civil Action No. 07-12325 (NG), Massachusetts, consultant for plaintiff, 2011. (see also Soneeya v. Spencer, 851 F.Supp.2d 228 (D. Mass. 2012)
34. Hoyle v. Saha, malpractice case; consultant for defendant, 2011- 2014.
35. Champouillon v. State of TN; malpractice case; consultant for defendant, 2012-present.
36. Equivel v. State of Oregon; access to transgender health care for Oregon State employees; consultant to Lamdba Legal, 2012.
37. Kosilek v. MA DOC, expert witness for plaintiff, 2012-present; ("Kosilek III").
38. Binney v. South Carolina DOC, consultant and expert opinion by affidavit for plaintiff, 2013-present.
39. De'Lonta v. Harold W. Clarke et al. (Virginia Department of Corrections), consultant and expert opinion by affidavit to plaintiff, 2013-2014.
40. U.S. and Tudor v. Southeastern Oklahoma State University, expert consultant for plaintiff and the Department of Justice (Title VII discrimination case), by declaration for plaintiff, 2015-present.
41. Mott v. State of Kansas, consultant and expert opinion by affidavit for plaintiff (birth certificate change), 2015-2016.
42. Fuller v. MA Department of Corrections; expert opinion by affidavit and deposition, for plaintiff, 2015-2016.
43. Franklin v. Hardy, et al. (Illinois Department of Corrections); expert opinion by affidavit, for plaintiff, 2015-2016.
44. Dunn et al. v. Dunn et al. (Alabama Department of Corrections), expert consultant for plaintiff, 2016-2017.
45. Keohane v. Jones (Florida Department of Corrections), Case No.4:16-cv-511-MW-CAS, N. D. Fla, expert opinion by affidavit, deposition, and trial testimony for plaintiff, 2016-2017.
46. Rodgers v. State of Florida, Case #1998CF274, expert opinion by affidavit for defendant, 2016-present.
47. U.S. v. State of North Carolina, North Carolina Department of Public Safety, & University of North Carolina (HB2); 1:16-CV-00425, expert opinion by affidavits, for plaintiff (DOJ, Civil Rights Division, and ACLU), 2016-2017. Case dropped by Attorney General Sessions.
48. Hicklin v. Lombardi, et al., File No. 3587.53, (Missouri Department of Corrections, Corizon),

consultant for defendants (Corizon), 2017-present.
49. U.S. v. John Patrick Price, expert opinion by affidavit for defendant (Federal Public Defender, Western NC), 2017-present.
50. Jane Does 1-5 v. Donald J. Trump, James Mattis, et al, case number 17-cv-1597, District Columbia, expert opinion by declaration for plaintiffs, 2017-present.

**PUBLICATIONS:**

1. Brown G R: Morphologic complexity and its relationship to taxonomic rates of evolution. J Undergrad Res, 3:139-168, 1978.
2. Brown G R: Stadol dependence: another case. JAMA, 254(7):910, 1985.
3. Brown G R: Letter to the Editor. Newsletter of the Ohio Psychiatric Association, 10(1):8, 1986.
4. Brown G R: Resident Rounds. Column for Newsletter of the Ohio Psychiatric Association. 10(2), 10(3), 11(1),11(2), 1986-1987.
5. Brown G R: Anorexia nervosa complicated by Mycobacterium xenopi pulmonary infection. J Nerv Ment Dis, 175(10):629-632, 1987.
6. Brown G R: Mycobacterium xenopi infection complicating anorexia nervosa. Proceedings of the 29th Annual Meeting of American College of Physicians (Air Force Regional Meeting), 22-25 March, 1987.
7. Brown G R: Buspar, a new anxiolytic. Letter to the Editor, Journal of the Ohio State Medical Association, Spring, 1987.
8. Brown G R: Transsexuals in the military: flight into hypermasculinity. Abstract. Proceedings of the 10th International Symposium on Gender Dysphoria (Amsterdam, The Netherlands) 7 June, 1987.
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**BOOK CHAPTERS:**

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2. Brown G R: Gender reassignment: Psychiatric, endocrinologic, and surgical management (with Leiter E, Futterweit W). Chapter 68. In Webster G, Kirby R, King L, Goldwasser B (eds.): Reconstructive Urology, Blackwell Scientific Publications, London, 1992.

3. Goldschmidt M, Temoshok L, Brown G R: Women and HIV/AIDS. In Niven C, Carroll D (Eds.): The Health Psychology of Women, Harwood Academic Publishers, London, 1993.

4. Brown G R, Philbrick K: Sexual and Gender Identity Disorders in the Consultation-Liaison Psychiatry Setting. In Rundell J, Wise M (Eds.): Textbook of Consultation-Liaison Psychiatry, APA Press, Washington, D.C., 1996.

5. Brown G R: Transvestism. Chapter 71, pages 1977-2000. In Gabbard G (Ed.): Treatments of Psychiatric Disorders: The DSM-IV Edition, APA Press, Washington, D.C., 1995.

6. Brown G R: Women in the Closet: Relationships with Transgendered Men. In Denny D (Ed.): Current Concepts in Cross-Gender Identity: A New Synthesis, Chapter 21, pp. 353-371, Garland Press, New York, 1998.

7. Brown G R, Kendall S, Ledsky R: Sexual Dysfunction in HIV-Seropositive Women Without AIDS. In Ross M (Ed): HIV/AIDS and Sexuality, Haworth Press, New York, 73-98, 1995.

8. Brown G R: Gender Disorders and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual, 17th (Centennial) Edition, Merck Research Labs, Rahway, N.J., 1999.

9. Brown G R: Gender Disorders and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual of Medical Information, Home Edition, Merck Research Labs, Rahway, N.J., 1997.

10. Brown G R, Philbrick K: Sexual and Gender Identity Disorders in the Consultation-Liaison Psychiatry Setting. In Rundell J, Wise M (Eds.): Concise Guide to the Textbook of Consultation-Liaison Psychiatry, APA Press, Washington, D.C., 1999.

11. Brown G R: Transvestism. In Gabbard G and Atkinson S (Eds.): Synopsis of Treatments of Psychiatric Disorders, Second Edition, APA Press, Washington, D.C., 829-836, 1996.

12. Brown G R: Transvestism and Gender Identity Disorders. . In Gabbard G (Ed.): Treatments of Psychiatric Disorders, Third Edition, APPI, Washington, D.C., Chapter 73, pages 2007-2067, 2001.

13. Brown G R, Gass G, Philbrick K: Sexual and Gender Identity Disorders in the Consultation-Liaison Psychiatry Setting. In Rundell J, Wise M (Eds.): Textbook of Consultation-Liaison Psychiatry, Second Edition, APA Press, Washington, D.C. Chapter 22, pages 455-476, 2002.

14. Brown G R, Ceniceros S: Human Sexuality in Health and Disease. In Wedding D (Ed.): Behavior and Medicine, 3rd Edition, Hogrefe & Huber, Seattle, Chapter 12, pages 171-183, 2001.

15. Brown G R: Sexuality. In Beers M (Ed): The Merck Manual of Medical Information, Home Edition, 2nd Edition, Merck Research Labs, Rahway, N.J., 2003.

16. Brown GR, Haaser RC: Sexual Disorders in the General Hospital Setting. In Levenson J (ed): Consultation-Liaison Psychiatry, American Psychiatric Press Inc., Washington, D.C., Chapter 17, pages 359-386, 2004.

17. Brown G R: Gender Disorders and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual of Medical Information, 18th edition, Chapter 203, Merck Research Labs, Rahway, N.J., 2006.

18. Rahimian J, Bergman J, Brown G R, Ceniceros S: Human Sexuality. In Wedding D and Stuber M (Ed): Behavior and Medicine, 4th Edition, Hogrefe & Huber, Seattle, Chapter 12, 2006 (currently being used as the core textbook in a number of medical school curricula, including ETSU).

19. Brown GR: Gender Disorders and Sexual Dysfunctions. The Merck Manual of Women's and Men's Health. Simon & Schuster, Pocket Books, Chapter 2, pages 21-29, 2007.

20. Brown G R: Gender Disorders and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual of Medical Information, 19th edition, Chapter 203, Merck Research Labs, Rahway, NJ, July, 2011.

21. Brown G R: Sexual Disorders. In Berkow R (Ed): The Merck Home Health Handbook, Second Edition, Chapter 135, pages 627-630, Merck Research Labs, Whitehouse Station, NJ, 2009.

22. Rahimian J, Bergman J, Brown G R, Ceniceros S: Human Sexuality. In Wedding D and Stuber M (Ed): Behavior and Medicine, 5th Edition, Hogrefe & Huber, Seattle, Chapter 12, pages 153-164, 2010 (currently being used as the core textbook in a number of medical school curricula).

23. Brown G R: Gender Dysphoria and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual of Medical Information, 20th edition, Merck Research Labs, Rahway, NJ, , on line open access textbook chapter available at: http://www.merckmanuals.com/professional/psychiatric-disorders/sexuality,-gender-dysphoria,-and-paraphilias/gender-dysphoria-and-transsexualism, 2016.

24. Brown G R: Gender Dysphoria and Sexual Dysfunctions. In Berkow R (Ed): The Merck Manual of Medical Information, Home Edition, 20th edition, Merck Research Labs, Rahway, NJ, on line open access textbook chapter available at: http://www.merckmanuals.com/home/mental-health-disorders/sexuality/gender-dysphoria-and-transsexualism, 2016.

25. Shipherd J, Kauth M, Brown GR: Implementing a Transgender Care Policy in a National Healthcare System. Chapter 13, in Shipherd J and Kauth M (Eds): Adult Transgender Care: An Interdisciplinary Approach for Training Mental Health Professionals, Routledge, in press, 2017.

**BOOK REVIEWS:**

Garner D M, Garfinkel P E (eds.): Diagnostic Issues in Anorexia Nervosa and Bulimia Nervosa. Reviewed for Journal of Nervous and Mental Diseases, 177(5):307-308, 1989.

Kanas N: Group Therapy for Schizophrenic Patients. Reviewed for Psychiatric Times, June, 1997.

**PROFESSIONAL PUBLICATIONS REVIEWED/EDITED:**

Reviewer, Journal of Clinical Psychiatry, 1987 to present
Reviewer, Psychosomatics, 1989 to present
Reviewer, Journal of AIDS, 1990 to 2001
Reviewer, Psychology and Health, 1992
Editorial Board, San Antonio M.D., 1991-1993
Reviewer, International Journal of Psychiatry in Medicine, 1994-2006
Reviewer, CNS Drugs, 1995-2002.
Reviewer, Southern Medical Journal, 1995-2013
Reviewer, AIDS Patient Care, 1996-2003
Editorial Board, International Journal of Transgenderism, 1997-present
Reviewer, Federal Practitioner, 2000-present
Reviewer, Journal of the American Geriatrics Society, 2000-2003
Reviewer, Bipolar Disorders, 2005-2017
Reviewer, Journal of Sexual Medicine, 2009-present
Reviewer, European Psychiatry, 2010-present
Reviewer, International Journal of Sexual Health, 2011-present
Reviewer, American Journal of Public Health, 2011-present
Editorial Board, LGBT Health, 2013-present
Reviewer, Canadian Medical Association Journal, 2013-present
Reviewer, Suicide and Life-Threatening Behavior, 2015-present
Editorial Board, Transgender Health, 2015-present
Reviewer, Journal of Correctional Healthcare, 2017-present
Reviewer, Breast Cancer Research and Treatment, 2017-present

**PRESENTATIONS:**

Behavioral Medicine Lecture Series, Kettering Medical Center, Kettering, Ohio. Ten parts. January 24-June 25, 1985.
"Sex Reassignment Surgery: Surgical Cure or Well-Meaning Mutilation?", Good Samaritan Hospital, Dayton, Ohio. March 5, 1985.
"The Difficult Patient: Recognition, Understanding, and Management", The Marriott Hotel, Dayton, Ohio. March 6, 1985, (Category I, CME credit).
"Transsexualism: Literature Review and Case Report", Wright State University, Dayton, Ohio. March 19, 1985.
"Pseudoseizures: When is a Jerk not a Fit?", Bergamo Conference Center, Kettering, Ohio. April 19, 1985. (Category I, CME credit).
"Transsexualism: What Sex am I?", University Center, Wright State University, Dayton, Ohio. September 17, 1985.
"Transsexualism and the Military", Good Samaritan Hospital, Dayton, Ohio. March 18, 1986.
"Clinical Utility of the House-Tree-Person Test", Diversion Program, Dayton, Ohio. April 9, 1986.
"The Silent Mitwelt", Bergamo Conference Center, Kettering, Ohio. April 18, 1986. (Category I, CME credit).
"Clinical Recognition of Alexithymia", Diversion Program, Dayton, Ohio. June 3, 1986.
"Male-to-Female Transsexualism - Case Study", Case Western Reserve University, Cleveland, Ohio. July 18, 1986.
"Zoophilia: Literature Review and Case Study", Case Western Reserve University, Cleveland, Ohio. July 31, 1986.
"Neuropsychiatry of Alexithymia", Good Samaritan Hospital, Dayton, Ohio. October 14, 1986.
"Penile Auto-Injection: New Treatment for Organic Impotence", Diversion Program, Dayton, Ohio. August 12, 1986.

"Gender Identity Development in Children and Adolescents", Diversion Program, Dayton, Ohio. August 26, 1986.
"Paraphilias", Good Samaritan Hospital Seminar, Dayton, Ohio. November 17, 1986.
"Introduction to Gender Disorders", Good Samaritan Hospital, Dayton, Ohio. December 15, 1986, January 5, 1987.
"Strategic Psychotherapy, Part I", Wright State University, Department of Psychiatry, Dayton, Ohio. December 23, 1986.
"Strategic Psychotherapy, Part II", Wright State University, Department of Psychiatry, Dayton, Ohio. December 30, 1986.
"Transsexualism: Dilemmas in Diagnosis", Good Samaritan Hospital, Dayton, Ohio. January 19, 1987.
"Transsexualism: Live Interview Presentation", Wright State University, Department of Psychiatry, Dayton, Ohio. January 20, 1987.
"Anxiety Disorders: New Treatment Approaches", Wright State University, Department of Family Practice, Dayton, Ohio. January 29, 1987.
"Gender Dysphoria", Wright State University Medical School, Dayton, Ohio. February 10, 1987.
"Bioethical Issues in Sex Reassignment", Good Samaritan Hospital, Dayton, Ohio. February 2, 1987.
"Mycobacterium xenopi Pulmonary Infection Complicated by Anorexia Nervosa", presentation at the 29th Annual Meeting of the Society of Air Force Physicians, New Orleans, Louisiana. March 23, 1987.
"The Transsexual Flight into Hypermasculinity", presentation at the Tenth International Symposium on Gender Dysphoria, Amsterdam, The Netherlands. June 10, 1987.
"Grand Rounds: Gender Disorders", Institute of Living, Hartford, Connecticut, April 30, 1987.
"Affective Disorders", three hour lecture series, Wilford Hall Medical Center, San Antonio, Texas, September, 1987.
"Grand Rounds: Transsexualism", Maine Medical Center, Portland, Maine, November 4, 1987.
"Opportunistic Infection in Anorexia Nervosa", 34th Annual Meeting of The Acadamy of Psychosomatic Medicine, Las Vegas, Nevada, November 14, 1987.
"Grand Rounds: Gender Disorders, An Overview", Wilford Hall Medical Center, San Antonio, Texas, December 17, 1987.
"Women Who Marry Transvestites", accepted for presentation at XXI Annual Meeting of AASECT, San Francisco, California, April 26, 1988 (no funding available).
"Psychiatric Manifestations of HIV Infection", Texas Medical Association Annual Session, San Antonio, Texas, May 13, 1988.
"Introduction to Gender Disorders", University of Texas Health Science Center, San Antonio, Grand Rounds, September 27, 1988.
"Transsexualism and Gender Disorders", Bexar County Psychiatric Society, San Antonio, Texas, October 18, 1988.
"Psychiatric Diagnoses in HIV-seropositive Air Force Personnel", Maine Medical Center, Portland, Maine, November 5, 1988.
"Symposium on HIV-seropositivity and Psychiatry", Program Coordinator, Behavioral Health Sciences Symposium, Sheppard AFB, Wichita Falls, Texas, November 8, 1988.
"Childhood Gender Disorders", Laurel Ridge Hospital, San Antonio, Texas, January 24, 1989.
"Prospective Study of Psychiatric Morbidity in HIV-seropositive Women", Annual Meeting of the American Psychosomatic Society, San Francisco, California, March 10, 1989.
"Psychiatric Findings in HIV-seropositive Air Force Women", Walter Reed Army Institute of Research, Bethesda, Maryland, March 31, 1989.
"Psychiatric findings in HIV-seropositive persons in a mandatory HIV screening program", (abstract and poster session, with J Rundell, S Paolucci), Fifth International Conference on AIDS, Montreal, Canada, June 5, 1989.
"Alcohol Use and HIV-seropositivity", (poster presentation, with K Drexler, J Rundell),

American Psychiatric Association Annual Meeting, San Francisco, California, May, 1989.

"Current Legal Status of Transsexualism in the Military Setting", Eleventh International Symposium on Gender Dysphoria, Cleveland, Ohio, September, 1989.

"Grand Rounds: Transsexualism in the Military", Wilford Hall Medical Center, December 14, 1989 (videotape available on request).

"Psychosexual and Gender Disorders", 6 session advanced seminar for psychiatric residents, University of Texas Health Science Center, San Antonio, January to February, 1990.

"Update on HIV Psychiatric Research in the USAF: 1990", Behavioral Health Sciences Symposium, Wichita Falls, Texas, 25 April, 1990.

"Psychiatric Morbidity in HIV-seropositive Women without AIDS", 143rd Annual Meeting of the American Psychiatric Association, New York, May 14, 1990.

"HIV Infection and Perception of Social Support", (Rundell, Ursano, Brown), 143rd Annual Meeting of the American Psychiatric Association, New York, May 14, 1990.

"Relative Frequency of HIV Disease as a Cause of Mood Disorder in a General Hospital", (Rundell, Brown), Neurological and Neuropsychological Complications of HIV Infection Conference, Monterrey, California, June 17, 1990.

"CSF Parameters, Immune Status, Serum Viral Titers, Anxiety, and Depression in HIV Disease", (Rundell, Praus, Brown), Neurological and Neuropsychological Complications of HIV Infection Conference, Monterrey, California, June 17, 1990.

"CSF Findings and Request for Psychiatric Examination in HIV-Infected Patients", (Rundell, Brown, et al.), poster presentation, Neurological and Neuropsychological Complications of HIV Infection Conference, Monterrey, California, June 17-19, 1990.

"Methods Employed by and Length of Knowledge of HIV-Seropositivity of HIV-infected Suicide Attempters", (Rundell, Brown, Kyle, et al.), 37th Annual Meeting of the Academy of Psychosomatic Medicine, Phoenix, Arizona, November 18, 1990.

"Psychiatric Morbidity in HIV-seropositive Women: Results of a Three Year Prospective Study", (Brown, Rundell, Temoshok, et al.), 37th Annual Meeting of the Academy of Psychosomatic Medicine, Phoenix, Arizona, November 16, 1990.

"Psychiatric Issues in the Evaluation of Spouses of Cross-dressers," Fairfax Hospital, Falls Church, Virginia, November 30, 1990.

"Measurement of Negative Affect in HIV-seropositive Individuals," (Jenkins, Carey, Temoshok, Brown, et al.), 12th Annual Meeting of The Society of Behavioral Medicine, Washington, D.C., March 20, 1991.

"Psychiatric and Neuropsychiatric Morbidity in Early HIV Disease," Grand Rounds presentation with S. McManis, University of Texas Health Science Center, San Antonio, Texas, April 30, 1991.

"Neuropsychiatric Impairment Early in the Course of HIV Infection," (McManis, Brown, Zachary, et al.), 7th International Conference on AIDS, Florence, Italy, June 17, 1991.

Nine presentations/new research posters/symposia presented at the 144th Annual Meeting of the American Psychiatric Association, New Orleans, Louisiana, May 11-15, 1991 (see Publications section, #50-58, for titles).

Two presentations at the 7th International Conference on AIDS, Florence, Italy, June 15-17, 1991 (see Publications section, #59-60, for titles).

"Methodological Advantages of Comprehensive Multidisciplinary Consultation-Liaison Psychiatry Research: HIV Research as a Model," (Rundell, Temoshok, Brown, et al.), Annual Meeting of the Academy of Psychosomatic Medicine, Atlanta, Georgia, October 17, 1991.

"HIV Psychiatric Research in the Air Force," Grand Rounds presentation, Mayo Clinic, Rochester, Minnesota, July 9, 1991.

"Neuropsychiatric Morbidity in early HIV Disease: Implications for Military Occupational Function," (Brown, Rundell, McManis, Kendall), Aerospace Medicine Symposium on Allergic, Immunological, and Infectious Disease Problems in Aerospace Medicine, NATO Advisory Group for Aerospace Research and

Development Conference, Rome, Italy, October, 1991; presented by J. Rundell in my absence due to lack of funding.

Four oral presentations and two poster presentations at the First International Conference on the Biopsychosocial Aspects of HIV Infection, Amsterdam, The Netherlands, 22-25 September, 1991 (see Publications section, #61-66, for titles).

"Biopsychosocial HIV Research in the U.S. Military," Invited Grand Rounds presentation, University of South Dakota School of Medicine, Sioux Falls, South Dakota, October 25, 1991.

"Biopsychosocial Issues in Treating HIV-seropositive Women," Fairfax Hospital Evening CME Lecture Series, Falls Church, Virginia, December 11, 1991.

"Psychiatric Issues in Women with HIV," Fairfax County Health Department, Falls Church, Virginia, December 12, 1991.

"Suicidality in Men with Early HIV Disease," American Psychosomatic Society 50th Annual Meeting, New York, New York, April 1, 1992.

USAF HIV "Train-the-Trainer" Course; course organizer, presenter, and comprehensive course assessment (pretest, posttests), San Antonio, Texas, April 7-9, 1992.

"Clinical Utility and Diagnostic Sensitivity of the Michigan Alcoholism Screening Test in Patients with HIV Disease," (Rundell, Brown), Annual Meeting of the Academy of Psychosomatic Medicine, San Diego, CA, October 31, 1992.

"Longitudinal Neuropsychological Findings in HIV Positive Males," (Goethe, Richie, Brown, et al), 8th International AIDS Conference, Amsterdam, The Netherlands, July 20, 1992.

"HIV and Women: Challenge for the 90's," Grand Rounds presentation, Geisinger Medical Center, Danville, PA, August 6, 1992.

"Psychosocial Dimensions of Depression in Early HIV Disease," (Jenkins R, Rundell J, Brown G, Law W, Temoshok L), Annual Meeting of the American Psychological Association, Washington, D.C., August 15, 1992.

"Psychiatric Presentations of HIV Disease," AIDS and Mental Health Program sponsored by San Antonio VA and UTHSC-SA, Corpus Christi, TX, September 18, 1992.

"Major Depression in HIV Disease Before AIDS: Clinical Features and Associated Factors," (Rundell J, Brown G, Jenkins R, Kendall S, Temoshok L), Annual Meeting of the Academy of Psychosomatic Medicine, San Diego, CA, 29 October, 1992.

"HIV Risk Behavior Surveys in the U.S. Military -- What Have We Learned?," Wilford Hall Medical Center Scientific Group Meeting, San Antonio, TX, 16 November 1992.

"Biopsychosocial Aspects of Early HIV Disease in Women," Grand Rounds, Michigan State University/St. Lawrence Hospital, Lansing, MI, 18 December 1992.

"Methodological Issues in Assessing Risk Behaviors in an HIV Sero-positive Military Sample," (Coyle C, Blake S, Brown GR, Ledsky R, Temoshok L), Special Citation Poster Presentation, Proceedings of the Fourteenth Annual Meeting of the Society of Behavioral Medicine, San Francisco, CA, March 10, 1993.

"Gender differences in transmission risk behavior, affect, and social support in HIV-positive individuals," (Nannis E, Temoshok L, Jenkins R, Blake S, Sharp E,Jenkins P, Brown G, Patterson T, Coyle C, Brandt U, Johnson C),Proceedings of the Fourteenth Annual Meeting of The Society of Behavioral Medicine, San Francisco, CA, March 10, 1993.

"Psychosocial stressors and vulnerability to psychiatric distress in early-stage HIV," (Zachary R, Brown GR, Kendall S, Coyle C, McManis S), Proceedings of the Fourteenth Annual Meeting of The Society of Behavioral Medicine, San Francisco, CA, March 10, 1993.

"Establishing databased research in an academic department of psychiatry," invited address to the Department of Psychiatry, Jefferson Medical College, College of Physicians, Philadelphia, PA, April 30, 1993.

Two Workshops, three poster sessions, 1993 Annual Meeting of the American Psychiatric Association, San Francisco, CA, May 22-24, 1993.

"Treating Depression in Early HIV Disease," Grand Rounds, Oklahoma University

School of Medicine, Oklahoma City, OK, December 1, 1993.
"Diagnosis and Treatment of Transvestism," Tulane University School of Medicine, Department of Psychiatry presentation, December 2, 1993.
"Psychiatric Disorders in Early HIV Disease," Grand Rounds, Tulane University School of Medicine, New Orleans, LA, December 3, 1993.
"Diagnosis and Treatment of Gender Identity Disorders," invited presentation at Keesler Air Force Base Medical Center, Biloxi, MS, January 13, 1994.
"Personality Disorders in HIV-positive Persons: Association with Other Measures of Psychiatric Morbidity," poster presentation, (Richards J, McManis S, Brown G), Annual Meeting of the American Psychiatric Association, Philadelphia, PA, May 23, 1994.
"Psychiatric Issues in HIV/AIDS," invited presentation, Huntsville Mental Health Community, Huntsville Space and Science Center, Huntsville, AL, November 12, 1994.
"Diagnosis and Treatment of Gender Identity Disorders," Grand Rounds, Tulane University School of Medicine, New Orleans, LA, April 29, 1994.
"Management of Depression in Early HIV Disease," Upper East Tennessee Psychiatric Association Meeting, Kingsport, TN, June 2, 1994.
"Sertindole in the Treatment of Chronic Schizophrenia: a Phase III Controlled Trial," Grand Rounds, East Tennessee State University, Johnson City, TN, September 30, 1994.
"New Onset of Sexual Dysfunction in HIV-seropositive Women: Results of a Prospective Study," 88th Annual Scientific Assembly of the Southern Medical Association, Orlando, Florida, November 3, 1994.
"Gender Identity Disorders in the VAMC Setting," Grand Rounds, Atlanta VAMC, December 13, 1994.
"Managing Depression in Early Stage HIV Disease," Grand Rounds, Salem VAMC, December 22, 1994.
"Biopsychosocial Aspects of HIV Disease in Men," Invited Speaker, Mississippi Pharmacists Association MidWinter Meeting, Jackson, MS, February 12, 1995.
"Biopsychosocial Aspects of HIV Disease in Men," Invited Speaker, Mississippi Pharmacists Association MidWinter Meeting, Oxford, MS, February 19, 1995.
"Biopsychosocial Aspects of HIV Disease in Women," Grand Rounds, East Tennessee State University, Johnson City, TN, March 17, 1995.
"Managing Insomnia," primary care provider educational meeting, Bristol, TN, May 22, 1995.
"Diagnosis and Treatment of Gender Identity Disorders: DSM-IV Approach," Grand Rounds, Geisinger Medical Center, Danville, PA, June 15, 1995.
"Psychosocial Characteristics of 739 Transgendered Men," (Brooks G, Brown GR, Askew J), 41st Annual Meeting of the Southeastern Psychological Association, Savannah, GA, March 12, 1995.
"Personality Characteristics and Sexual Functioning of 188 American Transgendered Men: Comparison of Patients with Nonpatients." 14th Harry Benjamin International Gender Dysphoria Symposium, Irsee/Ulm Germany, September 9, 1995.
"Sertindole HCl: A Novel Antipsychotic With a Favorable Side Effect Profile." 89th Scientific Assembly of the Southern Medical Association, Kansas City, Missouri, November 17, 1995.
"Long term Safety of Treatment with Sertindole, a Novel Antipsychotic." (Radford M, Brown GR, Matthew H) poster, 89th Scientific Assembly of the Southern Medical Association, Kansas City, Missouri, November 17, 1995.
"Diagnosis and Newer Treatments for Schizophrenia." Invited Presentation. Central Appalachia Services, Kingsport, TN, December 7, 1995.
"Personality and Sexuality in Transvestism." Grand Rounds, University of Texas Health Sciences Center, San Antonio, Texas, December 12, 1995.
"HIV/AIDS and Sexuality." Grand Rounds, Wilford Hall Medical Center, San Antonio,

Texas, December 14, 1995.
"How Research Can Enhance Your Career." Invited Presentation to Department of Psychiatry, Wilford Hall Medical Center, San Antonio, Texas, December 13, 1995.
"Conducting Research With Stigmatized Populations." Journal Club Presentation, University of Texas Health Sciences Center, Department of Psychiatry, San Antonio, Texas, December 12, 1995.
"Sexuality in HIV/AIDS." Grand Rounds, Bowman Gray Medical School, Department of Psychiatry, Wake Forest University, Winston-Salem, North Carolina, January 19, 1996.
"Gender Identity Disorders." Grand Rounds, Lakeshore Mental Health Institute, Knoxville, Tennessee, February 14, 1996.
"New Approaches to the Management of Schizophrenia," Helen Ross McNabb Center, Knoxville, Tennessee, February 14, 1996.
"Diagnosis and Management of Gender Dysphoria," Grand Rounds, University of Alabama at Birmingham, March 5, 1996.
"Depression and Primary Care," Morristown, TN Primary Care Provider's CE Group, Morristown, TN, June 27, 1996.
"Personality and Sexuality in Transgendered Men," paper presentation, American Psychological Association, Toronto, Canada, August 13, 1996.
"Gender Identity Disorders," paper presentation at Southern Psychiatric Association Annual Meeting, Santa Fe, New Mexico, September 25, 1996.
"Sleep Disorders," Grand Rounds, Salisbury VAMC, Salisbury, North Carolina, August 21, 1996.
"Depression in Primary Care Settings," Nurse Practitioner-Physician Assistant Association of Northeast Tennessee, Johnson City, Tennessee, September 11, 1996.
Visiting Professorship, Menninger Clinic and Foundation; included Grand Rounds, case presentation and discussion, meetings with residents and staff; Topeka, KS, October 10-11, 1996.
"New Approaches to the Treatment of Schizophrenia," Grand Rounds, Lakeshore Mental Health Institute, Knoxville, Tennessee, October 30, 1996.
"HIV Disease in Women: Sexual Manifestations," symposium presentation at Academy of Psychosomatic Medicine Annual Meeting, San Antonio, Texas, November 14, 1996.
"HIV and Sexuality," Grand Rounds, Atlanta VAMC/Emery University, Atlanta, Georgia, December 3, 1996.
"Santa Claus is a Cross-Dresser (and so are his little elves)," invited address for the Upper East Tennessee Psychiatric Association, a component of the Tennessee District Branch of the American Psychiatric Association, Johnson City, TN, December 9, 1996.
"Depression and Sexuality," Tazewell County Medical Society, Richlands, Virginia, March 25, 1997.
"Identifying and Treating Depression in Primary Care," Annual Meeting of the Nurse Practitioner's and Physician's Assistants of East Tennessee, Johnson City, TN, March 25, 1997.
"Managing Sexual Side Effects of Antidepressant Treatment," Harlan County Medical Society, Harlan, Kentucky, March 11, 1997.
"Depression and Intimacy," Chatanooga Psychiatric Society, Chatanooga, TN, April 21, 1997.
“Depression and Sexuality,” Lakeshore Mental Health Institute Grand Rounds, Knoxville, TN, April 9, 1997.
“Managing Sexual Side Effects of Antidepressants,” Southern Highlands Pharmacist’s Society, Abingdon, Virginia, April 29, 1997.
“Transgendered Families,” Lakeshore Mental Health Institute Grand Rounds, Knoxville, TN, April 30, 1997.
“Depression and Intimacy,” Buchanan County Medical Society, Grundy, VA, May 8, 1997.
“Depression, Sexuality, and Treatment,” Highlands Psychiatric Society, Abingdon, VA, May 9, 1997.

"Managing Sexual Side Effects of Antidepressants in Primary Care," Chatanooga Family Practice Association, Chatanooga, TN, May 20, 1997.
"Double Trouble: Depression and Anxiety in Primary Care," LeFlore County Medical Center, Greenwood Mississippi, May 29, 1997.
"HIV and Sexuality," ETSU Medicine and Sexuality Symposium, Johnson City, TN, June 13, 1997.
"Depression and Sexuality," ETSU Medicine and Sexuality Symposium, Johnson City, TN, June13, 1997.
"Transgenderism," Grand Rounds, Overlook Mental Health Center, Knoxville, TN, June 25, 1997.
"Managing Sexual Side Effects of Antidepressants in Primary Care," Wise County Medical Society, Norton, Virginia, July 11, 1997.
"APA Guideline on the Treatment of Schizophrenia," Smoky Mountain Chapter of the Tennessee Psychiatric Association, Knoxville, TN, July 22, 1997.
"Nicotine Dependence: Kicking the Habit," August Monthly Meeting of the Tricities Nurse Practitioner-Physician Assistants Association, Johnson City, TN, August 14, 1997.
"Biopsychosocial Issues in Women with HIV Disease," Monthly Meeting of OB-GYN Society of Tricities, Johnson City, TN, August 26, 1997.
"Revision of the HBIGDA Standards of Care: Opportunities and Controversies," Biannual Meeting of the Harry Benjamin International Gender Dysphoria Association, Vancouver, British Columbia, Canada, September 11, 1997.
"Anxiety and Depression in Primary Care: Double Trouble," Primary Care Grand Rounds, Fort Campbell, KY, October 1, 1997.
"Treatment Guidelines for Schizophrenia," Psychiatry Grand Rounds, Lexington VAMC, Lexington, KY, September 17, 1997.
"Gender Dysphoria in the Military Setting," Grand Rounds, Wilford Hall Medical Center, San Antonio, TX, December 18, 1997.
"Clinical Issues in Transgendered Families," Grand Rounds, University of Texas Health Sciences Center, San Antonio, December 16, 1997.
"Depression and Sexuality," Southwest Virginia Counsel of Nurse Practitioners, Abingdon, Virginia, November 1, 1997.
"Depression and Anxiety Disorders in Primary Care," Annual Meeting of the Nurse Practitioner Physician Assistant Association of Northeast TN, Johnson City, TN, February 23, 1998.
"Differentiating SSRI's in Clinical Practice," Richmond Psychiatric Society Meeting, Richmond, VA, January 22, 1998.
"Gender Identity Disorders," Grand Rounds, University of VA, Roanoke, VA, February 19, 1998.
"Smoking Cessation: Modern Approaches," Monthly Meeting of the East TN Hospital Pharmacists Association, Kingsport, TN, February 24, 1998.
"Identification and Treatment of Gender Dysphoria Syndromes," Grand Rounds, University of Mississippi, Jackson, MS, February 27, 1998.
"Gender Dysphoria Syndromes in Primary Care," Nurse Practitioner Physician Assistant Association of Northeast TN, Kingsport, TN, March 19, 1998.
"Treatment Guidelines for Schizophrenia," Grand Rounds, University of Kentucky, Louisville, KY, April 23, 1998.
"Gender Identity Disorders," Grand Rounds, University of Alabama at Huntsville, Huntsville, AL, May 21, 1998.
"Nicotine Reduction Strategies," Grand Rounds, Southwest Virginia Mental Health Institute, Marion, VA, May 27, 1998.
"Depression and Anxiety Management in Primary Care," East Tennessee State University Dept. of Psychiatry Symposium on "Psychiatry in the Trenches", Johnson City, TN, June 12, 1998.
"Managing Depression in Primary Care," Grand Rounds, Internal Medicine Department, East Tennessee State University, Johnson City, TN, June 16, 1998.

"Mood Disorders in Women," Roanoke Psychiatric Society, Roanoke, VA, June 17, 1998.
"Gender Identity Disorders," Grand Rounds, Loyola University Strich School of Medicine, Chicago, IL, June 18, 1998.
"Standards of Care for Gender Identity Disorders," Grand Rounds, University of Louisiana, Baton Rouge, LA, July 21, 1998.
"Depression and Sexuality," Fall Symposium of the Mental Health Association of Knoxville, September 11, 1998.
"Pharmacotherapy of Agitation in the Elderly," Kentucky Pharmacists' Association, Lexington, Kentucky, September 20, 1998.
"Women and Mood/Anxiety Disorders," monthly meeting of the Nurse Practitioners-Physician Assistants, Johnson City, TN, October 1, 1998.
"Killing the Bore: How to Give Effective Medical Presentations That Keep an Audience Awake," Grand Rounds, ETSU Dept. of Psychiatry, Johnson City, TN, October 16,1998.
"Pharmacologic Management of Agitation in the Elderly," Detroit Psychiatric Society, Detroit, Michigan, December 22, 1998.
"Nicotine Dependence: Kicking the "Habit," Wise County Medical Society, Wise, Virginia, January 14, 1999.
"Mood Disorders in Women," Chatanooga Psychiatric Society, Chatanooga, TN, January 18, 1999.
"From Menarche to Menopause: Mood and Anxiety Disorders in Women," Greene County Medical Society, Greeneville, TN, February 2, 1999.
"From Menarche to Menopause: Mood and Anxiety Disorders in Women," Annual Meeting of the TriCities Nurse Practitioner-Physician Assistant Association, Johnson City, TN, February 23, 1999.
"Comparison of Risperidone and Olanzapine: RIS-112 Study," Upper East TN Psychiatric Society, Johnson City, TN, March 4, 1999.
"New Directions in Treating Schizophrenia," CME, Inc. sponsored faculty member, Los Angeles, California, March 27, 1999.
"Pharmacologic Management of Agitation in Dementia," University of Alabama Pharmacotherapeutics Conference, Huntsville, AL, April 24, 1999.
"Mood and Anxiety Disorders in Women," University of Alabama Pharmacotherapeutics Conference, Huntsville, AL, April 24, 1999.
"Behavioral Problems in Dementia," Grand Rounds, Alvin York VAMC, Murfreesboro, TN, April 29, 1999.
Pharmacological Management of Agitation in Dementia," Grand Rounds, Lakeshore Mental Health Institute, Knoxville, TN, May 7, 1999.
"Psychiatric Disorders in Women," Women's Health Symposium, University of Alabama, Huntsville, AL, May 14, 1999.
"Loxitane: A New Look at an Old Drug," Lakeshore Mental Health Institute, Knoxville, TN, June 4, 1999.
"Psychiatric Disorders in Women," University of Tennessee at Knoxville, OB-GYN Grand Rounds, June 4, 1999.
"Working With Transgendered Clients," workshop presented at A Search for New Understanding of Lesbian, Gay, and Bisexual Issues, East Tennessee State University, Johnson City, TN, September 24, 1999.
"Optimizing Treatment for Schizophrenia", CME, Inc. Symposium, Cleveland, Ohio, September 25, 1999.
"Diagnosis and Treatment of Depression in Primary Care," Grand Rounds, James H. Quillen VA Medical Center-ETSU Department of Medicine, Johnson City, TN, September 28, 1999
"Gender Identity Disorder," Annual Meeting of the Southern Psychiatric Association, Hot Springs, Virginia, September 30, 1999.
"Management of Insomnia," Annual Meeting of the Tennessee Association of Physicians' Assistants, Gatlinburg, TN, October 12, 1999.
"Sexual Dysfunction in Primary Care Practice," Behavioral Health in Primary Care Symposium,

East Tennessee State University, Johnson City, TN, October 16, 1999.
"Management of Insomnia: New Directions," monthly meeting of the Upper East Tennessee Psychiatric Association, Bristol, TN, October 19, 1999.
"Depression and Anxiety in Women Through the Life Cycle," Johnson City Women's Health Center Grand Rounds, Johnson City, TN, October 27, 1999.
"Selecting Antidepressant Treatment," invited presentation and panel discussion, New Orleans Academy of Internal Medicine, January 10, 2000.
"Managing Insomnia in Primary Care," Grand Rounds, Holston Valley Medical Center, Kingsport, TN, January 31, 2000.
"Gender Identity Disorders." Grand Rounds, University of Cincinnati, Cincinnati, OH, January 26, 2000.
"Selecting Antidepressants in Primary Care, " Rural Health Cooperative, Kingsport, TN, February 7, 2000.
Visiting Professor, Loyola University Medical School, Chicago, IL (two presentations), February 10, 2000.
"Managing Insomnia in the New Millennium," Annual Meeting of the East TN Nurse Practitioner's and Physicians' Assistants Association, Johnson City, TN, February 22, 2000.
"Sexual Dysfunction in Primary Care," Annual Meeting of the East TN Nurse Practitioner's and Physicians' Assistants Association, Johnson City, TN, February 22, 2000.
"Depression and PTSD in Women," Grand Rounds, Department of OB-GYN, University of Tennessee, Knoxville, March 17, 2000.
"Depression and Anxiety in Primary Care Practice," Grand Rounds, Department of Internal Medicine, University of Tennessee, Knoxville, March 16, 2000.
"Diabetes, Glucose Regulation, and Schizophrenia," Upper East Tennessee Psychiatric Society, Johnson City, TN, April 13, 2000
"Sexual Dysfunction in Primary Care Practice," Annual Meeting of the Tennessee Osteopathic Medicine Association, Chatanooga, TN, May 7, 2000.
"Diabetes, Weight Gain, and Schizophrenia," Grand Rounds, Lakeshore Mental Health Institute, Knoxville, TN, July 20, 2000.
"Bipolar Disorder: Monotherapy versus Combination Therapy", national CME Category I lecture series sponsored by Medical Education Resources and Curry, Martin, and Schiavelli, to 17 cities between May and November, 2000.
"Managing Depression and Anxiety Disorders," invited presentation to the Annual Meeting of the Tennessee Academy of Family Practice, Jackson, TN, August 19, 2000.
"Managing Insomnia," monthly meeting of the Tazwell County Medical Society, Richlands, Virginia, August 23, 2000.
"Sexual Dysfunction," Grand Rounds, ETSU Department of OB/GYN, Johnson City, TN, September 6, 2000.
"Depression and Sexuality," Grand Rounds, Holston Valley Hospital, Bristol, TN, September 25, 2000.
"Depression and Anxiety in Primary Care: Case Conference/Grand Rounds," Southern Medical Association Annual Meeting, Orlando, Florida, November 2, 2000.
"Depression in Primary Care Settings," Hamblen County Medical Society, Morristown, TN, November 21, 2000.
"Sleep Disorders," Nurse Practitioners-Physicians Assistant Association Monthly Meeting, Johnson City, TN, December 7, 2000.
"CD-ROM Workshop, Anxiety and Depression", Annual Meeting of the Holston Valley Nurse Practitioners-Physicians Assistants Association, Johnson City, TN, February 26, 2001.
"The Harry Benjamin Standards of Care in Prison: Benefits for Transsexual Healthcare," International Foundation for Gender Education Annual Symposium, Chicago, Il, March 24, 2001.
"Why Internists Should Care About Treating Depression," Grand Rounds, Department of Internal Medicine, ETSU, Johnson City, TN, April 3, 2001.
"Antidepressants: Effective Side Effect Management," Annual Meeting of the Tennessee Osteopathic Medicine Association, Memphis, TN, April 21, 2001.
"Gender Identity Disorder: Management," invited presentation, Smokey Mountain Chapter of the

Tennessee Psychiatric Association, Knoxville, TN, April 24, 2001.
"Gender Identity Disorder," Grand Rounds, Department of Psychiatry, Memphis VAMC, May 24, 2001.
"Antipsychotic Efficacy Uncompromised by Side Effects," Grand Rounds, Department of Psychiatry, UT Memphis, May 25, 2001.
"Sexual Dysfunctions in Primary Care," International Medical Update Symposium, Johnson City, TN, August 2, 2001.
"Diagnosis and Treatment of Gender Dysphoria," Grand Rounds, Department of Psychology, James H. Quillen VAMC, August 3, 2001.
"Management of Bipolar Disorder," Grand Rounds, Meharry Medical College, Nashville, TN, August 21, 2001.
"Medical Treatment of Agitation in Dementia," Fall Symposium of the Mental Health Association of Knoxville, September 13, Knoxville, TN.
"Monotherapy vs. Combination Therapy in the Management of Mania," Fall Symposium of the Mental Health Association of Knoxville, September 14, Knoxville, TN
"Optimizing Treatment for Bipolar Disorder," quarterly meeting of the Upper East Tennessee Psychiatric Association, Johnson City, TN, September 20, 2001.
"Gender Identity Disorders: Diagnosis and Management," Grand Rounds, Institute of Living/Hartford Hospital Departments of Psychiatry and Psychology, Hartford, CT, October 17, 2001.
"Gender Identity Disorder Complicated by Dissociative Identity Disorder: Report of a Successful Case," XVII Symposium of the Harry Benjamin International Gender Dysphoria Association, Galveston, TX, November 3, 2001.
"Mood Disorders in Women," monthly meeting of the TriCities Nurse Practitioners Association, Johnson City, TN, December 10, 2001.
"Substance Use Disorders Complicating Common Psychiatric Disorders," Grand Rounds, Holston Valley Hospital, Bristol, TN, December 18, 2001.
"Women's Health Issues in Psychiatry," OB-GYN Grand Rounds, East Tennessee State University, Johnson City, TN, May 8, 2002.
"Matching the Neurotransmitter to the Patient," ½ day CME presentation, World Medical Conferences, Jackson, Mississippi, May 18, 2002.
"Matching the Neurotransmitter to the Patient," ½ day CME presentation, World Medical Conferences, Albany, New York, June 1, 2002.
"Killing the Bore: How to Give Effective Medical Presentations That Keep People Awake," Grand Rounds, Dept. of Psychiatry, ETSU, Johnson City, TN, August 9, 2002.
"Current Issues in Treatment of Dementia," Roanoke Psychiatric Society, Roanoke, VA, June 26, 2002.
"Comfort Foods: Should We Just Surrender Now?," Northeast Tennessee Nurse Practitioner's Association Annual Meeting, Bristol, TN, September 14, 2002.
"Gender Identity Disorders: Diagnosis and Management," Psychiatry Grand Rounds, University of Florida, Gainesville, Florida, September 20, 2002.
"Gender Identity Disorders: Diagnosis and Management," Psychiatry Grand Rounds, Meharry Medical College, Nashville, TN, October 9, 2002.
"New Issues in the Management of Bipolar Disorder," Grand Rounds, Lakeshore Mental Health Institute, Knoxville, TN, October 5, 2002.
"Pharmacological Management of Dementia," Psychiatry Grand Rounds, Western State Hospital, Staunton, Virginia, March 19, 2003.
"Appropriate Use of Antipsychotics in Primary Care Practice," Tricounty Medical Society Meeting, Johnson City, TN, April 3, 2003.
"Appropriate Use of Antipsychotics in Primary Care Practice," 2003 Primary Care Conference, Johnson City, TN, April 1, 2003.
"Pharmacological Management of Dementia," Grand Rounds, Gaston Memorial Hospital, Gastonia, NC, May 13, 2003.
"Brown G R, McBride L, Williford W, Bauer M: Impact of childhood sexual abuse on bipolar disorder. Proceedings of the 5th International Conference on Bipolar Disorders, Pittsburgh, PA, 2003 (poster presented by Dr. Bauer in my absence).

"Aripiprazole Use in Psychiatry," Grand Rounds, Lakeshore Mental Health Institute, Knoxville, TN, August 22, 2003.
"Use of Anticonvulsants in Psychotic Disorders," Tennessee Psychiatric Association, Smoky Mountain Chapter Meeting, Knoxville, TN, August 28, 2003.
"Application of the Harry Benjamin International Gender Dysphoria Association's Standards of Care to the Prison Setting: Recent Victories for Transgender Healthcare in the USA," 18th Biennial Symposium of the HBIGDA, Gent, Belgium, September 11, 2003.
"Family and Systems Aggression Towards Therapists Working with Transgendered Clients," 18th Biennial Symposium of the HBIGDA, Gent, Belgium, September 12, 2003.
"Impact of Childhood Abuse on Disease Course in Veterans with Bipolar Disorder," 97th Annual Meeting of the Southern Medical Association, Atlanta, Georgia, November 8, 2003.
"Gender Dysphoria: Diagnosis and Management," Grand Rounds presentation, Marshall Medical School, Huntington, West Virginia, January 9, 2004.
"Gender Dysphoria: Diagnosis and Management," Grand Rounds presentation, Catawba State Hospital, Roanoke, Virginia, March 17, 2004.
"Treatment Resistant Schizophrenia," Grand Rounds presentation, Broughton State Hospital, Morganton, North Carolina, March 25, 2004.
"Antipsychotic Use in Geriatric Populations," Grand Rounds presentation, Tampa VAMC, Tampa, Florida, April 23, 2004.
"Gender Identity Disorders,", Grand Rounds presentation, University of TN College of Medicine, Memphis, TN, May 14, 2004.
"Overcoming Barriers to Treatment Success in Chronic Mental Illnesses," Grand Rounds, Salisbury VAMC, Salisbury, NC, June 3, 2004.
"Dissociative Identity Disorder Comorbid with Gender Identity Disorder: Review of the Literature and Long-term Case Presentation," Southern Psychiatric Association, Savannah, Georgia, October 2, 2004.
"Bipolar Disorder in Primary Care," CME Cat 1 presentation, Knoxville, TN, December 1, 2004.
"Bipolar Disorder and Impulsive Aggression in Primary Care Settings," CME Cat 1 presentation to Tricities Nurse Practitioner Association, December 16, 2004.
"Overcoming Barriers to Treatment in Chronic Mental Illnesses," North Carolina Advanced Practice Nurses Association, Greensboro, NC, February 13, 2005.
"Bipolar Disorder in the Primary Care Setting: What to do?," 9th Annual Update for Nurse Practitioners, Johnson City, TN, March 21, 2005.
"Current Controversies in the Use of SSRI's," TriCounty Medical Society, Johnson City, TN, May 5, 2005.
"Transgender client aggression towards therapists," XIX Biennial Symposium of the Harry Benjamin International Gender Dysphoria Association, Bologna, Italy, April 9, 2005.
"Gender identity disorder comorbid with dissociative identity disorder: review of the literature and 7 year followup case presentation. XIX Biennial Symposium of the Harry Benjamin International Gender Dysphoria Association, Bologna, Italy, April 9, 2005.
"Current Controversies in the Use of SSRI's," CME symposium, Southern Medical Association 9th Annual Scientific Symposium, San Antonio, TX, November 12, 2005.
"Gender Identity Disorder: Diagnosis and Management,", Grand Rounds, University of South Florida, Tampa, Florida, January 6, 2006 (Videotaped version of presentation available at www.TheCJC.com).
"Gender Identity Disorders," East Tennessee State University Women's Health Program, CME Cat 1 symposium, Johnson City, TN, March 24, 2006.
"Update on Bipolar Disorder," Millennium Center, CME Cat I program, Johnson City, TN, March 31, 2006.
"Dealing with Chronic Mental Illness: Barriers to Treatment Success," Southside Virginia Psychiatric Society Quarterly Meeting, Richmond, Virginia, April 3, 2006.
"Management of Gender Identity Disorders," Intermountain Psychological Association, invited presentation, Johnson City, TN, June 8, 2006.
"Transgender Health Issues," Emory and Henry Lyceum Series, Emory, Virginia, September 18, 2006.
"Impact of Childhood Abuse in Veterans with Bipolar Disorder," 65th Annual Scientific Meeting of

the Southern Psychiatric Association, Baltimore, Maryland, September 29, 2006.

"Appropriate Use of Antipsychotics in Primary Care Settings," 100th Annual Meeting of the Southern Medical Association, Charlotte, NC, October 14, 2006.

"Impact of Childhood Abuse on the Course of Bipolar Disorder," Keynote speaker, Perspectives In Health, Texas Department of State Health Services Annual CME Symposium, Austin, Texas, October 27, 2006.

"Autocastration as Surgical Self-Treatment in Incarcerated Persons with Gender Identity Disorder," Southern Psychiatric Association Annual Meeting, Memphis, TN, August, 2007.

"Autocastration as Surgical Self-Treatment in Incarcerated Persons with Gender Identity Disorder," XX Biennial Symposium of the World Professional Association for Transgender Health, Chicago, Illinois, September, 2007.

"Gender Identity Disorders in the Military and VA," Panel discussion and presentation. XX Biennial Symposium of the World Professional Association for Transgender Health, Chicago, Illinois, September, 2007.

"Diagnosis and Treatment of Gender Identity Disorders," Mountain Update on Psychiatry, ETSU CME Symposium, October 19, 2007.

"Voice Parameters That Result in Identification or Misidentification of Biological Gender in Male-to-Female Transgender Veterans," poster presentation at the First Annual Gender Spectrum Health Fair, Sponsored by the Alliance for Gender Awareness, Inc and Rutgers Office of Social Justice Education LGBT Communities Rutgers University College, New Brunswick, NJ, November 8, 2007 (with R King et al, coauthors).

"Voice Parameters That Result in Identification or Misidentification of Biological Gender in Male-to-Female Transgender Veterans," poster presentation at the XX Biennial Symposium of the World Professional Association for Transgender Health, Chicago, Illinois, September, 2007 (with R King, et al, coauthors).

"Voice Parameters That Result in Identification or Misidentification of Biological Gender in Male-to-Female Transgender Veterans," poster presentation at the Southern Medical Association Annual Scientific Meeting, Nashville, TN, September, 2008 (presented by E McDuffie on behalf of Brown, King, et al, coauthors).

"Evaluation and Management of Gender Identity Disorders," Cat I, 1.5 hour CME program, Annual Meeting of the Alaska Psychiatric Association, Alyeska, Alaska, April 18, 2009.

"Forensic Issues and Case Presentations on GID," Cat I, 1.5 hour CME program, Annual Meeting of the Alaska Psychiatric Association, Alyeska, Alaska, April 18, 2009.

“70 Veterans with Gender Identity Disturbances: A Descriptive Study,” XXI Biennial Symposium of the World Professional Association for Transgender Health, Oslo, Norway, June 18, 2009.

“70 Veterans with Gender Identity Disturbances: A Descriptive Study”, Annual Scientific Meeting of the Southern Medical Association, Dallas , Texas, December 4, 2009.

“Overview of Autocastration and Surgical Self Treatment in Prisons”, National Commission on Correctional Healthcare Annual Meeting, October 10, 2010, Las Vegas, Nevada (invited two hour CME CAT I program)

“Autocastration- Overview and Case Series Presentation,” Grand Rounds, East Tennessee State University, Johnson City, TN, April 29, 2011.

“Providing Healthcare for Transgender and Intersex Veterans,” Live Meeting Series broadcast nationally by VA Talent Management System. Co-Presenters Leonard Pogache, MD, Meri Mallard, RN; CME category I credit for each of 3 programs completed, November 22 (2 programs) and November 30, 2011.

“PBM Guidelines for Providing Care for Transgender and Intersex Veterans,” copresenter with Lisa Longo, Pharm.D, Live Meeting Series broadcast nationally by VA Talent Management System, May 10 and May 14, 2012.

“Providing Culturally Competent Care for Transgender Veterans,” invited Keynote address at Houston VAMC for symposium (CEU accredited) on LGBT Veteran healthcare, Houston, TX, August 17, 2012.

“Update on Version 7 of the WPATH Standards of Care,” invited Keynote address for Mountain Area Health Education Center’s Southeastern Summit on Transgender Healthcare,

Category 1 CME accredited, Asheville, NC, August 24, 2012.

"History of Transgender Healthcare in the Department of Veterans Affairs," invited Keynote address for Mountain Area Health Education Center's Southeastern Summit on Transgender Healthcare, Category 1 CME accredited, Asheville, NC, August 25, 2012.

"Qualitative Analysis of Transgender Inmates' Correspondence: Implications for health Services in Departments of Correction", National Commission on Correctional Healthcare Annual Meeting, October 14, 2012, Las Vegas, Nevada (invited one hour CME CAT I program).

"Cross Sex Hormonal Treatment for Transgender Veterans," national Live Meeting for Women's Health Program, Department of Veterans Affairs, July 16, 2013.

"Transgender Health Care Training for VA Health Care Providers", 3 hours Category 1 CME accredited , Minneapolis, MN, September 26, 2013.

"Sex Reassignment Options", national presentation to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, July 2, 2013.

"Access to Care for Gender Dysphoric Inmates: Issues and Cases," Invited plenary speaker for the 21st Annual Forensic Rights and Treatment Conference, sponsored by Drexel University College of Medicine, Category 1 CME credit (1.5 hours), Harrisburg, PA, December 5, 2013.

"Forensic Aspects of Transgender Health Care in Prison," Grand Rounds, East Tennessee State University, Category 1 CME, March 7, 2014.

"Health Disparities Research: Suicidality in Gender Minorities as a Research Model," Grand Rounds, East Tennessee State University, Category 1 CME credit, May 20, 2014.

"Sex reassignment surgeries: female-to-male," national presentation to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, Cat I CME, June 24, 2014.

"Sex reassignment surgeries: male-to-female," national presentation to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, Cat I CME, July 8, 2014.; December 2, 9, 16, 23, 2014; February 24, 20-15.

"Medico-Legal Aspects of Providing Transgender Healthcare for Inmates," invited 2.5 hour presentation for national training program in LGBT healthcare for the Federal Bureau of Prisons, September 4, 2014.

"Mental health and medical outcome disparities in 5,135 transgender veterans: a case-control study," 32nd Annual Conference of the Gay and Lesbian Medical Association, Category 1 CME credit, Baltimore, MD, September 11, 2014.

"Mental health and medical outcome disparities in 5,135 transgender veterans: a case-control study," Vanderbilt University Grand Rounds, Department of Psychiatry, Cat 1 CME credit, Nashville, TN, September 26, 2014.

"Mental health and medical outcome disparities in 5,135 transgender veterans: a case-control study," Drexel University Grand Rounds, Department of Psychiatry, Cat 1 CME credit, Philadelphia, PA, October 23, 2014.

"Pharmacotherapy issues with gender dysphoria," College of Psychiatric and Neuropsychiatric Pharmacists, Annual Meeting, Cat I CME credit, Tampa, FL, April 19, 2015.

"Lesbian, gay, bisexual, and transgender (LGBT) sociopolitical indicators and mental health diagnoses among transgender Veterans receiving VA care. Blosnich, J.R., Marsiglio, M.C., Gao, S., Gordon, A.J., Shipherd, J.C., Kauth, M., Brown, G.R., Fine, M.J. (2015, July). Department of Veterans Affairs Health Services Research & Development/Quality Enhancement Research Initiative National Conference, Philadelphia, PA, July, 2015.

"Killing the Bore: How to Give Effective Medical Presentations," East Tennessee State University Department of Psychiatry and Behavioral Sciences Grand Rounds (Cat I CME), May 1, 2015.

"Sex reassignment surgeries: male-to-female," national presentation to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health

consultations, Cat I CME, July 21, July 28, 2015

"Sex reassignment surgeries: female-to-male," national presentation to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, Cat I CME, September 15, September 22, 2015.

"Transgender military service: Moving past ignorance in DoD and VHA," invited Keynote Address, Rush Medical University, Cat I CME credit, Chicago, IL, October 9, 2015.

"Health correlates of criminal justice involvement in 4,793 transgender veterans. Poster Presentation at the Annual National Conference on Correctional Health Care, Denver, CO, October 18, 2015.

"Open Transgender Military Service: Health Considerations," presentation to medical leadership of the USMC, Washington, DC, by videolink, January 27, 2016.

"Sex reassignment surgeries; masculinizing and feminizing," national presentations to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, Cat I CME, June 7 and 28, 2016.

"Orange is not the new black—yet," Symposium on prison transgender mental health care and update on recent court cases supporting access to transgender health care in US prisons, 24th Biennial Scientific Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, Cat I CME (1.5 hours), June 20, 2016.

"Harry Benjamin Plenary Lecture," invited Keynote address for the 24th Biennial Scientific Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, Cat 1 CME, June 18, 2016. Available at www.wpath2016.com, timer marker 4:20.

"Health correlates of criminal justice involvement in 4,793 transgender veterans. Poster Presentation at the 24th Biennial Scientific Symposium of the World Professional Association for Transgender Health, Amsterdam,The Netherlands, Cat I CME, June 18, 2016.

"Breast cancer in a cohort of 5,135 transgender veterans over time," 24th Biennial Scientific Symposium of the World Professional Association for Transgender Health, Amsterdam, The Netherlands, Cat 1 CME, June 20, 2016.

"Impact of social determinants of health on medical conditions among transgender Veteran," Blosnich J, Marsiglio M, Dichter M., Gao S., Gordon M, Shipherd J, Kauth M, Brown G, Fine M. VA HSR&D Field-Based Meeting to Engage Diverse Stakeholders and Operational Partners in Advancing Health Equity in the VA Healthcare System. Philadelphia, PA, September, 2016

"Current and past military context and overview of transgender military service," Caring for Transgender Persons in a Changing Environment, Walter Reed National Military Medical Center and Uniformed Services University of the Health Sciences, Bethesda, MD, Cat I CME, 13 September, 2016.

"State of the Science: Current VHA research findings, policies, and transgender health care delivery model," Caring for Transgender Persons in a Changing Environment, Walter Reed National Military Medical Center and Uniformed Services University of the Health Sciences, Bethesda, MD, Cat I CME, September 13, 2016.

"Social determinants of health and their associations with medical conditions among transgender veterans," presented by first author John Blosnich, Ph.D., Field-Based Meeting to Engage Diverse Stakeholders and Operational Partners in Advancing Health Equity in the VA Healthcare System, Philadelphia, PA, September 20, 2016.

"Update on the Mountain Home Transgender Veteran Research Protocol," Grand

Rounds, East Tennessee State University, Johnson City, TN, Cat 1 CME, September 23, 2016.

"History of transgender people in the military," Southeastern Transgender Health Summit 2016 Overcoming Barriers, Mountain Area Health Education Center, Asheville, NC, Cat 1 CME, September 25, 2016.

"Update on VA care for transgender veterans and summary of research." Southeastern Transgender Health Summit 2016 Overcoming Barriers, Mountain Area Health Education Center, Asheville, NC, Cat 1 CME, September 25, 2016.

"Transgender inmates in prison: perspectives from expert witnesses," Symposium Chair and presenter, United States Professional Association for Transgender Health, First Scientific Meeting, Los Angeles, CA, Cat 1 CME (1.5 hours), February 3, 2017.

"Changes in prescriptions of cross-sex hormones and psychotropic medications for 4,409 transgender veterans receiving services at VHA facilities," United States Professional Association for Transgender Health, First Scientific Meeting, Los Angeles, CA, Cat 1 CME, February 3, 2017.

"Sex reassignment surgeries; masculinizing and feminizing," national presentations to VA SCAN-ECHO and regional consultation teams responsible for VA transgender health consultations, Cat I CME, 4 hours, February 21, 28; May 9, 16, 2017.

"Transgender Health Care, Research, and Regulations in the Department of Defense," 4 hour/half day CME Cat I symposium (solo presenter), 2017 USMEPCOM Medical Leadership Training Seminar, San Antonio, TX, May 2, 2017.

"Transgender Health Care, Research, and Regulations in the Department of Defense," 4 hour CME Cat I symposium (solo presenter), Department of the Army, Fort Knox, KY, July 25, 2017.

"Transgender Health in the Prison Setting: Medical and Legal Issues," Oklahoma Department of Corrections statewide training workshop, Oklahoma City, OK, August 21, 2017.

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**SYMPOSIA ORGANIZED AND/OR MODERATED:**

1. Psychosocial Aspects of HIV Disease in the Military, organizer/moderator/ presenter, Wichita Falls, Texas, 25 April, 1990.

2. Full Day Roundtable Symposium on Atypical Antipsychotics, organizer/moderator, Excerpta Medica, Asheville, North Carolina, 22 April, 1995.

3. Mountain Update on Anxiety Disorders, Course Director, East Tennessee State University, Blowing Rock, North Carolina, 28-29 April, 1995.

4. Medicine and Sexuality Course, Course Director, East Tennessee State University and James H. Quillen VAMC, Johnson City, TN, 13 June, 1997.

5. Half Day audiotaped symposium moderater/organizer on Innovative Uses of Atypical Antipsychotics, Excerpta Medica, Blackberry Inn, Townsend, TN, 16 November, 1997.

6. Novel Uses of Atypical Antipsychotics, Symposium Moderator, Marriot Griffin Resort, Janssen Research Foundation, Lexington, KY, 4 December, 1998.

7. Novel Uses of Atypical Antipsychotics, Symposium Moderator, Blackberry Inn, Townsend, TN, 10 April, 1999.

8. Psychiatry and Neurology Poster Session Moderator for Southern Medical Association's 97th Annual Scientific Assembly, Atlanta, Georgia, November 6, 2003.

9. Moderator for East Tennessee State University Department of Psychiatry monthly Journal Club/Critical Evaluation of the Literature series, 2002-2011.

**TELEVISED and TAPED MEDIA EVENTS:**

WKPT local television interview on sleep disorders, Johnson City, 1995.

TNN (The Nashville Network), filmed winning an international revolver competition and then interviewed on silhouette handgun shooting, Oakridge, TN, 1998.

CME, Inc. audiotaped faculty presentations as advertised in "Psychiatric Times," various cities and topics.

Channel 5, London, England; documentary on psychiatric aspects of firearms, 2004.

"Cruel and Unusual", documentary on transgender health care issues in the prison setting, 2005 release, available from jbaus@aol.com; aired on Women's Entertainment channel on July 2, 2007

ABC 20/20, "Becoming Diane" segment on gender identity disorders, October 12, 2005.

The Carter Jenkins Center, www.thecjc.org, taped CME cat I lecture available on the internet, "Evaluation and Management of Gender Identity Disorder," January 6, 2006.

CNN, Kosilek Trial testimony/interview, June 1, 2006.

CNBC, "The Big Idea with Donny Deutsch," interview, June 6, 2006.

PBS News Hour, Transgender Soldiers Gain Ground as US Military Transitions, May 9, 2016, http://www.pbs.org/newshour/bb/transgender-soldiers-gain-ground-as-u-s-military-transitions/

Multiple Psychiatry Grand Rounds completed at ETSU, 2010-present, available at the ETSU CME Office website, www.etsu.edu/CME

**RESEARCH PROJECTS AND GRANT SUPPORT:**

Principal Investigator, "Phase III Comparison of Two Doses of Risperidone For Acute Exacerbations of Chronic Schizophrenia." Inpatient setting, grant support from Janssen Pharmaceutica, approximately $50,000. Completed 1996.

Principal Investigator, Sexual Functioning and Personality Characteristics of Transgendered Men in a Nonclinical Setting. Collaboration with Tom Wise, M.D. (Chair, Dept. of Psychiatry, Fairfax Hospital, Falls Church, VA), Peter Fagan, Ph.D. (Johns Hopkins Sexual Behaviors Consultation Unit), and Paul Costa, Ph.D. (NIMH). Completed 1990-1995.

DSM-IV Reliability Field Trials, Site Coordinator, 10 investigators, completed in 1995.

Principal Investigator, Psychosocial Adjustment of Spouses of Transgendered Men; study involving long-term support group work and nationwide questionnaire data collection from 1986 to 1997. Completed. Private non-profit organization grant support received.

Coinvestigator, International Study of 800 Transgender Men: The Boulton and Park Experience. 1988-1992. This was the largest community based survey study of transgender people in the U.S. conducted to date. Completed.

Principal Investigator, "A Double-Blind, Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of Sertindole and Three Doses of Haloperidol in Schizophrenic Patients." Phase III trial, inpatient setting. Grant support by Abbott Laboratories, approximately $60,000 over one year. Completed 1994-1995. Contributed to FDA consideration of Serlect for U.S. marketing, 1996-1997.

Principal Investigator, "An Open Label, Long Term, Safety Study of Sertindole in Schizophrenic Patients." Phase II trial, outpatient setting. Grant support from Abbott Laboratories, approximately $50,000 over two years. Completed 1996.

Principal Investigator, "Biopsychosocial Natural History Study of HIV Infection in the USAF." RO-1 equivalent grant from Henry M. Jackson Foundation for the Advancement of Military Medicine, approximately $2,000,000. Completed 1987-1993, including pilot data collection.

Unrestricted Educational Grants, $19,000, for Mountain Update on Anxiety Disorders CME conference (SKB, Lilly, Mead-Johnson), 1995.

Unrestricted Educational Grants totaling approximately $30,000 annually in support of the VAMC/ETSU Psychiatry Grand Rounds and Visiting Professor Program, 1994-2000; 2002-2006. Grant funding following CME guidelines and administered through the ETSU Office of Continuing Education.

Principal Investigator, "Double-Blind Crossover Study of Zolpidem and Temazepam in Elderly, Hospitalized Patients." Funded through Psychiatry Research Fund, Mountain Home VAMC, and Chair of Excellence in Geriatrics, ETSU. Approved study, ultimately closed due to lack of appropriate subjects available for recruitment.

Principal Investigator, "A Randomized, Double-Blind Placebo Controlled Study of Risperidone for Treatment of Behavioral Disturbances in Subjects with Dementia." Collaboration with R. Hamdy, Cecile Quillen Chair of Excellence in Geriatrics, approximately $100,000 at full recruitment, 1995-1997; completed.

Associate Investigator, "Use of Nefazodone in Depressed Women with Premenstrual Amplification of Symptoms: a Pilot Study." Principal Investigator: Merry Miller, M.D. $5,000 pilot study grant, 1996-1999; completed.

Associate Investigator, "Voice Characteristics Associated with Gender Misidentification: A Pilot Study." Principal Investigator: Robert King, M.A. Unfunded study in data analysis phase, 2001-2005; completed in 2007.

Principal Investigator, Johnson City site, VA Cooperative Study #430, “Reducing the Efficacy-Effectiveness Gap in Bipolar Disorder.” Health services research conducted at 12 sites nationwide. Grant for this site’s operations total $435,000 over five years of study, 1997-2003; completed.

Coinvestigator, “Treatment for Erectile Disorder with Viagra in a VA Population: Efficacy and Patient and Partner Satisfaction.” Principal Investigator: William Finger, Ph.D. Approximately $30,000 total grant over two year period, 2000-2001; study concluded.

Principal Investigator, Johnson City site, “A Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Three Fixed Doses of Aripiprazole in the Treatment of Institutionalized Patients with Psychosis Associated with Dementia of the Alzheimer’s Type.” Phase III clinical

trial, sponsored by Bristol-Meyers Squibb, 2000-2001, $174,000 at full recruitment. Extension phase, 42 weeks, separate grant at maximum of $232,800. Approved April, 2000; completed.

Coinvestigator, “Effects of zaleplon on postural stability in the elderly.“ Principal Investigator: Faith Akin, Ph.D. $1000 grant for subject recruitment expenses, 2000-2001.

Principal Investigator, James H. Quillen VA site, “ZODIAK study; An International, Multicenter Large Simple Trial (LST) To Compare the Cardiovascular Safety of Ziprasidone and Olanzapine.” Pfizer Pharmaceuticals, approximately $20,000 at full recruitment. Approved April, 2002, recruitment completed and closed in 2004. Results published: Strom B, Eng S, Faich G, et al: comparative mortality associated with ziprasidone and olanzapine in real-world use among 18,154 patients with schizophrenia: The ziprasidone Observational Study of Cardiac Outcomes (ZODIAC). Amer J Psychiatry 168(2):193-201, 2011.

Coinvestigator, “Survey of Family and Systems Aggression Against Therapists.” Unfunded study, completed between 2002 and 2003; Randi Ettner, Ph.D., Principle Investigator; completed.

Coinvestigator, “Effect of Olanzapine on the Auditory Gating Deficit in Patients with Schizophrenia.” Principal Investigator: Barney Miller, Ph.D. Investigator-initiated study funded by Lilly, approximately $85,000. 2002. Study did not recruit subjects at ETSU and was closed 2003.

Principal Investigator, multicenter study, “The SOURCE Study: Schizophrenia Outcomes, Utilization, Relapse, and Clinical Evaluation.” Janssen Research, $100,000 grant at full recruitment (two year open label followup study of risperidone Consta), 2005-2007; second highest recruitment of 43 centers in multicenter study. Completed. See publications from this study under the Publications section, numbers 128 and 129.

Coauthor on grants to VA Central Office for program enhancements to mental health programs at Mountain Home VAMC; approximately $2,000,000 received for additional staff and support for residential treatment programs and PTSD clinic expansion, 2006-2007.

Principal Investigator in conjunction with Herbert Meltzer, MD, Vanderbilt University, " High Dose Risperidone Consta for Patients with Schizophrenia with Unsatisfactory Response to Standard Dose Risperidone or Long-Acting Injectable." Phase IV study of outpatients with schizophrenia who are partially responsive to risperidone oral and/or long-acting injectable, using a double-blind methodology to study doses between 50 and 100 mg every two weeks. Site funding of approximately $100,000. 2008-2010. Approved by ETSU IRB but negotiations between sponsor and Department of Veterans Affairs were not completed on intellectual property rights. Study not initiated at Mountain Home VAMC.

Principal Investigator (Everett McDuffie, MD, coinvestigator), "Descriptive study of veterans with gender identity disturbances: Characteristics and comorbidities, 1987-2007." Unfunded study that is first to characterize a population of 75 U.S. veterans with gender identity disturbances over a 20 year time frame. Completed 2009.

Principal Investigator: “Analysis of State and Federal Prison Directives Related to Transgender Inmate Medical Care and Placement.” Unfunded review of existing prison policies through the end of 2007. Completed 2008.

Principal Investigator: “Qualitative Analysis of Concerns of Transgender Inmates in the United States. Unfunded analysis of 129 letters from self-identified transgender inmates across the US.” Completed 2012.

Coinvestigator, “Prevalence and Suicidality in Transgender Veterans”; coinvestigator with collaborators at the VA Center of Excellence for Suicide Prevention. 2011-2013. Completed;

publication of results in October, 2013.

Principal Investigator, “Assessing Health Outcomes, Health Care Utilization, and Health Disparities in Transgender Veterans Receiving Care in the Veterans Health Administration.” Approved by ETSU IRB 7/1/13; protocol remains open. Six manuscripts published; one in preparation.

Consultant, Patient-Centered Outcomes Research Institute grant on transgender healthcare outcomes (STRONG), Michael Goodman, MD, Principal Investigator, Emery University, 2014-present.

**References available upon request.**

# Exhibit B

# DEPARTMENT OF DEFENSE REPORT AND RECOMMENDATIONS ON MILITARY SERVICE BY TRANSGENDER PERSONS

FEBRUARY 2018

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## Executive Summary

It is a bedrock principle of the Department of Defense that any eligible individual[1] who can meet the high standards for military service without special accommodations should be permitted to serve. This is no less true for transgender persons than for any other eligible individual. This report, and the recommendations contained herein, proceed from this fundamental premise.

The starting point for determining a person's qualifications for military duty is whether the person can meet the standards that govern the Armed Forces. Federal law requires that anyone entering into military service be "qualified, effective, and able-bodied."[2] Military standards are designed not only to ensure that this statutory requirement is satisfied but to ensure the overall military effectiveness and lethality of the Armed Forces.

The purpose of the Armed Forces is to fight and win the Nation's wars. No human endeavor is more physically, mentally, and emotionally demanding than the life and death struggle of battle. Because the stakes in war can be so high—both for the success and survival of individual units in the field and for the success and survival of the Nation—it is imperative that all Service members are physically and mentally able to execute their duties and responsibilities without fail, even while exposed to extreme danger, emotional stress, and harsh environments.

Although not all Service members will experience direct combat, standards that are applied universally across the Armed Forces must nevertheless account for the possibility that any Service member could be thrust into the crucible of battle at any time. As the Department has made clear to Congress, "[c]ore to maintaining a ready and capable military force is the understanding that each Service member is required to be available and qualified to perform assigned missions, including roles and functions outside of their occupation, in any setting."[3] Indeed, there are no occupations in the military that are exempt from deployment.[4] Moreover, while non-combat positions are vital to success in war, the physical and mental requirements for those positions should not be the barometer by which the physical and mental requirements for all positions, especially combat positions, are defined. Fitness for combat must be the metric against which all standards and requirements are judged. To give all Service members the best chance of success and survival in war, the Department must maintain the highest possible standards of physical and mental health and readiness across the force.

While individual health and readiness are critical to success in war, they are not the only measures of military effectiveness and lethality. A fighting unit is not a mere collection of individuals; it is a unique social organism that, when forged properly, can be far more powerful than the sum of its parts. Human experience over millennia—from the Spartans at Thermopylae to the band of brothers of the 101st Airborne Division in World War II, to Marine squads fighting building-to-building in Fallujah—teaches us this. Military effectiveness requires

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[1] 10 U.S.C. §§ 504, 505(a), 12102(b).
[2] 10 U.S.C. § 505(a).
[3] Under Secretary of Defense for Personnel and Readiness, "Fiscal Year 2016 Report to Congress on the Review of Enlistment of Individuals with Disabilities in the Armed Forces," pp. 8-9 (Apr. 2016).
[4] Id.

transforming a collection of individuals into a single fighting organism—merging multiple individual identities into one. This transformation requires many ingredients, including strong leadership, training, good order and discipline, and that most intangible, but vital, of ingredients—unit cohesion or, put another way, human bonding.

Because unit cohesion cannot be easily quantified, it is too often dismissed, especially by those who do not know what Justice Oliver Wendell Holmes called the "incommunicable experience of war."[5] But the experience of those who, as Holmes described, have been "touched with fire" in battle and the experience of those who have spent their lives studying it attest to the enduring, if indescribable, importance of this intangible ingredient. As Dr. Jonathan Shay articulated it in his study of combat trauma in Vietnam, "[s]urvival and success in combat often require soldiers to virtually read one another's minds, reflexively covering each other with as much care as they cover themselves, and going to one another's aid with little thought for safety."[6] Not only is unit cohesion essential to the health of the unit, Dr. Shay found that it was essential to the health of the individual soldier as well. "Destruction of unit cohesion," Dr. Shay concluded, "cannot be overemphasized as a reason why so many psychological injuries that might have healed spontaneously instead became chronic."[7]

Properly understood, therefore, military effectiveness and lethality are achieved through a combination of inputs that include individual health and readiness, strong leadership, effective training, good order and discipline, and unit cohesion. To achieve military effectiveness and lethality, properly designed military standards must foster these inputs. And, for the sake of efficiency, they should do so at the least possible cost to the taxpayer.

To the greatest extent possible, military standards—especially those relating to mental and physical health—should be based on scientifically valid and reliable evidence. Given the life-and-death consequences of warfare, the Department has historically taken a conservative and cautious approach in setting the mental and physical standards for the accession and retention of Service members.

Not all standards, however, are capable of scientific validation or quantification. Instead, they are the product of professional military judgment acquired from hard-earned experience leading Service members in peace and war or otherwise arising from expertise in military affairs. Although necessarily subjective, this judgment is the best, if not only, way to assess the impact of any given military standard on the intangible ingredients of military effectiveness mentioned above—leadership, training, good order and discipline, and unit cohesion.

For decades, military standards relating to mental health, physical health, and the physiological differences between men and women operated to preclude from military service transgender persons who desired to live and work as the opposite gender.

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[5] *The Essential Holmes: Selections from the Letters, Speeches, Judicial Opinions, and Other Writings of Oliver Wendell Holmes, Jr.*, p. 93 (Richard Posner, ed., University of Chicago Press 1992).
[6] Jonathan Shay, *Achilles in Vietnam*, p. 61 (Atheneum 1994).
[7] Id. at 198.

Relying on a report by an outside consultant, the RAND National Defense Research Institute, the Department, at the direction of Secretary Ashton Carter, reversed that longstanding policy in 2016. Although the new policy—the "Carter policy"—did not permit all transgender Service members to change their gender to align with their preferred gender identity, it did establish a process to do so for transgender Service members who were diagnosed with gender dysphoria—that is, the distress or impairment of functioning that is associated with incongruity between one's biological sex and gender identity. It also set in motion a new accession policy that would allow applicants who had a history of gender dysphoria, including those who had already transitioned genders, to enter into military service, provided that certain conditions were met. Once a change of gender is authorized, the person must be treated in all respects in accordance with the person's preferred gender, whether or not the person undergoes any hormone therapy or surgery, so long as a treatment plan has been approved by a military physician.

The new accession policy had not taken effect when the current administration came into office. Secretary James Mattis exercised his discretion and approved the recommendation of the Services to delay the Carter accession policy for an additional six months so that the Department could assess its impact on military effectiveness and lethality. While that review was ongoing, President Trump issued a memorandum to the Secretary of Defense and the Secretary of Homeland Security with respect to the U.S. Coast Guard expressing that further study was needed to examine the effects of the prior administration's policy change. The memorandum directed the Secretaries to reinstate the longstanding preexisting accession policy until such time that enough evidence existed to conclude that the Carter policy would not have negative effects on military effectiveness, lethality, unit cohesion, and military resources. The President also authorized the Secretary of Defense, in consultation with the Secretary of Homeland Security, to address the disposition of transgender individuals who were already serving in the military.

Secretary Mattis established a Panel of Experts that included senior uniformed and civilian leaders of the Department and U.S. Coast Guard, many with experience leading Service members in peace and war. The Panel made recommendations based on each Panel member's independent military judgment. Consistent with those recommendations, the Department, in consultation with the Department of Homeland Security, recommends the following policy to the President:

A. Transgender Persons Without a History or Diagnosis of Gender Dysphoria, Who Are Otherwise Qualified for Service, May Serve, Like All Other Service Members, in Their Biological Sex. Transgender persons who have not transitioned to another gender and do not have a history or current diagnosis of gender dysphoria—i.e., they identify as a gender other than their biological sex but do not currently experience distress or impairment of functioning in meeting the standards associated with their biological sex—are qualified for service, provided that they, like all other persons, satisfy all standards and are capable of adhering to the standards associated with their biological sex. This is consistent with the Carter policy, under which transgender persons without a history or diagnosis of gender dysphoria must serve, like everyone else, in their biological sex.

B. Transgender Persons Who Require or Have Undergone Gender Transition Are Disqualified. Except for those who are exempt under this policy, as described below, and except where waivers or exceptions to policy are otherwise authorized, transgender persons who are diagnosed with gender dysphoria, either before or after entry into service, and require transition-related treatment, or have already transitioned to their preferred gender, should be ineligible for service. For reasons discussed at length in this report, the Department concludes that accommodating gender transition could impair unit readiness; undermine unit cohesion, as well as good order and discipline, by blurring the clear lines that demarcate male and female standards and policies where they exist; and lead to disproportionate costs. Underlying these conclusions is the considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.

C. Transgender Persons With a History or Diagnosis of Gender Dysphoria Are Disqualified, Except Under Certain Limited Circumstances. Transgender persons who are diagnosed with, or have a history of, gender dysphoria are generally disqualified from accession or retention in the Armed Forces. The standards recommended here are subject to the same procedures for waiver or exception to policy as any other standards. This is consistent with the Department's handling of other mental conditions that require treatment. As a general matter, only in the limited circumstances described below should persons with a history or diagnosis of gender dysphoria be accessed or retained.

1. *Accession of Individuals Diagnosed with Gender Dysphoria.* Persons with a history of gender dysphoria may access into the Armed Forces, provided that they can demonstrate 36 consecutive months of stability (i.e., absence of gender dysphoria) immediately preceding their application; they have not transitioned to the opposite gender; and they are willing and able to adhere to all standards associated with their biological sex.

2. *Retention of Service Members Diagnosed with Gender Dysphoria.* Consistent with the Department's general approach of applying less stringent standards to retention than to accession in order to preserve the Department's substantial investment in trained personnel, Service members who are diagnosed with gender dysphoria after entering military service may be retained without waiver, provided that they are willing and able to adhere to all standards associated with their biological sex, the Service member does not require gender transition, and the Service member is not otherwise non-deployable for more than 12 months or for a period of time in excess of that established by Service policy (which may be less than 12 months).[8]

3. *Exempting Current Service Members Who Have Already Received a Diagnosis of Gender Dysphoria.* Transgender Service members who were diagnosed with gender dysphoria by a military medical provider after the effective date of the Carter policy, but before the effective date of any new policy, may continue to receive all medically necessary care,

[8] Under Secretary of Defense for Personnel and Readiness, "DoD Retention Policy for Non-Deployable Service Members" (Feb. 14, 2018).

to change their gender marker in the Defense Enrollment Eligibility Reporting System (DEERS), and to serve in their preferred gender, even after the new policy commences. This includes transgender Service members who entered into military service after January 1, 2018, when the Carter accession policy took effect by court order. The Service member must, however, adhere to the Carter policy procedures and may not be deemed to be non-deployable for more than 12 months or for a period of time in excess of that established by Service policy (which may be less than 12 months). While the Department believes that its solemn promise to these Service members, and the investment it has made in them, outweigh the risks identified in this report, should its decision to exempt these Service members be used by a court as a basis for invalidating the entire policy, this exemption is and should be deemed severable from the rest of the policy.

Although the precise number is unknown, the Department recognizes that many transgender persons who desire to serve in the military experience gender dysphoria and, as a result, could be disqualified under the recommended policy set forth in this report. Many transgender persons may also be unwilling to adhere to the standards associated with their biological sex as required by longstanding military policy. But others have served, and are serving, with distinction under the standards for their biological sex, like all other Service members. Nothing in this policy precludes service by transgender persons who do not have a history or diagnosis of gender dysphoria and are willing and able to meet all standards that apply to their biological sex.

Moreover, nothing in this policy should be viewed as reflecting poorly on transgender persons who suffer from gender dysphoria, or have had a history of gender dysphoria, and are accordingly disqualified from service. The vast majority of Americans from ages 17 to 24—that is, 71%—are ineligible to join the military without a waiver for mental, medical, or behavioral reasons.[9] Transgender persons with gender dysphoria are no less valued members of our Nation than all other categories of persons who are disqualified from military service. The Department honors all citizens who wish to dedicate, and perhaps even lay down, their lives in defense of the Nation, even when the Department, in the best interests of the military, must decline to grant their wish.

Military standards are high for a reason—the trauma of war, which all Service members must be prepared to face, demands physical, mental, and moral standards that will give all Service members the greatest chance to survive the ordeal with their bodies, minds, and moral character intact. The Department would be negligent to sacrifice those standards for any cause. There are serious differences of opinion on this issue, even among military professionals, but in the final analysis, given the uncertainty associated with the study and treatment of gender dysphoria, the competing interests involved, and the vital interests at stake—our Nation's defense and the success and survival of our Service members in war—the Department must proceed with caution.

[9] The Lewin Group, Inc., "Qualified Military Available (QMA) and Interested Youth: Final Technical Report," p. 26 (Sept. 2016).

## History of Policies Concerning Transgender Persons

For decades, military standards have precluded the accession and retention of certain transgender persons.[10] Accession standards—i.e., standards that govern induction into the Armed Forces—have historically disqualified persons with a history of "transsexualism." Also disqualified were persons who had undergone genital surgery or who had a history of major abnormalities or defects of the genitalia. These standards prevented transgender persons, especially those who had undergone a medical or surgical gender transition, from accessing into the military, unless a waiver was granted.

Although retention standards—i.e., standards that govern the retention and separation of persons already serving in the Armed Forces—did not require the mandatory processing for separation of transgender persons, it was a permissible basis for separation processing as a physical or mental condition not amounting to a disability. More typically, however, such Service members were processed for separation because they suffered from other associated medical conditions or comorbidities, such as depression, which were also a basis for separation processing.

At the direction of Secretary Carter, the Department made significant changes to these standards. These changes—i.e., the "Carter policy"—prohibit the separation of Service members on the basis of their gender identity and allow Service members who are diagnosed with gender dysphoria to transition to their preferred gender.

Transition-related treatment is highly individualized and could involve what is known as a "medical transition," which includes cross-sex hormone therapy, or a "surgical transition,"

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[10] For purposes of this report, the Department uses the broad definition of "transgender" adopted by the RAND National Defense Institute in its study of transgender service: "an umbrella term used for individuals who have sexual identity or gender expression that differs from their assigned sex at birth." RAND National Defense Research Institute, *Assessing the Implications of Allowing Transgender Personnel to Serve Openly*, p.75 (RAND Corporation 2016), available at https://www.rand.org/content/dam/rand/pubs/research_reports/RR1500/RR1530/RAND_RR1530.pdf ("RAND Study"). According to the Human Rights Campaign, "[t]he transgender community is incredibly diverse. Some transgender people identify as male or female, and some identify as genderqueer, nonbinary, agender, or somewhere else on or outside of the spectrum of what we understand gender to be." Human Rights Campaign, "Understanding the Transgender Community," https://www.hrc.org/resources/understanding-the-transgender-community (last visited Feb. 14, 2018). A subset of transgender persons are those who have been diagnosed with gender dysphoria. According to the *Diagnostic and Statistical Manual of Mental Disorders* published by the American Psychiatric Association, "gender dysphoria" is a "marked incongruence between one's experienced/expressed gender and assigned gender" that "is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, pp. 452-53 (5th ed. 2013). Based on these definitions, a person can be transgender without necessarily having gender dysphoria (i.e., the transgender person does not suffer "clinically significant distress or impairment" on account of gender incongruity). A 2016 survey of active duty Service members estimated that approximately 1% of the force—8,980 Service members—identify as transgender. Office of People Analytics, Department of Defense, "2016 Workplace and Gender Relations Survey of Active Duty Members, Transgender Service Members," pp. 1-2. Currently, there are 937 active duty Service members who have been diagnosed with gender dysphoria since June 30, 2016. In addition, when using the term "biological sex" or "sex," this report is referring to the definition of "sex" in the RAND study: "a person's biological status as male or female based on chromosomes, gonads, hormones, and genitals (intersex is a rare exception)." RAND Study at 75.

which includes sex reassignment surgery. Service members could also forego medical transition treatment altogether, retain all of their biological anatomy, and live as the opposite gender—this is called a "social transition."

Once the Service member's transition is complete, as determined by the member's military physician and commander in accordance with his or her individualized treatment plan, and the Service member provides legal documentation of gender change, the Carter policy allows for the Service member's gender marker to be changed in the DEERS. Thereafter, the Service member must be treated in every respect—including with respect to physical fitness standards; berthing, bathroom, and shower facilities; and uniform and grooming standards—in accordance with the Service member's preferred gender. The Carter policy, however, still requires transgender Service members who have not changed their gender marker in DEERS, including persons who identify as other than male or female, to meet the standards associated with their biological sex.

The Carter policy also allows accession of persons with gender dysphoria who can demonstrate stability in their preferred gender for at least 18 months. The accession policy did not take effect until required by court order, effective January 1, 2018.

The following discussion describes in greater detail the evolution of accession and retention standards pertaining to transgender persons.

Transgender Policy Prior to the Carter Policy

A. Accession Medical Standards

DoD Instruction (DoDI) 6130.03, *Medical Standards for Appointment, Enlistment, or Induction in the Military Services*, establishes baseline accession medical standards used to determine an applicant's medical qualifications to enter military service. This instruction is reviewed every three to four years by the Accession Medical Standards Working Group (AMSWG), which includes medical and personnel subject matter experts from across the Department, its Military Services, and the U.S. Coast Guard. The AMSWG thoroughly reviews over 30 bodily systems and medical focus areas while carefully considering evidence-based clinical information, peer-reviewed scientific studies, scientific expert consensus, and the performance of existing standards in light of empirical data on attrition, deployment readiness, waivers, and disability rates. The AMSWG also considers inputs from non-government sources and evaluates the applicability of those inputs against the military's mission and operational environment, so that the Department and the Military Services can formally coordinate updates to these standards.

Accession medical standards are based on the operational needs of the Department and are designed to ensure that individuals are physically and psychologically "qualified, effective, and able-bodied persons"[11] capable of performing military duties. Military effectiveness requires that the Armed Forces manage an integrated set of unique medical standards and qualifications because all military personnel must be available for worldwide duty 24 hours a day without

[11] 10 U.S.C. § 505(a).

restriction or delay. Such duty may involve a wide range of demands, including exposure to danger or harsh environments, emotional stress, and the operation of dangerous, sensitive, or classified equipment. These duties are often in remote areas lacking immediate and comprehensive medical support. Such demands are not normally found in civilian occupations, and the military would be negligent in its responsibility if its military standards permitted admission of applicants with physical or emotional impairments that could cause harm to themselves or others, compromise the military mission, or aggravate any current physical or mental health conditions that they may have.

In sum, these standards exist to ensure that persons who are under consideration for induction into military service are:

- free of contagious diseases that probably will endanger the health of other personnel;
- free of medical conditions or physical defects that may require excessive time lost from duty for necessary treatment or hospitalization, or probably will result in separation from service for medical unfitness;
- medically capable of satisfactorily completing required training;
- medically adaptable to the military environment without the necessity of geographical area limitations; and
- medically capable of performing duties without aggravation of existing physical defects or medical conditions.[12]

Establishing or modifying an accession standard is a risk management process by which a health condition is evaluated in terms of the probability and effect on the five listed outcomes above. These standards protect the applicant from harm that could result from the rigors of military duty and help ensure unit readiness by minimizing the risk that an applicant, once inducted into military service, will be unavailable for duty because of illness, injury, disease, or bad health.

Unless otherwise expressly provided, a current diagnosis or verified past medical history of a condition listed in DoDI 6130.03 is presumptively disqualifying.[13] Accession standards reflect the considered opinion of the Department's medical and personnel experts that an applicant with an identified condition should only be able to serve if they can qualify for a waiver. Waivers are generally only granted when the condition will not impact the individual's assigned specialty or when the skills of the individual are unique enough to warrant the additional risk. Waivers are not generally granted when the conditions of military service may aggravate the existing condition. For some conditions, applicants with a past medical history may nevertheless be eligible for accession if they meet the requirements for a certain period of "stability"—that is, they can demonstrate that the condition has been absent for a defined period

[12] Department of Defense Instruction 6130.03, *Medical Standards for Appointment, Enlistment, or Induction in the Military Services* (Apr. 28, 2010), incorporating Change 1, p. 2 (Sept. 13, 2011) ("DoDI 6130.03").
[13] Id. at 10.

of time prior to accession.[14] With one exception,[15] each accession standard may be waived in the discretion of the accessing Service based on that Service's policies and practices, which are driven by the unique requirements of different Service missions, different Service occupations, different Service cultures, and at times, different Service recruiting missions.

Historically, mental health conditions have been a great concern because of the unique mental and emotional stresses of military service. Mental health conditions frequently result in attrition during initial entry training and the first term of service and are routinely considered by in-service medical boards as a basis for separation. Department mental health accession standards have typically aligned with the conditions identified in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), which is published by the American Psychiatric Association (APA). The DSM sets forth the descriptions, symptoms, and other criteria for diagnosing mental disorders. Health care professionals in the United States and much of the world use the DSM as the authoritative guide to the diagnosis of mental disorders.

Prior to implementation of the Carter policy, the Department's accession standards barred persons with a "[h]istory of psychosexual conditions, including but not limited to transsexualism, exhibitionism, transvestism, voyeurism, and other paraphilias."[16] These standards were consistent with DSM-III, which in 1980, introduced the diagnosis of transsexualism.[17] In 1987, DSM-III-R added gender identity disorder, non-transsexual type.[18] DSM-IV, which was published in 1994, combined these two diagnoses and called the resulting condition "gender identity disorder."[19] Due to challenges associated with updating and publishing a new iteration of DoDI 6130.03, the DoDI's terminology has not changed to reflect the changes in the DSM, including further changes that will be discussed later.

DoDI 6130.03 also contains other disqualifying conditions that are associated with, but not unique to, transgender persons, especially those who have undertaken a medical or surgical transition to the opposite gender. These include:

- a history of chest surgery, including but not limited to the surgical removal of the breasts,[20] and genital surgery, including but not limited to the surgical removal of the testicles;[21]

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[14] See, e.g., id. at 47.
[15] The accession standards for applicants with HIV are not waivable absent a waiver from both the accessing Service and the Under Secretary of Defense for Personnel and Readiness. See Department of Defense Instruction 6485.01, *Human Immunodeficiency Virus (HIV) in Military Service Members* (Jun. 7, 2013).
[16] DoDI 6130.03 at 48.
[17] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-III)*, pp. 261-264 (3rd ed. 1980).
[18] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)*, pp. 76-77 (3rd ed. revised 1987).
[19] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*, pp. 532-538 (4th ed. 1994).
[20] DoDI 6130.03 at 18.
[21] Id. at 25-27.

- a history of major abnormalities or defects of the genitalia, including but not limited to change of sex, hermaphroditism, penis amputation, and pseudohermaphroditism;[22]
- mental health conditions such as suicidal ideation, depression, and anxiety disorder;[23] and
- the use of certain medications, or conditions requiring the use of medications, such as hormone therapies and anti-depressants.[24]

Together with a diagnosis of transsexualism, these conditions, which were repeatedly validated by the AMSWG, provided multiple grounds for the disqualification of transgender persons.

B. Retention Standards

The standards that govern the retention of Service members who are already serving in the military are generally less restrictive than the corresponding accession standards due to the investment the Department has made in the individual and their increased capability to contribute to mission accomplishment.

Also unlike the Department's accession standards, each Service develops and applies its own retention standards. With respect to the retention of transgender Service members, these Service-specific standards may have led to inconsistent outcomes across the Services, but as a practical matter, before the Carter policy, the Services generally separated Service members who desired to transition to another gender. During that time, there were no express policies allowing individuals to serve in their preferred gender rather than their biological sex.

Previous Department policy concerning the retention (administrative separation) of transgender persons was not clear or rigidly enforced. DoDI 1332.38, *Physical Disability Evaluation*, now cancelled, characterized "sexual gender and identity disorders" as a basis for allowing administrative separation for a condition not constituting a disability; it did not require mandatory processing for separation. A newer issuance, DoDI 1332.18, *Disability Evaluation System (DES)*, August 5, 2014, does not reference these disorders but instead reflects changes in how such medical conditions are characterized in contemporary medical practice.

Earlier versions of DoDI 1332.14, *Enlisted Administrative Separations*, contained a cross reference to the list of conditions not constituting a disability in former DoDI 1332.38. This was how "transsexualism," the older terminology, was used as a basis for administrative separation. Separation on this basis required formal counseling and an opportunity to address the issue, as well as a finding that the condition was interfering with the performance of duty. In practice, transgender persons were not usually processed for administrative separation on account of gender dysphoria or gender identity itself, but rather on account of medical comorbidities (e.g., depression or suicidal ideation) or misconduct due to cross dressing and related behavior.

[22] Id.
[23] Id. at 47-48.
[24] Id. at 48.

The Carter Policy

At the direction of Secretary Carter, the Department began formally reconsidering its accession and retention standards as they applied to transgender persons with gender dysphoria in 2015. This reevaluation, which culminated with the release of the Carter policy in 2016, was prompted in part by amendments to the DSM that appeared to change the diagnosis for gender identity disorder from a disorder to a treatable condition called gender dysphoria. Starting from the assumption that transgender persons are qualified for military service, the Department sought to identify and remove the obstacles to such service. This effort resulted in substantial changes to the Department's accession and retention standards to accommodate transgender persons with gender dysphoria who require treatment for transitioning to their preferred gender.

A. Changes to the DSM

When the APA published the fifth edition of the DSM in May 2013, it changed "gender identity disorder" to "gender dysphoria" and designated it as a "condition"—a new diagnostic class applicable only to gender dysphoria—rather than a "disorder."[25] This change was intended to reflect the APA's conclusion that gender nonconformity alone—without accompanying distress or impairment of functioning—was not a mental disorder.[26] DSM-5 also decoupled the diagnosis for gender dysphoria from diagnoses for "sexual dysfunction and parphilic disorders, recognizing fundamental differences between these diagnoses."[27]

According to DSM-5, gender dysphoria in adolescents and adults is "[a] marked incongruence between one's experience/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).
- 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).

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[25] See American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, pp. 451-459 (5th ed. 2013) ("DSM-5").

[26] RAND Study at 77; see also Hayes Directory, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria" (May 15, 2014), p. 1 ("This change was intended to reflect a consensus that gender nonconformity is not a psychiatric disorder, as it was previously categorized. However, since the condition may cause clinically significant distress and since a diagnosis is necessary for access to medical treatment, the new term was proposed."); Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, pp. 1182-83 (2016) ("In the DSM-5, [gender dysphoria] has replaced the diagnosis of 'gender identity disorder' in order to place the focus on the dysphoria and to diminish the pathology associated with identity incongruence.").

[27] Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, p. 1183 (2016).

- A strong desire for the primary and/or secondary sex characteristics of the other gender.
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
- 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).

Importantly, DSM-5 observed that gender dysphoria "is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."[28]

B. The Department Begins Review of Transgender Policy

On July 28, 2015, then Secretary Carter issued a memorandum announcing that no Service members would be involuntarily separated or denied reenlistment or continuation of service based on gender identity or a diagnosis of gender dysphoria without the personal approval of the Under Secretary of Defense for Personnel and Readiness.[29] The memorandum also created the Transgender Service Review Working Group (TSRWG) "to study the policy and readiness implications of welcoming transgender persons to serve openly."[30] The memorandum specifically directed the working group to "start with the presumption that transgender persons can serve openly without adverse impact on military effectiveness and readiness, unless and except where objective practical impediments are identified."[31]

As part of this review, the Department commissioned the RAND National Defense Research Institute to conduct a study to "(1) identify the health care needs of the transgender population, transgender Service members' potential health care utilization rates, and the costs associated with extending health care coverage for transition-related treatments; (2) assess the potential readiness impacts of allowing transgender Service members to serve openly; and (3) review the experiences of foreign militaries that permit transgender Service members to serve openly."[32] The resulting report, entitled *Assessing the Implications of Allowing Transgender Personnel to Serve Openly*, reached several conclusions. First, the report estimated that there are between 1,320 and 6,630 transgender Service members already serving in the active component of the Armed Forces and 830 to 4,160 in the Selected Reserve.[33] Second, the report predicted "annual gender transition-related health care to be an extremely small part of the overall health care provided to the [active component] population."[34] Third, the report estimated that active component "health care costs will increase by between $2.4 million and $8.4 million annually—an amount that will have little impact on and represents an exceedingly small proportion of

[28] American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, p. 453 (5th ed. 2013).
[29] Memorandum from Ashton Carter, Secretary of Defense, "Transgender Service Members" (July 28, 2015).
[30] Id.
[31] Id.
[32] RAND Study at 1.
[33] Id. at x-xi.
[34] Id. at xi.

[active component] health care expenditures (approximately $6 billion in FY 2014)."[35] Fourth, the report "found that less than 0.0015 percent of the total available labor-years would be affected, based on estimated gender transition-related health care utilization rates."[36] Finally, the report concluded that "[e]xisting data suggest a minimal impact on unit cohesion as a result of allowing transgender personnel to serve openly."[37] "Overall," according to RAND, "our study found that the number of U.S. transgender Service members who are likely to seek transition-related care is so small that a change in policy will likely have a marginal impact on health care costs and the readiness of the force."[38]

The RAND report thus acknowledged that there will be an adverse impact on health care utilization and costs, readiness, and unit cohesion, but concluded nonetheless that the impact will be "negligible" and "marginal" because of the small estimated number of transgender Service members relative to the size of the active component of the Armed Forces. Because of the RAND report's macro focus, however, it failed to analyze the impact at the micro level of allowing gender transition by individuals with gender dysphoria. For example, as discussed in more detail later, the report did not examine the potential impact on unit readiness, perceptions of fairness and equity, personnel safety, and reasonable expectations of privacy at the unit and sub-unit levels, all of which are critical to unit cohesion. Nor did the report meaningfully address the significant mental health problems that accompany gender dysphoria—from high rates of comorbidities and psychiatric hospitalizations to high rates of suicide ideation and suicidality—and the scope of the scientific uncertainty regarding whether gender transition treatment fully remedies those problems.

C. New Standards for Transgender Persons

Based on the RAND report, the work of the TSRWG, and the advice of the Service Secretaries, Secretary Carter approved the publication of DoDI 1300.28, *In-service Transition for Service Members Identifying as Transgender*, and Directive-type Memorandum (DTM) 16-005, "Military Service of Transgender Service Members," on June 30, 2016. Although the new retention standards were effective immediately upon publication of the above memoranda, the accession standards were delayed until July 1, 2017, to allow time for training all Service members across the Armed Forces, including recruiters, Military Entrance Processing Station (MEPS) personnel, and basic training cadre, and to allow time for modifying facilities as necessary.

1. *Retention Standards*. DoDI 1300.28 establishes the procedures by which Service members who are diagnosed with gender dysphoria may administratively change their gender. Once a Service member receives a gender dysphoria diagnosis from a military physician, the physician, in consultation with the Service member, must establish a treatment plan. The treatment plan is highly individualized and may include cross-sex hormone therapy (i.e., medical transition), sex reassignment surgery (i.e., surgical transition), or simply living as the opposite gender but without any cross-sex hormone or surgical treatment (i.e., social

[35] Id. at xi-xii.
[36] Id. at xii.
[37] Id.
[38] Id. at 69.

transition). The nature of the treatment is left to the professional medical judgment of the treating physician and the individual situation of the transgender Service member. The Department does not require a Service member with gender dysphoria to undergo cross-sex hormone therapy, sex reassignment surgery, or any other physical changes to effectuate an administrative change of gender. During the course of treatment, commanders are authorized to grant exceptions from physical fitness, uniform and grooming, and other standards, as necessary and appropriate, to transitioning Service members. Once the treating physician determines that the treatment plan is complete, the Service member's commander approves, and the Service member produces legal documentation indicating change of gender (e.g., certified birth certificate, court order, or U.S. passport), the Service member may request a change of gender marker in DEERS. Once the DEERS gender marker is changed, the Service member is held to all standards associated with the member's transitioned gender, including uniform and grooming standards, body composition assessment, physical readiness testing, Military Personnel Drug Abuse Testing Program participation, and other military standards congruent to the member's gender. Indeed, the Service member must be treated in all respects in accordance with the member's transitioned gender, including with respect to berthing, bathroom, and shower facilities. Transgender Service members who do not meet the clinical criteria for gender dysphoria, by contrast, remain subject to the standards and requirements applicable to their biological sex.

2. *Accession Standards*. DTM 16-005 directed that the following medical standards for accession into the Military Services take effect on July 1, 2017:

(1) A history of gender dysphoria is disqualifying, unless, as certified by a licensed medical provider, the applicant has been stable without clinically significant distress or impairment in social, occupational, or other important areas of functioning for 18 months.

(2) A history of medical treatment associated with gender transition is disqualifying, unless, as certified by a licensed medical provider:

(a) the applicant has completed all medical treatment associated with the applicant's gender transition; and
(b) the applicant has been stable in the preferred gender for 18 months; and
(c) if the applicant is presently receiving cross-sex hormone therapy post-gender transition, the individual has been stable on such hormones for 18 months.

(3) A history of sex reassignment or genital reconstruction surgery is disqualifying, unless, as certified by a licensed medical provider:

(a) a period of 18 months has elapsed since the date of the most recent of any such surgery; and

(b) no functional limitations or complications persist, nor is any additional surgery required.[39]

[39] Memorandum from Ashton Carter, Secretary of Defense, "Directive-type Memorandum (DTM) 16-005, 'Military Service of Transgender Service Members,'" Attachment, pp. 1-2 (June 30, 2016).

**Panel of Experts Recommendation**

The Carter policy's accession standards for persons with a history of gender dysphoria were set to take effect on July 1, 2017, but on June 30, after consultation with the Secretaries and Chiefs of Staff of each Service, Secretary Mattis postponed the new standards for an additional six months "to evaluate more carefully the impact of such accessions on readiness and lethality."[40] Secretary Mattis specifically directed that the review would "include all relevant considerations" and would last for five months, with a due date of December 1, 2017.[41] The Secretary also expressed his desire to have "the benefit of the views of the military leadership and of the senior civilian officials who are now arriving in the Department."[42]

While Secretary Mattis's review was ongoing, President Trump issued a memorandum, on August 25, 2017, directing the Secretary of Defense, and the Secretary of Homeland Security with respect to the U.S. Coast Guard, to reinstate longstanding policy generally barring the accession of transgender individuals "until such time as a sufficient basis exists upon which to conclude that terminating that policy and practice" would not "hinder military effectiveness and lethality, disrupt unit cohesion, or tax military resources."[43] The President found that "further study is needed to ensure that continued implementation of last year's policy change would not have those negative effects."[44] Accordingly, the President directed both Secretaries to maintain the prohibition on accession of transgender individuals "until such time as the Secretary of Defense, after consulting with the Secretary of Homeland Security, provides a recommendation to the contrary" that is convincing.[45] The President made clear that the Secretaries may advise him "at any time, in writing, that a change to this policy is warranted."[46] In addition, the President gave both Secretaries discretion to "determine how to address transgender individuals currently serving" in the military and made clear that no action be taken against them until a determination was made.[47]

On September 14, 2017, Secretary Mattis established a Panel of Experts to study, in a "comprehensive, holistic, and objective" manner, "military service by transgender individuals, focusing on military readiness, lethality, and unit cohesion, with due regard for budgetary constraints and consistent with applicable law."[48] He directed the Panel to "conduct an independent multi-disciplinary review and study of relevant data and information pertaining to transgender Service members."[49]

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[40] Memorandum from James N. Mattis, Secretary of Defense, "Accession of Transgender Individuals into the Military Services" (June 30, 2017).
[41] Id.
[42] Id.
[43] Memorandum from Donald J. Trump, President of the United States, "Military Service by Transgender Individuals" (Aug. 25, 2017).
[44] Id. at 1.
[45] Id. at 2.
[46] Id.
[47] Id.
[48] Memorandum from James N. Mattis, Secretary of Defense, "Terms of Reference—Implementation of Presidential Memorandum on Military Service by Transgender Individuals," pp. 1-2 (Sept. 14, 2017).
[49] Id. at 2.

The Panel consisted of the Under Secretaries of the Military Departments (or officials performing their duties), the Armed Services' Vice Chiefs (including the Vice Commandant of the U.S. Coast Guard), and the Senior Enlisted Advisors, and was chaired by the Under Secretary of Defense for Personnel and Readiness or an official performing those duties. The Secretary of Defense selected these senior leaders because of their experience leading warfighters in war and peace or their expertise in military operational effectiveness. These senior leaders also have the statutory responsibility to organize, train, and equip military forces and are uniquely qualified to evaluate the impact of policy changes on the combat effectiveness and lethality of the force. The Panel met 13 times over a span of 90 days.

The Panel received support from medical and personnel experts from across the Departments of Defense and Homeland Security. The Transgender Service Policy Working Group, comprised of medical and personnel experts from across the Department, developed policy recommendations and a proposed implementation plan for the Panel's consideration. The Medical and Personnel Executive Steering Committee, a standing group of the Surgeons General and Service Personnel Chiefs, led by Personnel and Readiness, provided the Panel with an analysis of accession standards, a multi-disciplinary review of relevant data, and information about medical treatment for gender dysphoria and gender transition-related medical care. These groups reported regularly to the Panel and responded to numerous queries for additional information and analysis to support the Panel's review and deliberations. A separate working group tasked with enhancing the lethality of our Armed Forces also provided a briefing to the Panel on their work relating to retention standards.

The Panel met with and received input from transgender Service members, commanders of transgender Service members, military medical professionals, and civilian medical professionals with experience in the care and treatment of individuals with gender dysphoria. The Panel also reviewed information and analyses about gender dysphoria, the treatment of gender dysphoria, and the effects of currently serving individuals with gender dysphoria on military effectiveness, unit cohesion, and resources. Unlike past reviews, the Panel's analysis was informed by the Department's own data and experience obtained since the Carter policy took effect.

To fulfill its mandate, the Panel addressed three questions:

- Should the Department of Defense access transgender individuals?
- Should the Department allow transgender individuals to transition gender while serving, and if so, what treatment should be authorized?
- How should the Department address transgender individuals who are currently serving?

After extensive review and deliberation, which included evidence in support of and against the Panel's recommendations, the Panel exercised its professional military judgment and made recommendations. The Department considered those recommendations and the information underlying them, as well as additional information within the Department, and now proposes the following policy consistent with those recommendations.

**Recommended Policy**

To maximize military effectiveness and lethality, the Department, after consultation with and the concurrence of the Department of Homeland Security, recommends cancelling the Carter policy and, as explained below, adopting a new policy with respect to the accession and retention of transgender persons.

The Carter policy assumed that transgender persons were generally qualified for service and that their accession and retention would not negatively impact military effectiveness. As noted earlier, Secretary Carter directed the TSRWG, the group charged with evaluating, and making recommendations on, transgender service, to "start with the presumption that transgender persons can serve openly without adverse impact on military effectiveness and readiness, unless and except where objective practical impediments are identified."[50] Where necessary, standards were adjusted or relaxed to accommodate service by transgender persons. The following analysis makes no assumptions but instead applies the relevant standards applicable to everyone to determine the extent to which transgender persons are qualified for military duty.

For the following reasons, the Department concludes that transgender persons should not be disqualified from service solely on account of their transgender status, provided that they, like all other Service members, are willing and able to adhere to all standards, including the standards associated with their biological sex. With respect to the subset of transgender persons who have been diagnosed with gender dysphoria, however, those persons are generally disqualified unless, depending on whether they are accessing or seeking retention, they can demonstrate stability for the prescribed period of time; they do not require, and have not undergone, a change of gender; and they are otherwise willing and able to meet all military standards, including those associated with their biological sex. In order to honor its commitment to current Service members diagnosed with gender dysphoria, those Service members who were diagnosed after the effective date of the Carter policy and before any new policy takes effect will not be subject to the policy recommended here.

Discussion of Standards

The standards most relevant to the issue of service by transgender persons fall into three categories: mental health standards, physical health standards, and sex-based standards. Based on these standards, the Department can assess the extent to which transgender persons are qualified for military service and, in light of that assessment, recommend appropriate policies.

A. Mental Health Standards

Given the extreme rigors of military service and combat, maintaining high standards of mental health is essential to military effectiveness and lethality. The immense toll that the burden and experience of combat can have on the human psyche cannot be overstated. Therefore, putting individuals into battle, who might be at increased risk of psychological injury, would be reckless, not only for those individuals, but for the Service members who serve beside them as well.

[50] Memorandum from Ashton Carter, Secretary of Defense, "Transgender Service Members" (July 28, 2015).

The Department's experience with the mental health issues arising from our wars in Afghanistan and Iraq, including post-traumatic stress disorder (PTSD), only underscores the importance of maintaining high levels of mental health across the force. PTSD has reached as high as 2.8% of all active duty Service members, and in 2016, the number of active duty Service members with PTSD stood at 1.5%.[51] Of all Service members in the active component, 7.5% have been diagnosed with a mental health condition of some type.[52] The Department is mindful of these existing challenges and must exercise caution when considering changes to its mental health standards.

Most mental health conditions and disorders are automatically disqualifying for accession absent a waiver. For example, persons with a history of bipolar disorder, personality disorder, obsessive-compulsive disorder, suicidal behavior, and even body dysmorphic disorder (to name a few) are barred from entering into military service, unless a waiver is granted.[53] For a few conditions, however, persons may enter into service without a waiver if they can demonstrate stability for 24 to 36 continuous months preceding accession. Historically, a person is deemed stable if they are without treatment, symptoms, or behavior of a repeated nature that impaired social, school, or work efficiency for an extended period of several months. Such conditions include depressive disorder (stable for 36 continuous months) and anxiety disorder (stable for 24 continuous months).[54] Requiring a period of stability reduces, but does not eliminate, the likelihood that the individual's depression or anxiety will return.

Historically, conditions associated with transgender individuals have been automatically disqualifying absent a waiver. Before the changes directed by Secretary Carter, military mental health standards barred persons with a "[h]istory of psychosexual conditions, including but not limited to transsexualism, exhibitionism, transvestism, voyeurism, and other paraphilias."[55] These standards, however, did not evolve with changing understanding of transgender mental health. Today, transsexualism is no longer considered by most mental health practitioners as a mental health condition. According to the APA, it is not a medical condition for persons to identify with a gender that is different from their biological sex.[56] Put simply, transgender status alone is not a condition.

Gender dysphoria, by contrast, is a mental health condition that can require substantial medical treatment. Many individuals who identify as transgender are diagnosed with gender dysphoria, but "[n]ot all transgender people suffer from gender dysphoria and that distinction," according to the APA, "is important to keep in mind."[57] The DSM-5 defines gender dysphoria as

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[51] Deployment Health Clinical Center, "Mental Health Disorder Prevalence among Active Duty Service Members in the Military Health System, Fiscal Years 2005-2016" (Jan. 2017).
[52] Id.
[53] DoDI 6130.03 at 47-48.
[54] Id.
[55] Id. at 48.
[56] DSM-5 at 452-53.
[57] American Psychiatric Association, "Expert Q & A: Gender Dysphoria," available at https://www.psychiatry.org/patients-families/gender-dysphoria/expert-qa (last visited Feb. 14, 2018). Conversely, not all persons with gender dysphoria are transgender. "For example, some men who are disabled in combat, especially if their injury includes genital wounds, may feel that they are no longer men because their bodies do not conform to their concept of manliness. Similarly, a woman who opposes plastic surgery, but who must undergo mastectomy because of breast

a "marked incongruence between one's experience/expressed gender and assigned gender, of at least 6 months duration," that is manifested in various specified ways.[58] According to the APA, the "condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."[59]

Transgender persons with gender dysphoria suffer from high rates of mental health conditions such as anxiety, depression, and substance use disorders.[60] High rates of suicide ideation, attempts, and completion among people who are transgender are also well documented in the medical literature, with lifetime rates of suicide attempts reported to be as high as 41% (compared to 4.6% for the general population).[61] According to a 2015 survey, the rate skyrockets to 57% for transgender individuals without a supportive family.[62] The Department is concerned that the stresses of military life, including basic training, frequent moves, deployment to war zones and austere environments, and the relentless physical demands, will be additional contributors to suicide behavior in people with gender dysphoria. In fact, there is recent evidence that military service can be a contributor to suicidal thoughts.[63]

Preliminary data of Service members with gender dysphoria reflect similar trends. A review of the administrative data indicates that Service members with gender dysphoria are eight times more likely to attempt suicide than Service members as a whole (12% versus 1.5%).[64]

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cancer, may find that she requires reconstructive breast surgery in order to resolve gender dysphoria arising from the incongruence between her body without breasts and her sense of herself as a woman." M. Jocelyn Elders, George R. Brown, Eli Coleman, Thomas Kolditz & Alan Steinman, "Medical Aspects of Transgender Military Service," *Armed Forces & Society*, p. 5 n.22 (Mar. 2014).

[58] DSM-5 at 452.

[59] DSM-5 at 453.

[60] Cecilia Dhejne, Roy Van Vlerken, Gunter Heylens & Jon Arcelus, "Mental health and gender dysphoria: A review of the literature," *International Review of Psychiatry*, Vol. 28, pp. 44-57 (2016); George R. Brown & Kenneth T. Jones, "Mental Health and Medical Health Disparities in 5135 Transgender Veterans Receiving Healthcare in the Veterans Health Administration: A Case-Control Study," *LGBT Health*, Vol. 3, p. 128 (Apr. 2016).

[61] Ann P. Haas, Philip L. Rodgers & Jody L. Herman, *Suicide Attempts among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey*, p. 2 (American Foundation for Suicide Prevention and The Williams Institute, University of California, Los Angeles, School of Law 2014), available at https://williamsinstitute.law.ucla.edu/wp-content/uploads/AFSP-Williams-Suicide-Report-Final.pdf; H.G. Virupaksha, Daliboyina Muralidhar & Jayashree Ramakrishna, "Suicide and Suicide Behavior among Transgender Persons," *Indian Journal of Psychological Medicine*, Vol.38, pp. 505-09 (2016); Claire M. Peterson, Abigail Matthews, Emily Copps-Smith & Lee Ann Conard, "Suicidality, Self-Harm, and Body Dissatisfaction in Transgender Adolescents and Emerging Adults with Gender Dysphoria," *Suicide and Life Threatening Behavior*, Vol. 47, pp. 475-482 (Aug. 2017).

[62] Ann P. Haas, Philip L. Rodgers & Jody L. Herman, *Suicide Attempts among Transgender and Gender Non-Conforming Adults: Findings of the National Transgender Discrimination Survey*, pp. 2, 12 (American Foundation for Suicide Prevention and The Williams Institute, University of California, Los Angeles, School of Law 2014), available at https://williamsinstitute.law.ucla.edu/wp-content/uploads/AFSP-Williams-Suicide-Report-Final.pdf.

[63] Raymond P. Tucker, Rylan J. Testa, Mark A.Reger, Tracy L. Simpson, Jillian C. Shipherd, & Keren Lehavot, "Current and Military-Specific Gender Minority Stress Factors and Their Relationship with Suicide Ideation in Transgender Veterans," *Suicide and Life Threatening Behavior* DOI: 10.1111/sltb.12432 (epub ahead of print), pp. 1-10 (2018); Craig J. Bryan, AnnaBelle O. Bryan, Bobbie N. Ray-Sannerud, Neysa Etienne & Chad E. Morrow, "Suicide attempts before joining the military increase risk for suicide attempts and severity of suicidal ideation among military personnel and veterans," *Comprehensive Psychiatry*, Vol. 55, pp. 534-541 (2014).

[64] Data retrieved from Military Health System data repository (Oct. 2017).

Service members with gender dysphoria are also nine times more likely to have mental health encounters than the Service member population as a whole (28.1 average encounters per Service member versus 2.7 average encounters per Service member).[65] From October 1, 2015 to October 3, 2017, the 994 active duty Service members diagnosed with gender dysphoria accounted for 30,000 mental health visits.[66]

It is widely believed by mental health practitioners that gender dysphoria can be treated. Under commonly accepted standards of care, treatment for gender dysphoria can include: psychotherapy; social transition—also known as "real life experience"—to allow patients to live and work in their preferred gender without any hormone treatment or surgery; medical transition to align secondary sex characteristics with patients' preferred gender using cross-sex hormone therapy and hair removal; and surgical transition—also known as sex reassignment surgery—to make the physical body—both primary and secondary sex characteristics—resemble as closely as possible patients' preferred gender.[67] The purpose of these treatment options is to alleviate the distress and impairment of gender dysphoria by seeking to bring patients' physical characteristics into alignment with their gender identity—that is, one's inner sense of one's own gender.[68]

Cross-sex hormone therapy is a common medical treatment associated with gender transition that may be commenced following a diagnosis of gender dysphoria.[69] Treatment for women transitioning to men involves the administration of testosterone, whereas treatment for men transitioning to women requires the blocking of testosterone and the administration of estrogens.[70] The Endocrine Society's clinical guidelines recommend laboratory bloodwork every 90 days for the first year of treatment to monitor hormone levels.[71]

As a treatment for gender dysphoria, sex reassignment surgery is "a unique intervention not only in psychiatry but in all of medicine."[72] Under existing Department guidelines

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[65] Data retrieved from Military Health System data repository (Oct. 2017). Study period was Oct. 1, 2015 to July 26, 2017.

[66] Data retrieved from Military Health System data repository (Oct. 2017).

[67] RAND Study at 5-7, Appendices A & C; see also Hayes Directory, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria," p. 1 (May 15, 2014) ("The full therapeutic approach to [gender dysphoria] consists of 3 elements or phases, typically in the following order: (1) hormones of the desired gender; (2) real-life experience for 12 months in the desired role; and (3) surgery to change the genitalia and other sex characteristics (e.g., breast reconstruction or mastectomy). However, not everyone with [gender dysphoria] needs or wants all elements of this triadic approach."); Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, p. 1183 (Oct. 2016) ("The Endocrine Society proposes a sequential approach in transsexual care to optimize mental health and physical outcomes. Generally, they recommend initiation of psychotherapy, followed by cross-sex hormone treatments, then [sex reassignment surgery].").

[68] RAND Study at 73.

[69] Wylie C. Hembree, Peggy Cohen-Kettenis, Lous Gooren, Sabine Hannema, Walter Meyer, M. Hassan Murad, Stephen Rosenthal, Joshua Safer, Vin Tangpricha, & Guy T'Sjoen, "Endocrine Treatment of Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *The Journal of Clinical Endocrinology & Metabolism*, Vol. 102, pp. 3869-3903 (Nov. 2017).

[70] Id. at 3885-3888.

[71] Id.

[72] Ceclilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. Johansson, Niklas Långström & Mikael Landén, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS One*, Vol. 6, pp. 1-8 (Feb. 2011); see also Hayes Directory, "Sex Reassignment Surgery for the Treatment of

implementing the Carter policy, men transitioning to women may obtain an orchiectomy (surgical removal of the testicles), a penectomy (surgical removal of the penis), a vaginoplasty (surgical creation of a vagina), a clitoroplasty (surgical creation of a clitoris), and a labiaplasty (surgical creation of the labia). Women transitioning to men may obtain a hysterectomy (surgical removal of the uterus), a mastectomy (surgical removal of the breasts), a metoidioplasty (surgical enlargement of the clitoris), a phalloplasty (surgical creation of a penis), a scrotoplasty (surgical creation of a scrotum) and placement of testicular prostheses, a urethroplasty (surgical enlargement of the urethra), and a vaginectomy (surgical removal of the vagina). In addition, the following cosmetic procedures may be provided at military treatment facilities as well: abdominoplasty, breast augmentation, blepharoplasty (eyelid lift), hair removal, face lift, facial bone reduction, hair transplantation, liposuction, reduction thyroid chondroplasty, rhinoplasty, and voice modification surgery.[73]

The estimated recovery time for each of the surgical procedures, even assuming no complications, can be substantial. For example, assuming no complications, the recovery time for a hysterectomy is up to eight weeks; a mastectomy is up to six weeks; a phalloplasty is up to three months; a metoidioplasty is up to eight weeks; an orchiectomy is up to six weeks; and a vaginoplasty is up to three months.[74] When combined with 12 continuous months of hormone therapy, which is required prior to genital surgery,[75] the total time necessary for surgical transition can exceed a year.

Although relatively few people who are transgender undergo genital reassignment surgeries (2% of transgender men and 10% of transgender women), we have to consider that the rate of complications for these surgeries is significant, which could increase a transitioning Service member's unavailability.[76] Even according to the RAND study, 6% to 20% of those receiving vaginoplasty surgery experience complications, meaning that "between three and 11 Service members per year would experience a long-term disability from gender reassignment

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Gender Dysphoria," p. 2 (May 15, 2014) (noting that gender dysphoria "does not readily fit traditional concepts of medical necessity since research to date has not established anatomical or physiological anomalies associated with [gender dysphoria]"); Hayes Annual Review, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria" (Apr. 18, 2017).

[73] Memorandum from Defense Health Agency, "Information Memorandum: Interim Defense Health Agency Procedures for Reviewing Requests for Waivers to Allow Supplemental Health Care Program Coverage of Sex Reassignment Surgical Procedures" (Nov. 13, 2017); see also RAND Study at Appendix C.

[74] University of California, San Francisco, Center of Excellence for Transgender Health, "Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People," available at http://transhealth.ucsf.edu/trans?page=guidelines-home (last visited Feb. 16, 2018); Discussion with Dr. Loren Schechter, Visiting Clinical Professor of Surgery, University of Illinois at Chicago (Nov. 9, 2017).

[75] RAND Study at 80; see also Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, p. 1184 (Oct. 2016) (noting that Endocrine Society criteria "require that the patient has been on continuous cross-sex hormones and has had continuous [real life experience] or psychotherapy for the past 12 months").

[76] Sandy E. James, Jody L. Herman, Susan Rankin, Mara Keisling, Lisa Mottet & Ma'ayan Anafi, *The Report of the 2015 U.S. Transgender Survey*, pp. 100-103 (National Center for Transgender Equality 2016) available at https://www.transequality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF.

surgery."[77] The RAND study further notes that of those receiving phalloplasty surgery, as many as 25%—one in four—will have complications.[78]

The prevailing judgment of mental health practitioners is that gender dysphoria can be treated with the transition-related care described above. While there are numerous studies of varying quality showing that this treatment can improve health outcomes for individuals with gender dysphoria, the available scientific evidence on the extent to which such treatments fully remedy all of the issues associated with gender dysphoria is unclear. Nor do any of these studies account for the added stress of military life, deployments, and combat.

As recently as August 2016, the Centers for Medicare and Medicaid Services (CMS) conducted a comprehensive review of the relevant literature, over 500 articles, studies, and reports, to determine if there was "sufficient evidence to conclude that gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria."[79] After reviewing the universe of literature regarding sex reassignment surgery, CMS identified 33 studies sufficiently rigorous to merit further review, and of those, "some were positive; others were negative."[80] "Overall," according to CMS, "the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding . . . , small sample sizes, lack of validated assessment tools, and considerable [number of study subjects] lost to follow-up."[81] With respect to whether sex reassignment surgery was "reasonable and necessary" for the treatment of gender dysphoria, CMS concluded that there was "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."[82]

Importantly, CMS identified only six studies as potentially providing "useful information" on the effectiveness of sex reassignment surgery. According to CRS, "the four best designed and conducted studies that assessed the 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 [sex reassignment surgery]."[83]

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[77] RAND Study at 40-41.
[78] Id. at 41.
[79] Tamara Jensen, Joseph Chin, James Rollins, Elizabeth Koller, Linda Gousis & Katherine Szarama, "Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria," Centers for Medicare & Medicaid Services, p. 9 (Aug. 30, 2016) ("CMS Report").
[80] Id. at 62.
[81] Id.
[82] Id. at 65. CMS did not conclude that gender reassignment surgery can never be necessary and reasonable to treat gender dysphoria. To the contrary, it made clear that Medicare insurers could make their own "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." Id. at 66. Nevertheless, CMS did decline to require all Medicare insurers to cover sex reassignment surgeries because it found insufficient scientific evidence to conclude that such surgeries improve health outcomes for persons with gender dysphoria.
[83] Id. at 62.

Additional studies found that the "cumulative rates of requests for surgical reassignment reversal or change in legal status" were between 2.2% and 3.3%.[84]

A sixth study, which came out of Sweden, is one of the most robust because it is a "nationwide population-based, long-term follow-up of sex-reassigned transsexual persons."[85] The study found increased mortality and psychiatric hospitalization for patients who had undergone sex reassignment surgery as compared to a healthy control group.[86] As described by CMS: "The mortality was primarily due to completed suicides (19.1-fold greater than in [the control group]), 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."[87]

According to the Hayes Directory, which conducted a review of 19 peer-reviewed studies on sex reassignment surgery, the "evidence suggests positive benefits," including "decreased [gender dysphoria], depression and anxiety, and increased [quality of life]," but "because of serious limitations," these findings "permit only weak conclusions."[88] It rated the quality of evidence as "very low" due to the numerous limitations in the studies and concluded that there is

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[84] Id.

[85] Ceclilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. Johansson, Niklas Långström & Mikael Landén, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS One*, Vol. 6, p. 6 (Feb. 2011); see also id. ("Strengths of this study include nationwide representativity over more than 30 years, extensive follow-up time, and minimal loss to follow-up. . . . Finally, whereas previous studies either lack a control group or use standardised mortality rates or standarised incidence rates as comparisons, we selected random population controls matched by birth year, and either birth or final sex.").

[86] Id. at 7; see also at 6 ("Mortality from suicide was strikingly high among sex-reassigned persons, also after adjustment for prior psychiatric morbidity. In line with this, sex-reassigned persons were at increased risk for suicide attempts. Previous reports suggest that transsexualism is a strong risk factor for suicide, also after sex reassignment, and our long-term findings support the need for continued psychiatric follow-up for persons at risk to prevent this. Inpatient care for psychiatric disorders was significantly more common among sex-reassigned persons than among matched controls, both before and after sex reassignment. It is generally accepted that transsexuals have more psychiatric ill-health than the general population prior to the sex reassignment. It should therefore come as no surprise that studies have found high rates of depression, and low quality of life, also after sex reassignment. Notably, however, in this study the increased risk for psychiatric hospitalization persisted even after adjusting for psychiatric hospitalization prior to sex reassignment. This suggests that even though sex reassignment alleviates gender dysphoria, there is a need to identify and treat co-occurring psychiatric morbidity in transsexual persons not only before but also after sex reassignment.").

[87] CMS Report at 62. It bears noting that the outcomes for mortality and suicide attempts differed "depending on when sex reassignment was performed: during the period 1973-1988 or 1989-2003." Ceclilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. Johansson, Niklas Långström & Mikael Landén, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS One*, Vol. 6, p. 5 (Feb. 2011). Even though both mortality and suicide attempts were greater for transsexual persons than the healthy control group across both time periods, this did not reach statistical significance during the 1989-2003 period. One possible explanation is that mortality rates for transsexual persons did not begin to diverge from the healthy control group until after 10 years of follow-up, in which case the expected increase in mortality would not have been observed for most of the persons receiving sex reassignment surgeries from 1989-2003. Another possible explanation is that treatment was of a higher quality from 1989-2003 than from 1973-1988.

[88] Hayes Directory, "Sex Reassignment Surgery for the Treatment of Gender Dysphoria," p. 4 (May 15, 2014).

not sufficient "evidence to establish patient selection criteria for [sex reassignment surgery] to treat [gender dysphoria]."[89]

With respect to hormone therapy, the Hayes Directory examined 10 peer-reviewed studies and concluded that a "substantial number of studies of cross-sex hormone therapy each show some positive findings suggesting improvement in well-being after cross-sex hormone therapy."[90] Yet again, it rated the quality of evidence as "very low" and found that the "evidence is insufficient to support patient selection criteria for hormone therapy to treat [gender dysphoria]."[91] Importantly, the Hayes Directory also found: "Hormone therapy and subsequent [sex reassignment surgery] failed to bring overall mortality, suicide rates, or death from illicit drug use in [male-to-female] patients close to rates observed in the general male population. It is possible that mortality is nevertheless reduced by these treatments, but that cannot be determined from the available evidence."[92]

In 2010, Mayo Clinic researchers conducted a comprehensive review of 28 studies on the use of cross-sex hormone therapy in sex reassignment and concluded that there was "very low quality evidence" showing that such therapy "likely improves gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life."[93] Not all of the studies showed positive results, but overall, after pooling the data from all of the studies, the researchers showed that 80% of patients reported improvement in gender dysphoria, 78% reported improvement in psychological symptoms, and 80% reported improvement in quality of life, after receiving hormone therapy.[94] Importantly, however, "[s]uicide attempt rates decreased after sex reassignment but stayed higher than the normal population rate."[95]

The authors of the Swedish study discussed above reached similar conclusions: "This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitali[z]ations in sex-reassigned transsexual individuals compared to a healthy control population. This highlights that post[-]surgical transsexuals are a risk group that need long-term psychiatric and somatic follow-up. Even though surgery and hormonal therapy alleviates gender dysphoria, it is apparently not sufficient to remedy the high rates of morbidity and mortality found among transsexual persons."[96]

Even the RAND study, which the Carter policy is based upon, confirmed that "[t]here have been no randomized controlled trials of the effectiveness of various forms of treatment, and

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[89] Id. at 3.
[90] Hayes Directory, "Hormone Therapy for the Treatment of Gender Dysphoria," pp. 2, 4 (May 19, 2014).
[91] Id. at 4.
[92] Id. at 3.
[93] Mohammad Hassan Murad, Mohamed B. Elamin, Magaly Zumaeta Garcia, Rebecca J. Mullan, Ayman Murad, Patricia J. Erwin & Victor M. Montori, "Hormonal therapy and sex reassignment: a systematic review and meta-analysis of qualify of life and psychosocial outcomes," *Clinical Endocrinology*, Vol. 72, p. 214 (2010).
[94] Id. at 216.
[95] Id.
[96] Ceclilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. Johansson, Niklas Långström & Mikael Landén, "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLoS One*, Vol. 6, pp. 1-8 (Feb. 2011).

most evidence comes from retrospective studies."[97] Although noting that "[m]ultiple observational studies have suggested significant and sometimes dramatic reductions in suicidality, suicide attempts, and suicides among transgender patients after receiving transition-related treatment," RAND made clear that "none of these studies were randomized controlled trials (the gold standard for determining treatment efficacy)."[98] "In the absence of quality randomized trial evidence," RAND concluded, "it is difficult to fully assess the outcomes of treatment for [gender dysphoria]."[99]

Given the scientific uncertainty surrounding the efficacy of transition-related treatments for gender dysphoria, it is imperative that the Department proceed cautiously in setting accession and retention standards for persons with a diagnosis or history of gender dysphoria.

B. Physical Health Standards

Not only is maintaining high standards of mental health critical to military effectiveness and lethality, maintaining high standards of physical health is as well. Although technology has done much to ease the physical demands of combat in some military specialties, war very much remains a physically demanding endeavor. Service members must therefore be physically prepared to endure the rigors and hardships of military service, including potentially combat. They must be able to carry heavy equipment sometimes over long distances; they must be able to handle heavy machinery; they must be able to traverse harsh terrain or survive in ocean waters; they must be able to withstand oppressive heat, bitter cold, rain, sleet, and snow; they must be able to endure in unsanitary conditions, coupled with lack of privacy for basic bodily functions, sometimes with little sleep and sustenance; they must be able to carry their wounded comrades to safety; and they must be able to defend themselves against those who wish to kill them.

Above all, whether they serve on the frontlines or in relative safety in non-combat positions, every Service member is important to mission accomplishment and must be available to perform their duties globally whenever called upon. The loss of personnel due to illness, disease, injury, or bad health diminishes military effectiveness and lethality. The Department's physical health standards are therefore designed to minimize the odds that any given Service member will be unable to perform his or her duties in the future because of illness, disease, or injury. As noted earlier, those who seek to enter military service must be free of contagious diseases; free of medical conditions or physical defects that could require treatment, hospitalization, or eventual separation from service for medical unfitness; medically capable of satisfactorily completing required training; medically adaptable to the military environment; and medically capable of performing duties without aggravation of existing physical defects or medical conditions.[100] To access recruits with higher rates of anticipated unavailability for deployment thrusts a heavier burden on those who would deploy more often.

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[97] RAND Study at 7.
[98] Id. at 10 (citing only to a California Department of Insurance report).
[99] Id.
[100] DoDI 6130.03 at 2.

Historically, absent a waiver, the Department has barred from accessing into the military anyone who had undergone chest or genital surgery (e.g., removal of the testicles or uterus) and anyone with a history of major abnormalities or defects of the chest or genitalia, including hermaphroditism and pseudohermaphroditism.[101] Persons with conditions requiring medications, such as anti-depressants and hormone treatment, were also disqualified from service, unless a waiver was granted.[102]

These standards have long applied uniformly to all persons, regardless of transgender status. The Carter policy, however, deviates from these uniform standards by exempting, under certain conditions, treatments associated with gender transition, such as sex reassignment surgery and cross-sex hormone therapy. For example, under the Carter policy, an applicant who has received genital reconstruction surgery may access without a waiver if a period of 18 months has elapsed since the date of the most recent surgery, no functional limitations or complications persist, and no additional surgery is required. In contrast, an applicant who received similar surgery following a traumatic injury is disqualified from military service without a waiver.[103] Similarly, under the Carter policy, an applicant who is presently receiving cross-sex hormone therapy post-gender transition may access without a waiver if the applicant has been stable on such hormones for 18 months. In contrast, an applicant taking synthetic hormones for the treatment of hypothyroidism is disqualified from military service without a waiver.[104]

C. Sex-Based Standards

Women have made invaluable contributions to the defense of the Nation throughout our history. These contributions have only grown more significant as the number of women in the Armed Forces has increased and as their roles have expanded. Today, women account for 17.6% of the force,[105] and now every position, including combat arms positions, is open to them.

The vast majority of military standards make no distinctions between men and women. Where biological differences between males and females are relevant, however, military standards do differentiate between them. The Supreme Court has acknowledged the lawfulness of sex-based standards that flow from legitimate biological differences between the sexes.[106] These sex-based standards ensure fairness, equity, and safety; satisfy reasonable expectations of privacy; reflect common practice in society; and promote core military values of dignity and respect between men and women—all of which promote good order, discipline, steady leadership, unit cohesion, and ultimately military effectiveness and lethality.

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[101] Id. at 25-27.
[102] Id. at 46-48.
[103] Id. at 26-27.
[104] Id. at 41.
[105] Defense Manpower Data Center, Active and Reserve Master Files (Dec. 2017).
[106] For example, in *United States v. Virginia*, the Court noted approvingly that "[a]dmitting women to [the Virginia Military Institute] would undoubtedly require alterations necessary to afford members of each sex privacy from the other sex in living arrangements, and to adjust aspects of the physical training programs." 518 U.S. 515, 550-51 n.19 (1996) (citing the statute that requires the same standards for women admitted to the service academies as for the men, "except for those minimum essential adjustments in such standards required because of physiological differences between male and female individuals").

For example, anatomical differences between males and females, and the reasonable expectations of privacy that flow from those differences, at least partly account for the laws and regulations that require separate berthing, bathroom, and shower facilities and different drug testing procedures for males and females.[107] To maintain good order and discipline, Congress has even required by statute that the sleeping and latrine areas provided for "male" recruits be physically separated from the sleeping and latrine areas provided for "female" recruits during basic training and that access by drill sergeants and training personnel "after the end of the training day" be limited to persons of the "same sex as the recruits" to ensure "after-hours privacy for recruits during basic training."[108]

In addition, physiological differences between males and females account for the different physical fitness and body fat standards that apply to men and women.[109] This ensures equity and fairness. Likewise, those same physiological differences also account for the policies that regulate competition between men and women in military training and sports, such as boxing and combatives.[110] This ensures protection from injury.

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[107] See, e.g., Department of the Army, Training and Doctrine Command, TRADOC Regulation 350-6, "Enlisted Initial Entry Training Policies and Administration," p. 56 (Mar. 20, 2017); Department of the Air Force, Air Force Instruction 32-6005, "Unaccompanied Housing Management," p. 35 (Jan 29., 2016); Department of the Army, Human Resources Command, AR 600-85, "Substance Abuse Program" (Dec. 28, 2012) ("Observers must . . . [b]e the same gender as the Soldier being observed.").

[108] See 10 U.S.C. § 4319 (Army), 10 U.S.C. § 6931 (Navy), and 10 U.S.C. § 9319 (Air Force) (requiring the sleeping and latrine areas provided for "male" recruits to be physically separated from the sleeping and latrine areas provided for "female" recruits during basic training); 10 U.S.C. § 4320 (Army), 10 U.S.C. § 6932 (Navy), and 10 U.S.C. § 9320 (Air Force) (requiring that access by drill sergeants and training personnel "after the end of the training day" be limited to persons of the "same sex as the recruits").

[109] See, e.g., Department of the Army, Army Regulation 600-9, "The Army Body Composition Program," pp. 21-31 (June 28, 2013); Department of the Navy, Office of the Chief of Naval Operations Instruction 6110.1J, "Physical Readiness Program," p. 7 (July 11, 2011); Department of the Air Force, Air Force Instruction 36-2905, "Fitness Program," pp. 86-95, 106-146 (Aug. 27, 2015); Department of the Navy, Marine Corps Order 6100.13, "Marine Corps Physical Fitness Program," (Aug. 1, 2008); Department of the Navy, Marine Corps Order 6110.3A, "Marine Corps Body Composition and Military Appearance Program," (Dec. 15, 2016); see also United States Military Academy, Office of the Commandant of Cadets, "Physical Program Whitebook AY 16-17," p. 13 (specifying that, to graduate, cadets must meet the minimum performance standard of 3:30 for men and 5:29 for women on the Indoor Obstacle Course Test); Department of the Army, Training and Doctrine Command, TRADOC Regulation 350-6, "Enlisted Initial Entry Training Policies and Administration," p. 56 (Mar. 20, 2017) ("Performance requirement differences, such as [Army Physical Fitness Test] scoring are based on physiological differences, and apply to the entire Army.").

[110] See, e.g., Headquarters, Department of the Army, TC 3-25.150, "Combatives," p. A-15 (Feb. 2017) ("Due to the physiological difference between the sexes and in order to treat all Soldiers fairly and conduct gender-neutral competitions, female competitors will be given a 15 percent overage at weigh-in."); id. ("In championships at battalion-level and above, competitors are divided into eight weight class brackets. . . . These classes take into account weight and gender."); Major Alex Bedard, Major Robert Peterson & Ray Barone, "Punching Through Barriers: Female Cadets Integrated into Mandatory Boxing at West Point," *Association of the United States Army* (Nov. 16, 2017), https://www.ausa.org/articles/punching-through-barriers-female-cadets-boxing-west-point (noting that "[m]atching men and women according to weight may not adequately account for gender differences regarding striking force" and that "[w]hile conducting free sparring, cadets must box someone of the same gender"); RAND Study at 57 (noting that, under British military policy, transgender persons "can be excluded from sports that organize around gender to ensure the safety of the individual or other participants"); see also International Olympic Committee Consensus Meeting on Sex Reassignment and Hyperandrogensim (Nov. 2015), https://stillmed.olympic.org/Documents/Commissions_PDFfiles/Medical_commission/2015-11_ioc_

Uniform and grooming standards, to a certain extent, are also based on anatomical differences between males and females. Even those uniform and grooming standards that are not, strictly speaking, based on physical biology nevertheless flow from longstanding societal expectations regarding differences in attire and grooming for men and women.[111]

Because these sex-based standards are based on legitimate biological differences between males and females, it follows that a person's physical biology should dictate which standards apply. Standards designed for biological males logically apply to biological males, not biological females, and vice versa. When relevant, military practice has long adhered to this straightforward and logical demarcation.

By contrast, the Carter policy deviates from this longstanding practice by making military sex-based standards contingent, not necessarily on the person's biological sex, but on the person's gender marker in DEERS, which can be changed to reflect the person's gender identity.[112] Thus, under the Carter policy, a biological male who identifies as a female (and changes his gender marker to reflect that gender) must be held to the standards and regulations for females, even though those standards and regulations are based on female physical biology, not female gender identity. The same goes for females who identify as males. Gender identity alone, however, is irrelevant to standards that are designed on the basis of biological differences.

Rather than apply only to those transgender individuals who have altered their external biological characteristics to fully match that of their preferred gender, under the Carter policy, persons need not undergo sex reassignment surgery, or even cross-sex hormone therapy, in order to be recognized as, and thus subject to the standards associated with, their preferred gender. A male who identifies as female could remain a biological male in every respect and still must be treated in all respects as a female, including with respect to physical fitness, facilities, and uniform and grooming. This scenario is not farfetched. According to the APA, not "all individuals with gender dysphoria desire a complete gender reassignment. . . . Some are satisfied with no medical or surgical treatment but prefer to dress as the felt gender in public."[113] Currently, of the 424 approved Service member treatment plans, at least 36 do not include cross-

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consensus_meeting_on_sex_reassignment_and_hyperandrogenism-en.pdf; NCAA Office of Inclusion; NCAA Inclusion of Transgender Student-Athletes (Aug. 2011), https://www.ncaa.org/sites/default/files/Transgender_Handbook_2011_Final.pdf.

[111] "The difference between men's and women's grooming policies recognizes the difference between the sexes; sideburns for men, different hairstyles and cosmetics for women. Establishing identical grooming and personal appearance standards for men and women would not be in the Navy's best interest and is not a factor in the assurance of equal opportunity." Department of the Navy, Navy Personnel Command, Navy Personnel Instruction 156651, "Uniform Regulations," Art. 2101.1 (July 7, 2017); see also Department of the Army, Army Regulation 670-1, "Wear and Appearance of Army Uniforms and Insignia," pp. 4-16 (Mar. 31, 2014); Department of the Air Force, Air Force Instruction 26-2903, "Dress and Personal Appearance of Air Force Personnel," pp. 17-27 (Feb. 9, 2017); Department of the Navy, Marine Corps Order P1020.34G, "Marine Corps Uniform Regulations," pp. 1-9 (Mar. 31, 2003).

[112] Department of Defense Instruction 1300.28, *In-service Transition for Service Members Identifying as Transgender*, pp. 3-4 (June 30, 2016).

[113] American Psychiatric Association, "Expert Q & A: Gender Dysphoria," available at https://www.psychiatry.org/patients-families/gender-dysphoria/expert-qa (last visited Feb. 14, 2018).

sex hormone therapy or sex reassignment surgery.[114] And it is questionable how many Service members will obtain any type of sex reassignment surgery. According to a survey of transgender persons, only 25% reported having had some form of transition-related surgery.[115]

The variability and fluidity of gender transition undermine the legitimate purposes that justify different biologically-based, male-female standards. For example, by allowing a biological male who retains male anatomy to use female berthing, bathroom, and shower facilities, it undermines the reasonable expectations of privacy and dignity of female Service members. By allowing a biological male to meet the female physical fitness and body fat standards and to compete against females in gender-specific physical training and athletic competition, it undermines fairness (or perceptions of fairness) because males competing as females will likely score higher on the female test than on the male test and possibly compromise safety. By allowing a biological male to adhere to female uniform and grooming standards, it creates unfairness for other males who would also like to be exempted from male uniform and grooming standards as a means of expressing their own sense of identity.

These problems could perhaps be alleviated if a person's preferred gender were recognized only after the person underwent a biological transition. The concept of gender transition is so nebulous, however, that drawing any line—except perhaps at a full sex reassignment surgery—would be arbitrary, not to mention at odds with current medical practice, which allows for a wide range of individualized treatment. In any event, rates for genital surgery are exceedingly low—2% of transgender men and 10% of transgender women.[116] Only up to 25% of surveyed transgender persons report having had some form of transition-related surgery.[117] The RAND study estimated that such rates "are typically only around 20 percent, with the exception of chest surgery among female-to-male transgender individuals."[118] Moreover, of the 424 approved Service member treatment plans available for study, 388 included cross-sex hormone treatment, but only 34 non-genital sex reassignment surgeries and one genital surgery have been completed thus far. Only 22 Service members have requested a waiver for a genital sex reassignment surgery.[119]

Low rates of full sex reassignment surgery and the otherwise wide variation of transition-related treatment, with all the challenges that entails for privacy, fairness, and safety, weigh in favor of maintaining a bright line based on biological sex—not gender identity or some variation thereof—in determining which sex-based standards apply to a given Service member. After all, a person's biological sex is generally ascertainable through objective means. Moreover, this approach will ensure that biologically-based standards will be applied uniformly to all Service members of the same biological sex. Standards that are clear, coherent, objective, consistent, predictable, and uniformly applied enhance good order, discipline, steady leadership, and unit cohesion, which in turn, ensure military effectiveness and lethality.

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[114] Data reported by the Departments of the Army, Navy, and Air Force (Oct. 2017).
[115] Id.
[116] Sandy E. James, Jody L. Herman, Susan Rankin, Mara Keisling, Lisa Mottet & Ma'ayan Anafi, *The Report of the 2015 U.S. Transgender Survey*, pp. 100-103 (National Center for Transgender Equality 2016) available at https://www.transequality.org/sites/default/files/docs/USTS-Full-Report-FINAL.PDF.
[117] Id. at 100.
[118] RAND Study at 21.
[119] Defense Health Agency, Supplemental Health Care Program Data (Feb. 2018).

New Transgender Policy

In light of the forgoing standards, all of which are necessary for military effectiveness and lethality, as well as the recommendations of the Panel of Experts, the Department, in consultation with the Department of Homeland Security, recommends the following policy:

A. Transgender Persons Without a History or Diagnosis of Gender Dysphoria, Who Are Otherwise Qualified for Service, May Serve, Like All Other Service Members, in Their Biological Sex.

Transgender persons who have not transitioned to another gender and do not have a history or current diagnosis of gender dysphoria—i.e., they identify as a gender other than their biological sex but do not currently experience distress or impairment of functioning in meeting the standards associated with their biological sex—are eligible for service, provided that they, like all other persons, satisfy all mental and physical health standards and are capable of adhering to the standards associated with their biological sex. This is consistent with the Carter policy, under which a transgender person's gender identity is recognized only if the person has a diagnosis or history of gender dysphoria.

Although the precise number is unknown, the Department recognizes that many transgender persons could be disqualified under this policy. And many transgender persons who would not be disqualified may nevertheless be unwilling to adhere to the standards associated with their biological sex. But many have served, and are serving, with great dedication under the standards for their biological sex. As noted earlier, 8,980 Service members reportedly identify as transgender, and yet there are currently only 937 active duty Service members who have been diagnosed with gender dysphoria since June 30, 2016.

B. Transgender Persons Who Require or Have Undergone Gender Transition Are Disqualified.

Except for those who are exempt under this policy, as described below in C.3, and except where waivers or exceptions to policy are otherwise authorized, persons who are diagnosed with gender dysphoria, either before or after entry into service, and require transition-related treatment, or have already transitioned to their preferred gender, should be disqualified from service. In the Department's military judgment, this is a necessary departure from the Carter policy for the following reasons:

1. *Undermines Readiness.* While transition-related treatments, including real life experience, cross-sex hormone therapy, and sex reassignment surgery, are widely accepted forms of treatment, there is considerable scientific uncertainty concerning whether these treatments fully remedy, even if they may reduce, the mental health problems associated with gender dysphoria. Despite whatever improvements in condition may result from these treatments, there is evidence that rates of psychiatric hospitalization and suicide behavior remain higher for persons with gender dysphoria, even after treatment, as compared to persons without gender dysphoria.[120] The persistence of these problems is a risk for readiness.

[120] See *supra* at pp. 24-26.

Another readiness risk is the time required for transition-related treatment and the impact on deployability. Although limited and incomplete because many transitioning Service members either began treatment before the Carter policy took effect or did not require sex reassignment surgery, currently available in-service data already show that, cumulatively, transitioning Service members in the Army and Air Force have averaged 167 and 159 days of limited duty, respectively, over a one-year period.[121]

Transition-related treatment that involves cross-sex hormone therapy or sex reassignment surgery could render Service members with gender dysphoria non-deployable for a significant period of time—perhaps even a year—if the theater of operations cannot support the treatment. For example, Endocrine Society guidelines for cross-sex hormone therapy recommend quarterly bloodwork and laboratory monitoring of hormone levels during the first year of treatment.[122] Of the 424 approved Service member treatment plans available for study, almost all of them—91.5%—include the prescription of cross-sex hormones.[123] The period of potential non-deployability increases for those who undergo sex reassignment surgery. As described earlier, the recovery time for the various sex reassignment procedures is substantial. For non-genital surgeries (assuming no complications), the range of recovery is between two and eight weeks depending on the type of surgery, and for genital surgeries (again assuming no complications), the range is between three and six months before the individual is able to return to full duty.[124] When combined with 12 continuous months of hormone therapy, which is recommended prior to genital surgery,[125] the total time necessary for sex reassignment surgery could exceed a year. If the operational environment does not permit access to a lab for monitoring hormones (and there is certainly debate over how common this would be), then the Service member must be prepared to forego treatment, monitoring, or the deployment. Either outcome carries risks for readiness.

Given the limited data, however, it is difficult to predict with any precision the impact on readiness of allowing gender transition. Moreover, the input received by the Panel of Experts varied considerably. On one hand, some commanders with transgender Service members

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[121] Data reported by the Departments of the Army and Air Force (Oct. 2017).

[122] Wylie C. Hembree, Peggy Cohen-Kettenis, Lous Gooren, Sabine Hannema, Walter Meyer, M. Hassan Murad, Stephen Rosenthal, Joshua Safer, Vin Tangpricha, & Guy T'Sjoen, "Endocrine Treatment of Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline," *The Journal of Clinical Endocrinology & Metabolism*, Vol. 102, pp. 3869-3903 (Nov. 2017).

[123] Data reported by the Departments of the Army, Navy, and Air Force (Oct. 2017). Although the RAND study observed that British troops who are undergoing hormone therapy are generally able to deploy if the "hormone dose is steady and there are no major side effects," it nevertheless acknowledged that "deployment to all areas may not be possible, depending on the needs associated with any medication (e.g., refrigeration)." RAND Study at 59.

[124] For example, assuming no complications, the recovery time for a hysterectomy is up to eight weeks; a mastectomy is up to six weeks; a phalloplasty is up to three months; a metoidioplasty is up to 8 weeks; an orchiectomy is up to 6 weeks; and a vaginoplasty is up to three months. See University of California, San Francisco, Center of Excellence for Transgender Health, "Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People," available at http://transhealth.ucsf.edu/trans?page=guidelines-home (last visited Feb. 16, 2018); see also Discussion with Dr. Loren Schechter, Visiting Clinical Professor of Surgery, University of Illinois at Chicago (Nov. 9, 2017).

[125] RAND Study at 80; see also id. at 7; Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, p. 1184 (Oct. 2016) (noting that Endocrine Society criteria "require that the patient has been on continuous cross-sex hormones and has had continuous [real life experience] or psychotherapy for the past 12 months").

reported that, from the time of diagnosis to the completion of a transition plan, the transitioning Service members would be non-deployable for two to two-and-a-half years.[126] On the other hand, some commanders, as well as transgender Service members themselves, reported that transition-related treatment is not a burden on unit readiness and could be managed to avoid interfering with deployments, with one commander even reporting that a transgender Service member with gender dysphoria under his command elected to postpone surgery in order to deploy.[127] This conclusion was echoed by some experts in endocrinology who found no harm in stopping or adjusting hormone therapy treatment to accommodate deployment during the first year of hormone use.[128] Of course, postponing treatment, especially during a combat deployment, has risks of its own insofar as the treatment is necessary to mitigate the clinically significant distress and impairment of functioning caused by gender dysphoria. After all, "when Service members deploy and then do not meet medical deployment fitness standards, there is risk for inadequate treatment within the operational theater, personal risk due to potential inability to perform combat required skills, and the potential to be sent home from the deployment and render the deployed unit with less manpower."[129] In short, the periods of transition-related non-availability and the risks of deploying untreated Service members with gender dysphoria are uncertain, and that alone merits caution.

Moreover, most mental health conditions, as well as the medication used to treat them, limit Service members' ability to deploy. Any DSM-5 psychiatric disorder with residual symptoms, or medication side effects, which impair social or occupational performance, require a waiver for the Service member to deploy.[130] The same is true for mental health conditions that pose a substantial risk for deterioration or recurrence in the deployed environment.[131] In managing mental health conditions while deployed, providers must consider the risk of exacerbation if the individual were exposed to trauma or severe operational stress. These determinations are difficult to make in the absence of evidence on the impact of deployment on individuals with gender dysphoria.[132]

The RAND study acknowledges that the inclusion of individuals with gender dysphoria in the force will have a negative impact on readiness. According to RAND, foreign militaries that allow service by personnel with gender dysphoria have found that it is sometimes necessary to restrict the deployment of transitioning individuals, including those receiving hormone therapy and surgery, to austere environments where their healthcare needs cannot be met.[133] Nevertheless, RAND concluded that the impact on readiness would be minimal—e.g., 0.0015% of available deployable labor-years across the active and reserve components—because of the

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[126] Minutes, Transgender Review Panel (Oct. 13, 2017).
[127] Id.
[128] Minutes, Transgender Review Panel (Nov. 9, 2017).
[129] Institute for Defense Analyses, "Force Impact of Expanding the Recruitment of Individuals with Auditory Impairment," pp. 60-61 (Apr. 2016).
[130] Modification Thirteen to U.S. Central Command Individual Protection and Individual, Unit Deployment Policy, Tab A, p. 8 (Mar. 2017).
[131] Id.
[132] See generally Memorandum from the Assistant Secretary of Defense for Health Affairs, "Clinical Practice Guidance for Deployment-Limiting Mental Disorders and Psychotropic Medications," pp. 2-4 (Oct. 7, 2013).
[133] RAND Study at 40.

exceedingly small number of transgender Service members who would seek transition-related treatment.[134] Even then, RAND admitted that the information it cited "must be interpreted with caution" because "much of the current research on transgender prevalence and medical treatment rates relies on self-reported, nonrepresentative samples."[135] Nevertheless, by RAND's standard, the readiness impact of many medical conditions that the Department has determined to be disqualifying—from bipolar disorder to schizophrenia—would be minimal because they, too, exist only in relatively small numbers.[136] And yet that is no reason to allow persons with those conditions to serve.

The issue is not whether the military can absorb periods of non-deployability in a small population; rather, it is whether an individual with a particular condition can meet the standards for military duty and, if not, whether the condition can be remedied through treatment that renders the person non-deployable for as little time as possible. As the Department has noted before: "[W]here the operational requirements are growing faster than available resources," it is imperative that the force "be manned with Service members capable of meeting all mission demands. The Services require that every Service member contribute to full mission readiness, regardless of occupation. In other words, the Services require all Service members to be able to engage in core military tasks, including the ability to deploy rapidly, without impediment or encumbrance."[137] Moreover, the Department must be mindful that "an increase in the number of non-deployable military personnel places undue risk and personal burden on Service members qualified and eligible to deploy, and negatively impacts mission readiness."[138] Further, the Department must be attuned to the impact that high numbers of non-deployable military personnel places on families whose Service members deploy more often to backfill or compensate for non-deployable persons.

In sum, the available information indicates that there is inconclusive scientific evidence that the serious problems associated with gender dysphoria can be fully remedied through transition-related treatment and that, even if it could, most persons requiring transition-related treatment could be non-deployable for a potentially significant amount of time. By this metric, Service members with gender dysphoria who need transition-related care present a significant challenge for unit readiness.

2. *Incompatible with Sex-Based Standards.* As discussed in detail earlier, military personnel policy and practice has long maintained a clear line between men and women where their biological differences are relevant with respect to physical fitness and body fat standards; berthing, bathroom, and shower facilities; and uniform and grooming standards. This line promotes good order and discipline, steady leadership, unit cohesion, and ultimately military

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[134] Id. at 42.
[135] Id. at 39.
[136] According to the National Institute of Mental Health, 2.8% of U.S. adults experienced bipolar disorder in the past year, and 4.4% have experienced the condition at some time in their lives. National Institute of Mental Health, "Bipolar Disorder" (Nov. 2017) https://www.nimh.nih.gov/health/statistics/bipolar-disorder.shtml. The prevalence of schizophrenia is less than 1%. National Institute of Mental Health, "Schizophrenia" (Nov. 2017) https://www.nimh.nih.gov/health/statistics/schizophrenia.shtml.
[137] Under Secretary of Defense for Personnel and Readiness, "Fiscal Year 2016 Report to Congress on the Review of Enlistment of Individuals with Disabilities in the Armed Forces," p. 9 (Apr. 2016).
[138] Id. at 10.

effectiveness and lethality because it ensures fairness, equity, and safety; satisfies reasonable expectations of privacy; reflects common practice in the society from which we recruit; and promotes core military values of dignity and respect between men and women. To exempt Service members from the uniform, biologically-based standards applicable to their biological sex on account of their gender identity would be incompatible with this line and undermine the objectives such standards are designed to serve.

First, a policy that permits a change of gender without requiring any biological changes risks creating unfairness, or perceptions thereof, that could adversely affect unit cohesion and good order and discipline. It could be perceived as discriminatory to apply different biologically-based standards to persons of the same biological sex based on gender identity, which is irrelevant to standards grounded in physical biology. For example, it unfairly discriminates against biological males who identify as male and are held to male standards to allow biological males who identify as female to be held to female standards, especially where the transgender female retains many of the biological characteristics and capabilities of a male. It is important to note here that the Carter policy does not require a transgender person to undergo any biological transition in order to be treated in all respects in accordance with the person's preferred gender. Therefore, a biological male who identifies as female could remain a biological male in every respect and still be governed by female standards. Not only would this result in perceived unfairness by biological males who identify as male, it would also result in perceived unfairness by biological females who identify as female. Biological females who may be required to compete against such transgender females in training and athletic competition would potentially be disadvantaged.[139] Even more importantly, in physically violent training and competition, such as boxing and combatives, pitting biological females against biological males who identify as female, and vice versa, could present a serious safety risk as well.[140]

This concern may seem trivial to those unfamiliar with military culture. But vigorous competition, especially physical competition, is central to the military life and is indispensable to the training and preparation of warriors. Nothing encapsulates this more poignantly than the words of General Douglas MacArthur when he was superintendent of the U.S. Military Academy and which are now engraved above the gymnasium at West Point: "Upon the fields of friendly

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[139] See *supra* note 109. Both the International Olympic Committee (IOC) and the National Collegiate Athletic Association (NCAA) have attempted to mitigate this problem in their policies regarding transgender athletes. For example, the IOC requires athletes who transition from male to female to demonstrate certain suppressed levels of testosterone to minimize any advantage in women's competition. Similarly, the NCAA prohibits an athlete who has transitioned from male to female from competing on a women's team without changing the team status to a mixed gender team. While similar policies could be employed by the Department, it is unrealistic to expect the Department to subject transgender Service members to routine hormone testing prior to biannual fitness testing, athletic competition, or training simply to mitigate real and perceived unfairness or potential safety concerns. See, e.g., International Olympic Committee Consensus Meeting on Sex Reassignment and Hyperandrogensim (Nov. 2015), https://stillmed.olympic.org/Documents/Commissions_PDFfiles/Medical_commission/2015-11_ioc_consensus_meeting_on_sex_reassignment_and_hyperandrogenism-en.pdf; NCAA Office of Inclusion, NCAA Inclusion of Transgender Student-Athletes (Aug. 2011), https://www.ncaa.org/sites/default/files/Transgender_Handbook_2011_Final.pdf.

[140] See *supra* note 109.

strife are sown the seeds that, upon other fields, on other days will bear the fruits of victory."[141] Especially in combat units and in training, including the Service academies, ROTC, and other commissioning sources, Service members are graded and judged in significant measure based upon their physical aptitude, which is only fitting given that combat remains a physical endeavor.

Second, a policy that accommodates gender transition without requiring full sex reassignment surgery could also erode reasonable expectations of privacy that are important in maintaining unit cohesion, as well as good order and discipline. Given the unique nature of military service, Service members of the same biological sex are often required to live in extremely close proximity to one another when sleeping, undressing, showering, and using the bathroom. Because of reasonable expectations of privacy, the military has long maintained separate berthing, bathroom, and shower facilities for men and women while in garrison. In the context of recruit training, this separation is even mandated by Congress.[142]

Allowing transgender persons who have not undergone a full sex reassignment, and thus retain at least some of the anatomy of their biological sex, to use the facilities of their identified gender would invade the expectations of privacy that the strict male-female demarcation in berthing, bathroom, and shower facilities is meant to serve. At the same time, requiring transgender persons who have developed, even if only partially, the anatomy of their identified gender to use the facilities of their biological sex could invade the privacy of the transgender person. Without separate facilities for transgender persons or other mitigating accommodations, which may be unpalatable to transgender individuals and logistically impracticable for the Department, the privacy interests of biological males and females and transgender persons could be anticipated to result in irreconcilable situations. Lieutenants, Sergeants, and Petty Officers charged with carrying out their units' assigned combat missions should not be burdened by a change in eligibility requirements disconnected from military life under austere conditions.

The best illustration of this irreconcilability is the report of one commander who was confronted with dueling equal opportunity complaints—one from a transgender female (i.e., a biological male with male genitalia who identified as female) and the other from biological females. The transgender female Service member was granted an exception to policy that allowed the Service member to live as a female, which included giving the Service member access to female shower facilities. This led to an equal opportunity complaint from biological females in the unit who believed that granting a biological male, even one who identified as a female, access to their showers violated their privacy. The transgender Service member responded with an equal opportunity complaint claiming that the command was not sufficiently supportive of the rights of transgender persons.[143]

The collision of interests discussed above are a direct threat to unit cohesion and will inevitably result in greater leadership challenges without clear solutions. Leaders at all levels

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[141] Douglas MacAruthur, *Respectfully Quoted: A Dictionary of Quotations* (1989), available at http://www.bartleby.com/73/1874.html.

[142] See *supra* note 108.

[143] Minutes, Transgender Review Panel (Oct. 13, 2017). Limited data exists regarding the performance of transgender Service members due to policy restrictions in Department of Defense 1300.28, *In-Service Transition for Transgender Service Members* (Oct. 1, 2016), that prevent the Department from tracking individuals who may identify as transgender as a potentially unwarranted invasion of personal privacy.

already face immense challenges in building cohesive military units. Blurring the line that differentiates the standards and policies applicable to men and women will only exacerbate those challenges and divert valuable time and energy from military tasks.

The unique leadership challenges arising from gender transition are evident in the Department's handbook implementing the Carter policy. The handbook provides guidance on various scenarios that commanders may face. One such scenario concerns the use of shower facilities: "A transgender Service member has expressed privacy concerns regarding the open bay shower configuration. Similarly, several other non-transgender Service members have expressed discomfort when showering in these facilities with individuals who have different genitalia." As possible solutions, the handbook offers that the commander could modify the shower facility to provide privacy or, if that is not feasible, adjust the timing of showers. Another scenario involves proper attire during a swim test: "It is the semi-annual swim test and a female to male transgender Service member who has fully transitioned, but did not undergo surgical change, would like to wear a male swimsuit for the test with no shirt or other top coverage." The extent of the handbook's guidance is to advise commanders that "[i]t is within [their] discretion to take measures ensuring good order and discipline," that they should "counsel the individual and address the unit, if additional options (e.g., requiring all personnel to wear shirts) are being considered," and that they should consult the Service Central Coordination Cell, a help line for commanders in need of advice.

These vignettes illustrate the significant effort required of commanders to solve challenging problems posed by the implementation of the current transgender service policies. The potential for discord in the unit during the routine execution of daily activities is substantial and highlights the fundamental incompatibility of the Department's legitimate military interest in uniformity, the privacy interests of all Service members, and the interest of transgender individuals in an appropriate accommodation. Faced with these conflicting interests, commanders are often forced to devote time and resources to resolve issues not present outside of military service. A failure to act quickly can degrade an otherwise highly functioning team, as will failing to seek appropriate counsel and implementing a faulty solution. The appearance of unsteady or seemingly unresponsive leadership to Service member concerns erodes the trust that is essential to unit cohesion and good order and discipline.

The RAND study does not meaningfully address how accommodations for gender transition would impact perceptions of fairness and equity, expectations of privacy, and safety during training and athletic competition and how these factors in turn affect unit cohesion. Instead, the RAND study largely dismisses concerns about the impact on unit cohesion by pointing to the experience of four countries that allow transgender service—Australia, Canada, Israel, and the United Kingdom.[144] Although the vast majority of armed forces around the world do not permit or have policies on transgender service, RAND noted that 18 militaries do, but only four have well-developed and publicly available policies.[145] RAND concluded that "the available research revealed no significant effect on cohesion, operational effectiveness, or

[144] RAND Study at 45.
[145] Id. at 50.

readiness."[146] It reached this conclusion, however, despite noting reports of resistance in the ranks, which is a strong indication of an adverse effect on unit cohesion.[147] Nevertheless, RAND acknowledged that the available data was "limited" and that the small number of transgender personnel may account for "the limited effect on operational readiness and cohesion."[148]

Perhaps more importantly, however, the RAND study mischaracterizes or overstates the reports upon which it rests its conclusions. For example, the RAND study cites *Gays in Foreign Militaries 2010: A Global Primer* by Nathaniel Frank as support for the conclusions that there is no evidence that transgender service has had an adverse effect on cohesion, operational effectiveness, or readiness in the militaries of Australia and the United Kingdom and that diversity has actually led to increases in readiness and performance.[149] But that particular study has nothing to do with examining the service of transgender persons; rather, it is about the integration of homosexual persons into the military.[150]

With respect to transgender service in the Israeli military, the RAND study points to an unpublished paper by Anne Speckhard and Reuven Paz entitled *Transgender Service in the Israeli Defense Forces: A Polar Opposite Stance to the U.S. Military Policy of Barring Transgender Soldiers from Service*. The RAND study cites this paper for the proposition that "there has been no reported effect on cohesion or readiness" in the Israeli military and "there is no evidence of any impact on operational effectiveness."[151] These sweeping and categorical claims, however, are based only on "six in-depth interviews of experts on the subject both inside and outside the [Israeli Defense Forces (IDF)]: two in the IDF leadership—including the spokesman's office; two transgender individuals who served in the IDF, and two professionals who serve transgender clientele—before, during and after their IDF service."[152] As the RAND report observed, however: "There do appear to be some limitations on the assignment of transgender personnel, particularly in combat units. Because of the austere living conditions in these types of units, necessary accommodations may not be available for Service members in the midst of a gender transition. As a result, transitioning individuals are typically not assigned to combat units."[153] In addition, as the RAND study notes, under the Israeli policy at the time, "assignment of housing, restrooms, and showers is typically linked to the birth gender, which does not change in the military system until after gender reassignment surgery."[154] Therefore, insofar as a Service member's change of gender is not recognized until after sex reassignment

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[146] Id. at 45.
[147] Id.
[148] Id.
[149] Id.
[150] Nathaniel Frank, "Gays in Foreign Militaries 2010: A Global Primer," p. 6 *The Palm Center* (Feb. 2010), https://www.palmcenter.org/wpcontent/uploads/2017/12/FOREIGNMILITARIESPRIMER2010FINAL.pdf ("This study seeks to answer some of the questions that have been, and will continue to be, raised surrounding the instructive lessons from other nations that have lifted their bans on openly gay service.").
[151] Rand Study at 45.
[152] Anne Speckhard & Reuven Paz, "Transgender Service in the Israeli Defense Forces: A Polar Opposite Stance to the U.S. Military Policy of Barring Transgender Soldiers from Service," p. 3 (2014), http://www.researchgate.net/publication/280093066.
[153] RAND Study at 56.
[154] Id. at 55.

surgery, the Israeli policy—and whatever claims about its impact on cohesion, readiness, and operational effectiveness—are distinguishable from the Carter policy.

Finally, the RAND study cites to a journal article on the Canadian military experience entitled *Gender Identity in the Canadian Forces: A Review of Possible Impacts on Operational Effectiveness* by Alan Okros and Denise Scott. According to RAND, the authors of this article "found no evidence of any effect on unit or overall cohesion."[155] But the article not only fails to support the RAND study's conclusions (not to mention the article's own conclusions), but it confirms the concerns that animate the Department's recommendations. The article acknowledges, for example, the difficulty commanders face in managing the competing interests at play:

> Commanders told us that the new policy fails to provide sufficient guidance as to how to weigh priorities among competing objectives during their subordinates' transition processes. Although they endorsed the need to consult transitioning Service members, they recognized that as commanding officers, they would be called on to balance competing requirements. They saw the primary challenge to involve meeting trans individual's expectations for reasonable accommodation and individual privacy while avoiding creating conditions that place extra burdens on others or undermined the overall team effectiveness. To do so, they said that they require additional guidance on a range of issues including clothing, communal showers, and shipboard bunking and messing arrangements.[156]

Notwithstanding its optimistic conclusions, the article also documents serious problems with unit cohesion. The authors observe, for instance, that the chain of command "has not fully earned the trust of the transgender personnel," and that even though some transgender Service members do trust the chain of command, others "expressed little confidence in the system," including one who said, "I just don't think it works that well."[157]

In sum, although the foregoing considerations are not susceptible to quantification, undermining the clear sex-differentiated lines with respect to physical fitness; berthing, bathroom, and shower facilities; and uniform and grooming standards, which have served all branches of Service well to date, risks unnecessarily adding to the challenges faced by leaders at all levels, potentially fraying unit cohesion, and threatening good order and discipline. The Department acknowledges that there are serious differences of opinion on this subject, even among military professionals, including among some who provided input to the Panel of Experts,[158] but given the vital interests at stake—the survivability of Service members, including

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[155] Id. at 45.

[156] Alan Okros & Denise Scott, "Gender Identity in the Canadian Forces," *Armed Forces and Society* Vol. 41, p. 8 (2014).

[157] Id. at 9.

[158] While differences of opinion do exist, it bears noting that, according to a Military Times/Syracuse University's Institute for Veterans and Military Families poll, 41% of active duty Service members polled thought that allowing gender transition would hurt their unit's readiness, and only 12% thought it would be beneficial. Overall, 57% had a negative opinion of the Carter policy. Leo Shane III, "Poll: Active-duty troops worry about military's transgender

transgender persons, in combat and the military effectiveness and lethality of our forces—it is prudent to proceed with caution, especially in light of the inconclusive scientific evidence that transition-related treatment restores persons with gender dysphoria to full mental health.

3. *Imposes Disproportionate Costs.* Transition-related treatment is also proving to be disproportionately costly on a per capita basis, especially in light of the absence of solid scientific support for the efficacy of such treatment. Since implementation of the Carter policy, the medical costs for Service members with gender dysphoria have increased nearly three times—or 300%—compared to Service members without gender dysphoria.[159] And this increase is despite the low number of costly sex reassignment surgeries that have been performed so far.[160] As noted earlier, only 34 non-genital sex reassignment surgeries and one genital surgery have been completed,[161] with an additional 22 Service members requesting a waiver for genital surgery.[162] We can expect the cost disparity to grow as more Service members diagnosed with gender dysphoria avail themselves of surgical treatment. As many as 77% of the 424 Service member treatment plans available for review include requests for transition-related surgery, although it remains to be seen how many will ultimately obtain surgeries.[163] In addition, several commanders reported to the Panel of Experts that transition-related treatment for Service members with gender dysphoria in their units had a negative budgetary impact because they had to use operations and maintenance funds to pay for the Service members' extensive travel throughout the United States to obtain specialized medical care.[164]

Taken together, the foregoing concerns demonstrate why recognizing and making accommodations for gender transition are not conducive to, and would likely undermine, the inputs—readiness, good order and discipline, sound leadership, and unit cohesion—that are essential to military effectiveness and lethality. Therefore, it is the Department's professional military judgment that persons who have been diagnosed with, or have a history of, gender dysphoria and require, or have already undergone, a gender transition generally should not be eligible for accession or retention in the Armed Forces absent a waiver.

C. Transgender Persons With a History or Diagnosis of Gender Dysphoria Are Disqualified, Except Under Certain Limited Circumstances.

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policies," *Military Times* (July 27, 2017) available at https://www.militarytimes.com/news/pentagon-congress/2017/07/27/poll-active-duty-troops-worry-about-militarys-transgender-policies/.

[159] Minutes, Transgender Review Panel (Nov. 2, 2017).

[160] Minutes, Transgender Review Panel (Nov. 2, 2017).

[161] Data retrieved from Military Health System Data Repository (Nov. 2017).

[162] Defense Health Agency Data (as of Feb. 2018).

[163] Data reported by the Departments of the Army, Navy, and Air Force (Oct. 2017).

[164] Minutes, Transgender Review Panel (Oct. 13, 2017); see also Irene Folaron & Monica Lovasz, "Military Considerations in Transsexual Care of the Active Duty Member," *Military Medicine*, Vol. 181, p. 1185 (Oct. 2016) ("As previously discussed, a new diagnosis of gender dysphoria and the decision to proceed with gender transition requires frequent evaluations by the [mental health professional] and endocrinologist. However, most [military treatment facilities] lack one or both of these specialty services. Members who are not in proximity to [military treatment facilities] may have significant commutes to reach their required specialty care. Members stationed in more remote locations face even greater challenges of gaining access to military or civilian specialists within a reasonable distance from their duty stations.").

As explained earlier in greater detail, persons with gender dysphoria experience significant distress and impairment in social, occupational, or other important areas of functioning. Gender dysphoria is also accompanied by extremely high rates of suicidal ideation and other comorbidities. Therefore, to ensure unit safety and mission readiness, which is essential to military effectiveness and lethality, persons who are diagnosed with, or have a history of, gender dysphoria are generally disqualified from accession or retention in the Armed Forces. The standards recommended here are subject to the same procedures for waiver as any other standards. This is consistent with the Department's handling of other mental conditions that require treatment. As a general matter, only in the limited circumstances described below should persons with a history or diagnosis of gender dysphoria be accessed or retained.

1. *Accession of Individuals Diagnosed with Gender Dysphoria.* Given the documented fluctuations in gender identity among children, a history of gender dysphoria should not alone disqualify an applicant seeking to access into the Armed Forces. According to the DSM-5, the persistence of gender dysphoria in biological male children "has ranged from 2.2% to 30%," and the persistence of gender dysphoria in biological female children "has ranged from 12% to 50%."[165] Accordingly, persons with a history of gender dysphoria may access into the Armed Forces, provided that they can demonstrate 36 consecutive months of stability—i.e., absence of gender dysphoria—immediately preceding their application; they have not transitioned to the opposite gender; and they are willing and able to adhere to all standards associated with their biological sex. The 36-month stability period is the same standard the Department currently applies to persons with a history of depressive disorder. The Carter policy's 18-month stability period for gender dysphoria, by contrast, has no analog with respect to any other mental condition listed in DoDI 6130.03.

2. *Retention of Service Members Diagnosed with Gender Dysphoria.* Retention standards are typically less stringent than accession standards due to training provided and on-the-job performance data. While accession standards endeavor to predict whether a given applicant will require treatment, hospitalization, or eventual separation from service for medical unfitness, and thus tend to be more cautious, retention standards focus squarely on whether the Service member, despite his or her condition, can continue to do the job. This reflects the Department's desire to retain, as far as possible, the Service members in which it has made substantial investments and to avoid the cost of finding and training a replacement. To use an example outside of the mental health context, high blood pressure does not meet accession standards, even if it can be managed with medication, but it can meet retention standards so long as it can be managed with medication. Regardless, however, once they have completed treatment, Service members must continue to meet the standards that apply to them in order to be retained. Therefore, Service members who are diagnosed with gender dysphoria after entering military service may be retained without waiver, provided that they are willing and able to adhere to all standards associated with their biological sex, the Service member does not require gender transition, and the Service member is not otherwise non-deployable for more than 12 months or for a period of time in excess of that established by Service policy (which may be less than 12 months).[166]

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[165] DSM-5 at 455.

[166] Under Secretary of Defense for Personnel and Readiness, "DoD Retention Policy for Non-Deployable Service Members" (Feb. 14, 2018).

3. *Exempting Current Service Members Who Have Already Received a Diagnosis of Gender Dysphoria.* The Department is mindful of the transgender Service members who were diagnosed with gender dysphoria and either entered or remained in service following the announcement of the Carter policy and the court orders requiring transgender accession and retention. The reasonable expectation of these Service members that the Department would honor their service on the terms that then existed cannot be dismissed. Therefore, transgender Service members who were diagnosed with gender dysphoria by a military medical provider after the effective date of the Carter policy, but before the effective date of any new policy, may continue to receive all medically necessary treatment, to change their gender marker in DEERS, and to serve in their preferred gender, even after the new policy commences. This includes transgender Service members who entered into military service after January 1, 2018, when the Carter accession policy took effect by court order. The Service member must, however, adhere to the procedures set forth in DoDI 1300.28, and may not be deemed to be non-deployable for more than 12 months or for a period of time in excess of that established by Service policy (which may be less than 12 months). While the Department believes that its commitment to these Service members, including the substantial investment it has made in them, outweigh the risks identified in this report, should its decision to exempt these Service members be used by a court as a basis for invalidating the entire policy, this exemption instead is and should be deemed severable from the rest of the policy.

## Conclusion

In making these recommendations, the Department is well aware that military leadership from the prior administration, along with RAND, reached a different judgment on these issues. But as the forgoing analysis demonstrates, the realities associated with service by transgender individuals are more complicated than the prior administration or RAND had assumed. In fact, the RAND study itself repeatedly emphasized the lack of quality data on these issues and qualified its conclusions accordingly. In addition, that study concluded that allowing gender transition would impede readiness, limit deployability, and burden the military with additional costs. In its view, however, such harms were negligible in light of the small size of the transgender population. But especially in light of the various sources of uncertainty in this area, and informed by the data collected since the Carter policy took effect, the Department is not convinced that these risks could be responsibly dismissed or that even negligible harms should be incurred given the Department's grave responsibility to fight and win the Nation's wars in a manner that maximizes the effectiveness, lethality, and survivability of our most precious assets—our Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen.

Accordingly, the Department weighed the risks associated with maintaining the Carter policy against the costs of adopting a new policy that was less risk-favoring in developing these recommendations. It is the Department's view that the various balances struck by the recommendations above provide the best solution currently available, especially in light of the significant uncertainty in this area. Although military leadership from the prior administration reached a different conclusion, the Department's professional military judgment is that the risks associated with maintaining the Carter policy—risks that are continuing to be better understood as new data become available—counsel in favor of the recommended approach.

# Exhibit C

AMERICAN PSYCHOLOGICAL ASSOCIATION

March 26, 2018

# APA Statement Regarding Transgender Individuals Serving in Military

WASHINGTON — Following is a statement by Arthur C. Evans Jr., PhD, regarding President Trump's placing new limits on transgender individuals serving in the military:

"The American Psychological Association is alarmed by the administration's misuse of psychological science to stigmatize transgender Americans and justify limiting their ability to serve in uniform and access medically necessary health care."

"Substantial psychological research shows that gender dysphoria is a treatable condition, and does not, by itself, limit the ability of individuals to function well and excel in their work, including in military service. The science is clear that individuals who are adequately treated for gender dysphoria should not be considered mentally unstable. Additionally, the incidence of gender dysphoria is extremely low."

"No scientific evidence has shown that allowing transgender people to serve in the armed forces has an adverse impact on readiness or unit cohesion. What research does show is that discrimination and stigma undermine morale and readiness by creating a significant source of stress for sexual minorities that can harm their health and well-being."

APA's governing Council of Representatives adopted a resolution (http://www.apa.org/about/policy/chapter-12b.aspx#transgender) in 2008 supporting full equality for transgender and gender-variant people and calling for legal and social recognition of transgender individuals.

*The American Psychological Association, in Washington, D.C., is the largest scientific and professional organization representing psychology in the United States. APA's membership includes nearly 115,700 researchers, educators, clinicians, consultants and students. Through its divisions in 54 subfields of psychology and affiliations with 60 state, territorial and Canadian provincial associations, APA works to advance the creation, communication and application of psychological knowledge to benefit society and improve people's lives.*

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**Find this article at:**
https://www.apa.org/news/press/releases/2018/03/transgender-military.aspx

# Exhibit D

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
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April 3, 2018

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1000 Defense Pentagon
Washington, DC 20301-1000

Dear Secretary Mattis:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our concern about the new policy recently approved by President Trump imposing limits on transgender individuals serving in the military. This new policy, based on recommendations you made in February to President Trump, states that "transgender persons with a history or diagnosis of gender dysphoria—individuals who the policies state may require substantial medical treatment, including medications and surgery—are disqualified from military service except under certain limited circumstances" (Presidential Memorandum for the Secretary of Defense and the Secretary of Homeland Security Regarding Military Service by Transgender Individuals, May 23, 2018).

We believe there is no medically valid reason—including a diagnosis of gender dysphoria—to exclude transgender individuals from military service. Transgender individuals have served, and continue to serve, our country with honor, and we believe they should be allowed to continue doing so. We share the concerns recently expressed by former Surgeons General M. Joycelyn Elders and David Satcher that the Defense Department's February 22, 2018, Memorandum for the President mischaracterized and rejected the wide body of peer-reviewed research on the effectiveness of transgender medical care. This research, demonstrating that medical care for gender dysphoria is effective, was the rationale for the AMA's adoption of policy by our House of Delegates in 2015, that there is no medically valid reason to exclude transgender individuals from military service.

The AMA also supports public and private health insurance coverage for treatment of gender dysphoria as recommended by the patient's physician. We support the finding of the RAND study conducted for the Department of Defense on the impact of transgender individuals in the military that the financial cost is negligible and a rounding error in the defense budget. It should not be used as a reason to deny patriotic Americans an opportunity to serve their country. We should be honoring their service.

Sincerely,

James L. Madara, MD

# Exhibit E

AMERICAN PSYCHIATRIC ASSOCIATION

News Releases

Mar 24, 2018

# APA Reiterates Its Strong Opposition to Ban of Transgender Americans from Serving in U.S. Military

**WASHINGTON, D.C. —**The American Psychiatric Association (APA) today reiterated its strong opposition to a ban of transgender Americans from the U.S. military, first announced by President Trump in July of last year and brought to the forefront today with the release of a White House memo announcing that transgender individuals are disqualified from military services except under limited circumstances.

"The APA stands firmly against discrimination against anyone, and this ban is a discriminatory action," said APA CEO and Medical Director Saul Levin, M.D., M.P.A. "This ban not only harms those who have chosen to serve our country, but it also casts a pall over all transgender Americans. This discrimination has a negative impact on the mental health of those targeted."

The APA in 2012 passed a policy statement that opposed discrimination against transgender people and called for their civil rights to be protected. Transgender people do not have a mental disorder; thus, they suffer no impairment whatsoever in their judgment or ability to work.

"All Americans who meet the strenuous requirements and volunteer to serve in U.S. military should be given the opportunity to do so." Levin said.

## American Psychiatric Association

The American Psychiatric Association, founded in 1844, is the oldest medical association in the country. The APA is also the largest psychiatric association in the world with more than 37,800 physician members specializing in the diagnosis, treatment, prevention and research of mental illnesses. APA's vision is to ensure access to quality psychiatric diagnosis and treatment. For more information please visit www.psychiatry.org.

## Media Contacts

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# Exhibit F

**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).[1]

**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[.]"[2] 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(l)(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.[3] 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

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[1] *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.

[2] 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 http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm.

[3] 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."[4] 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.

[4] 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:[5]

> **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 salpingo-oophorectomy, 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.[6] 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

[5] NCDs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd.

[6] 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).[7] 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.)[8]

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[7] 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.

NCD Record at 19.

[8] 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.

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).[9] 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.[10] *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.[11] 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).

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[9] The NCD Ruling is at http://www.hhs.gov/dab/decisions/dabdecisions/ncd1403.pdf.

[10] The Board also published on its website notice providing an additional time period for interested parties to submit participation requests; none were received.

[11] 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.

**Analysis**

**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.[12] 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.

[12] 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, 25th 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 ¶ 5. Dr. Ettner stated that "Gender Identity Disorder is a serious medical condition codified in the International Classification of Diseases (10th revision; World Health Organization) and the [DSM]."[13] Ettner Decl. at ¶ 10; *see also* Ettner Supp. Decl. at ¶ 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

[13] 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 ¶ 6; Hsiao Decl. at ¶ 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[14] (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").

[14] 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.*[15]

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."[16] *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,"

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[15] 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.

[16] 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.

Hsiao Decl. at ¶ 9.

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 ¶ 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 ¶ 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 ¶¶ 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 ¶ 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,[17] 21,[18] 28.[19] 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 ¶ 14, citing study at AP Ex. 2.[20]

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[17] 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).

[18] Anne A. Lawrence, *Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery*, 35 Arch. Sex. Behav. 717-27 (2006).

[19] Christiane Spehr, *Male-to-Female Sex Reassignment Surgery in Transsexuals*, 10 Int'l J. Transgenderism 25-37 (2007).

[20] Bastian Amend, et al., *Surgical Reconstruction for Male-to-Female Sex Reassignment*, 64 Eur. Urol. 1-9 (2013).

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.[21] 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.

[21] 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.*[22]

#### *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.[23] 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

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[22] 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)).

[23] 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." Leis Letter at 2.

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.[24] 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

[24] 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) (http://web.archive.org/web/20061218132346/http://www.symposion.com/ijt/pfaefflin/1000.htm, 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.[25] 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;[26] 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.

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[25] 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).

[26] 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.[27] 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.[28] 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,[29] 29.[30] 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.[31] The study found that patients who underwent surgery "demonstrated dramatically improved psychosocial outcomes, compared to the still-waiting 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 ¶ 30, citing study at AP Ex. 17.[32]

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[27] 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).

[28] 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).

[29] 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).

[30] Svetlana Vujovic, M.D. Ph.D., *et al.*, *Transsexualism in Serbia: A Twenty-Year Follow-Up Study*, 6 J. Sex. Med. 1018-23 (2009).

[31] 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).

[32] 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).

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.[33] 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 . . . ." [34] *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.

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[33] CMS Manuals are available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html, accessed May 14, 2014.

[34] 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.[35] 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

[35] "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.[36] "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.[37]

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

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[36] http://www.dmhc.ca.gov/library/reports/news/dl12k.pdf, accessed May 14, 2014.

[37] HRC Corporate Quality Index (2013), available at http://www.hrc.org/corporate-equality-index, accessed April 25, 2014.

the WPATH standards of care have attained widespread acceptance.[38] S*ee* 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")."[39] 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.[40]

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,

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[38] 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.

[39] 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.

[40] 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).

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.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member

**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 Male-to-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 G

# 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 treatments, or any other potential 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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# Decision Memo

To: Administrative File: CAG #00446N

From: Tamara Syrek Jensen, JD
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Joseph Chin, MD, MS
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Director, Division of Items and Devices

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Analyst

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

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).

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 1, 1989 | 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.

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)

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 prosthetic devices, rigid penile implants, testicular prosthetic implants, and breast 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.

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 events-reoperations. 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

termination, completed, ongoing with sponsor update, and ongoing with estimated date of completion. 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 Assessmen**t

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.

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)

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.

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±7.6 (range 16–56) years and 31.4±11.4 (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±6.3 and 19.4±7.7 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 hormone-treated female-to-male patients. Asscheman et al. reported an elevated SMR for illicit drug use (n=1, SMR 25

[6.00-32.5]). This was the cause of one of the 12 deaths in the cohort.

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±9.1 years (n=120) and older than the age of patients without hormone treatment (25.9±7.5) (p=0.001). The age at hormone initiation, however, was 24.6±8.1 years.

Of those who had undergone reassignment surgery, 29 (36.7%) were female-to-male; 50 (63.3%) were male-to-female (ratio 1:1.7). The number of patients not on hormones and who had undergone at least one gender-related 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 mean scores for HAD-Anxiety, HAD – Depression, and SADS were in the normal range for 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 ± 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±9.9 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 health and quality of life questions. Hormone therapy was an important element for the general questions and for all 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, anti-social, 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±5.03; male-to-female: 6.58±4.21) and borderline results for anxiety (female-to-male: 7.09±5.11; male-to-female: 7.74±6.13, 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

semi-cross-sectional design (albeit over an extended time interval) using a self-designed tool and Axis V assessment. The study was prospective except for 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, ≥1 year of real-life experience in preferred gender, and ≥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 pre-formulated 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 ≥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 ≥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.

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).

Psychiatric disease was more common in those who initiated hormone therapy at an older age (>32 years) 63.9% versus 48.9% at a younger age and by natal gender (48.0% of female-to-male; 58.3% male-to-female). Mood disorders were more common in those who initiated hormone therapy at an older age (>32 years) 52.1% versus 36.0% at a younger age and this finding did not differ by natal gender (40.0% of female-to-male; 44.8% male-to- female). The presence of mood disorders increased the time to reassignment surgery in male-to-female patients.

*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±18.16 versus 71.9±18.31 and 71.51±16.40 versus 79.3±16.4 respectively. Scores were not different from the normative data for Dutch women: vitality: 64.3±19.7 or mental health 73.7±18.2. 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-to-male 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 overlap with the cohort populations studied by Heylens et al. or Weyers et al. is unknown.

*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±9.42) was statistically higher (better) than the natal gender unspecified SF-36 normative score (50±10) (p=<0.001), but was within one standard deviation of the normative mean. The Mental Summary Score (39.63±12.2) was statistically lower (worse) than the natal gender unspecified SF-36 normative score (50±10) (p<0.001), but was well within two standard deviations of the normative mean. Subcomponents of this score: Mental Health (42.12±10.2), Role Emotional (42.42±11.6), Social Functioning (43.14±10.9), and Vitality (46.22±9.9) 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 conducted, although the data were not stratified by type of therapeutic intervention (hormonal, as well as, surgical). Outcomes of hormone therapy were considered separately and dichotomously from reassignment surgery. The Mental Summary Score was statistically higher (better) in those who had "Ever Received Testosterone" (41.22±11.9) than those with "No Testosterone Usage" (36.08±12.6) (p=0.001). The Mental Summary Scores showed a trend towards statistical difference between those who "Ever Received Top Surgery" (41.21±11.6) and those without "Top Surgery" (38.01±12.5) (p=0.067). These differences were well 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 pre-specified 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.

Of participants, 63.2% of female-to-male patients cohabitated with partners of their natal gender; 46.9% of male-to-female patients with male partner preference cohabitated with partners of their natal gender; and no male-to-female patients with female partner preference cohabitated with partners of their natal gender.

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. conducted a prospective, blinded, observational study using a cross-sectional design and a self-designed anonymous questionnaire. The investigators 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; six (5.0%) reported not feeling accepted 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 self-designed 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±9 (range 18-70) years and mean duration after surgery was 3±1 (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.

*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 ≥6 months, and willingness to function in the life of the desired gender for ≥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±4.4 (range 14-36) and 27.4 ±4.0; (range 14-36); male-to-female 22.9±4.6 (range 14-36) and 24.7±4.3 (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

reassignment surgery. The reported age of onset was 8.6 years for female-to-male patients and 8.7 years for male-to-female patients.

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 ±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 score was 16.95±16.04 out of a maximal 36. The FSFI scores averaged 2.8 (6 point maximum): satisfaction 3.46±1.57, desire 3.12+1.47, arousal 2.95±2.17, lubrication 2.39±2.29, orgasm 2.82±2.29, and pain 2.21±2.46. Though these numbers were reported in 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±8.2 years (range 16 to 49) at the time of reassignment surgery and 37.1 ±8.2 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±20.7 versus 71.9±18.3 and 72.6±19.2 versus 79.3±16.4 respectively. These subscale scores were equivalent to the mean scores of the Dutch women.

None of the participants were dissatisfied with their hysterectomy-oophorectomy procedures; 4.1% were dissatisfied with their mastectomies because of extensive scarring; and 2.2% were dissatisfied with their phalloplasties. Of the participants, 17.9% were dissatisfied with the implantation of an erectile prosthetic device; 25 (51.0%) reported at least one post-operative complication associated with phalloplasty (e.g., infection, urethrostenosis, or fistula formation); 16 (50.0% of the 32 with an erectile prosthetic device) reported at least one post-operative complication associated with implantation of an erectile prosthetic (e.g., 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.

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 both primary sex trait reassignment 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±11.3 years; post-operative 38.2±9.0 years. The mean duration after reassignment surgery was 51±25 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±3.8 versus 5.1±3.7; male-to-female 8.1±4.5 versus 4.7±3.1 as well as statistically lower self-confidence in one's attractiveness: female-to-male 3.1±2.9 versus 8.9±3.1; male-to-female 7.0±2.9 vs 9.5±2.6.

*Mate-Kole C, Freschi M, Robin A. Aspects of psychiatric symptoms at different stages in the treatment of*

*transsexualism. Br J Psychiatry. 1988 Apr;152: 550-3.*

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 cross-sectional 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.

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 male controls and higher than that in female controls, 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 semi-matched 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±2.3 versus 20.9±1.9 (p<0.0001), personal limitation: 20.9±1.9 versus 11.6±0.4 (p<0.001), role limitation: 27.8+2.4 versus 34.6+1.7 (p=0.046), and general health: 31.7±2.2 versus 41.0±2.3 (p<0.02). There is a related paper by Kuhn

*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±9.5 years and female-to-male 33.3±10.0 years. The other control group consisted of patients with personality disorder. Of these, 101 (27 men (33.9±7.3 years) and 74 women (31.6±8.2) 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±1. The Global Assessment of Function was higher (better) in the gender dysphoric groups (78.0±8.9) than in the personality disorder cohort (53.0±9.0).

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±57 and 0.56±0.45. Although they were nominally higher than the healthy normative controls (males: 0.32±0.36 and females 0.41±0.43), 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 J. A psychological comparison of heterosexuals, transvestites, preoperative transsexuals, and postoperative transsexuals. J Nerv Ment Dis. 1985 Jun;173(6):358-65. (United States study)*

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 and for paranoid personality, paranoid schizophrenia, and schizoid personality in the post-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-blinded, observational study of nation-wide mortality using 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±8.7 (range 20–62) and 36.3± 10.1 (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 mortality studies by Dhejne et al. (2011) includes much, if not all, of the Landen (1998) patient population and much of 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.

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.*

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±32.4. The respective scores for the various gender dysphoric cohorts were 157.7±49.8 at initial presentation, 119.7±32.1 after hormone therapy, and 127.9±37.2 after surgery. The scores for the general population and the scores after either hormone treatment or surgical treatment did not differ.

*Kockott G, Fahrner EM. Transsexuals who have not undergone surgery: a follow-up study. Arch Sex 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±13.1 years, and the age of the patients who maintained a continued desire for surgery was 31.7±10.2 years. The age of the patients who hesitated about surgery was somewhat older, 40.3±9.4 years. The age of the patients who were no longer interested in surgery was 31.8±6.5 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

psychosocial adjustment while the second baseline score (16.7) would have categorized the patients as having "few difficulties" in psychosocial adjustment despite the absence 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 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.

Related papers include Meyer et al. (1971), Meyer et al. (1974a-d), and Derogatis et al. (1978) along with commentary response by Fleming et al. (1980).

*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 ±13.4 months (range 6 months to 4 years). The age was female-to-male 27.8±5.2 (range 23-37) and male-to-female 26.4±7.8 (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.*

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±0.67 to 0.26±0.34 (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.

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.

Subsequently, the study analysis was limited to adults. One hundred sixty-two (58 [35.8%] female-to-male and 104 [64.2%] male-to-female [ratio 1:1.8]) were eligible and provided pre-surgical test data, and 126 (77.8% of eligible adults) (49 [38.9%] female-to-male and 77 [61.1%] male-to-female [ratio 1:1.6]) provided post-surgical data. For those patients who completed reassignment, the mean age at the time of surgical request was 30.9 years (range 17.7-68.1) and 35.2 years (range 21.3-71.9) years at the time of follow-up. The intervals between hormone treatment initiation and surgery and surgery and follow-up were 20.4 months (range 12 to 73) and 21.3 months (range 12 to 47) respectively.

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±40.7 (scoring range 90 to 450) and normalized after surgery 120.3±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.

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 ≥2 year desire to change gender, a ≥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.

d.

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)

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:

[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 of Transsexual, Transgender, and Gender-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 evidence-based 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

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

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."

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.

**7. Consultation with Outside Experts**

Consistent with the authority at 1862(l)(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 specialty-focused 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: https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=282&ExpandComments=n#Results

**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 reassignment surgery when determined reasonable and necessary 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**: We acknowledge the public comments and that there has been a transformation in the treatment of individuals with gender dysphoria over time. In this NCA, we acknowledge that gender dysphoria is a recognized Diagnostic and Statistical Manual of Mental Disorders (DSM) condition. With respect to the concern about potential bias by Medicare contractors, we have no reason to expect that the judgments made on specific claims will be influenced by an overriding bias, hostility to patients with gender dysphoria, or discrimination. Moreover, the Medicare statue and our regulations provide a mechanism to appeal an adverse initial decision if a claim is denied and those rights may include the opportunity for judicial review. We believe the Medicare appeals process would provide an opportunity to correct any adverse decision that was perceived to have been influenced by bias.

**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 commenters requested that CMS consider that, "The established medical consensus is that GRS is a safe, effective, and medically necessary treatment for many individuals with gender dysphoria, and for some individuals with severe dysphoria, it is the only effective treatment."

**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.

**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. (https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id282.pdf) 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.

**8. Evidence Summary and Analysis**

**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.

**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" (https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html).

**13. §1557 of the Affordable Care Act (ACA)**

**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

commercial insurers. We do not issue coverage decisions to drive policy for other health organizations' 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 commenters stated that without Medicare coverage, surgery is difficult to afford and there may be a risk of negative consequences for the individual. One commenter suggested that CMS should consider prior-authorization 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.

## 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(l)(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.

**A. Quality of the Studies Reviewed**

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 non-longitudinal, 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.*

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 Chinese (Tsoi, 1993). Additional research is needed in this area.

**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.

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 on 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 would be 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 relating to counseling, hormone therapy treatments, or any other potential 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**

| DSM Version | Condition Name | Criteria | Criteria | Comments |
|---|---|---|---|---|
| DSM III<br>1980<br>*Chapter: Psychosexual Disorders* | ***Trans-sexualism***<br>*302.5x [Gender Identity Disorder of Child-hood (302.6)]* | Required A (cross-gender identification) and B (aversion to one's natal gender) criteria<br>Dx excluded by physical intersex condition<br>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<br>Distinguished from Atypical Gender Identity Disorder 302.85 |

| DSM Version | Condition Name | Criteria | Criteria | Comments |
|---|---|---|---|---|
| **DSM III-Revised 1987** *TS classified as an Axis II dx (personality disorders and mental retardation) in a different chapter. GID included under Disorders Usually First Evident in Infancy, Childhood, Adolescence* | ***Trans-sexualism*** *(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 1º and 2º sex characteristics and acquiring the sex characteristics of the other sex. Has reached puberty | Further characterization by sexual orientation<br>Distinguished from Gender Identity Disorder of Adolescence or Adulthood, Non-trans-sexual Type<br>•e.g., cross-dressing not for the purposes of sexual excitement<br>Gender Identity Disorder Not Otherwise Specified 302.6<br>•e.g., intersex conditions<br>Gender Identity Disorder Not Otherwise Specified 302.85<br>•e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex |
| | ***GID of adulthood***, non-trans-sexual type, added | | | |
| **DSM IV 1994** *Chapter: Sexual & Gender Identity Disorders* | ***Gender Identity Disorder*** in Adolescents and Adults (302.85) (Separate criteria & code for children, but same name) | Required A and B criteria<br>Dx excluded by physical intersex condition | Cross-gender identification<br>•e.g., Stated desire to be another sex<br>•e.g., Desire to live or be treated as a member of the other sex<br>•e.g., conviction that he/she has the typical feelings and reactions of the other sex<br>•e.g., frequent passing as the other sex<br>Persistent discomfort with his/her sex or sense of inappropriateness in the gender role of that sex.<br>•e.g., belief the he/she was born the wrong sex<br>•e.g., preoccupation with getting rid of 1º and 2º sex characteristics &/or acquiring sexual traits of the other sex<br>•Clinically significant distress or impairment in social, occupational, or other important areas of functioning | Further characterization by sexual orientation<br>Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6<br>•e.g., intersex conditions<br>•e.g., stress related cross-dressing<br>•e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex |
| **DSM IV-Revised 2000** *Chapter: Sexual & Gender Identity Disorders* | ***Gender Identity Disorder*** (Term trans-sexual-ism eliminated) | Required A & B criteria<br>Dx excluded by physical intersex condition | Cross-gender identification<br>•e.g., stated desire to be the other sex<br>•e.g., desire to live or be treated as the other sex<br>•e.g., conviction that he/she has the typical feelings & reactions of the other sex | Outcome may depend on time of onset<br>Further characterization by sexual orientation<br>Distinguished from Gender Identity Disorder Not Otherwise Specified 302.6 |

| DSM Version | Condition Name | Criteria | Criteria | Comments |
|---|---|---|---|---|
| | | | •e.g., frequent passing as the other sex<br>Persistent discomfort with his or her sex OR sense of inappropriateness in the gender role of that sex<br>•e.g., belief the he/she was born the wrong sex<br>•e.g., preoccupation with getting rid of 1º and 2º sex characteristics &/or acquiring sexual traits of the other sex<br>Clinically significant distress or impairment in social, occupational, or other important areas of functioning | •e.g., intersex conditions<br>•e.g., stress related cross-dressing<br>•e.g., persistent preoccupation with castration or penectomy w/o desire to acquire the sex traits of the other sex |
| **DSM V 2013** *Separate Chapter from Sexual Dysfunctions & Paraphilic Disorders* | ***Gender Dysphoria*** *(302.85)* | Gender nonconformity itself not considered to be a mental disorder<br><br>The dysphoria associated with the gender incongruence is<br><br>Eliminates A & B criteria<br><br>Considers gender incongruence to be a spectrum<br><br>Considers intersex/ "disorders of sex development" to be a subsidiary and not exclusionary to dx of GD | •Marked discordance between natal 1º and 2º sex characteristics* and experienced/expressed gender<br>•Conviction that he/she has the typical feelings & reactions of the other sex (or some alternative gender)<br>•Marked desire to be the other sex (or some alternative gender)<br>•Marked desire to desire be treated as the other sex (or some alternative gender)<br>•Marked desire to be rid of natal 1º and 2º sex characteristics**<br>•Marked desire to acquire 1º and 2º sex characteristics of the other sex (or some alternative gender)<br>Clinically significant distress or impairment in social, occupational, or other important areas of functioning<br><br>* or in young adolescents, the anticipated 2º sex characteristics<br>** or in young adolescents, prevent the development of the anticipated 2º sex characteristics<br><br>≥ 6 month marked discordance between natal gender & experienced/expressed gender as demonstrated by ≥ 6 criteria:<br>•Strong desire to be of the other gender or an insistence that one is of another gender. | Includes diagnosis for post transition state to permit continued treatment access<br><br>Includes disorders of sexual development such as congenital hyperplasia and androgen insensitivity syndromes |

| DSM Version | Condition Name | Criteria | Criteria | Comments |
|---|---|---|---|---|
| | | | •Strong preference for cross-gender roles in make-believe play.<br>•Strong preference for the toys, games, or activities of the other gender.<br>•Strong preference for playmates of the other gender.<br>•In boys, strong preference for cross-dressing; in girls, strong preference for wearing masculine clothing<br>•In boys, rejection of masculine toys, games, activities, avoidance of rough and tumble play; in girls, rejection of feminine toys, games, and activities. | |
| | **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 1º=primary 2º=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

generalizability of findings from individual studies to the Medicare population, and 3) overarching conclusions that can be drawn from the body of the evidence 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, rankings of research design have been based on the ability of each study design category 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 is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations 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<br>25 applications denied.<br>61 not granted full legal status<br>15 formal applications for surgical reversal | 681 | 681 (100%) | NA: Clinical data extracted retrospectively in earlier paper |
| Heylens | Longitudinal Controlled | 90 applicants for SRS<br>33 excluded<br>11 later excluded had not yet received SRS by study close. | 57 (46) | 46 (80.7%)<br>Only those w SRS evaluated | Psycho-social survey missing data for 3 at baseline & 4 after SRS.<br>SCL90 not completed by 1 at baseline, 10 after hormone tx, & 4 after SRS<br>missing data for another 1.1% to 11.1%. |
| Kockott | Longitudinal Controlled | 80 applicants for SRS<br>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.<br>Questions on financial sufficiency not answered by 1 surgical pt. |

| Author | Study Type | Recruitment Pool | Enrolled | % GRS | 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.<br>The number in the available patient pool was not specified. | 40 | 20 (50%) went to surgery | - |
| Meyer | Longitudinal Controlled | Recruitment pool: 100<br>50 were excluded. | 50 | 15 (30%) had undergone surgery<br>14 (28%) underwent surgery later | The assessments of all were complete |
| Rakic | Longitudinal Controlled | 92 were evaluated<br>54 were excluded from surgery<br>2 post SRS were lost to follow-up<br>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.<br>140 received recruitment letters.<br>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, friendships, & 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.<br>325 adult & adolescent applicants for SRS were recruited.<br>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.<br>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%)<br>75 (30.6%) facial<br>147 (59.5%) had received neither facial nor reassignment surgery | - |
| Beatrice | Cross-sectional | | 40 | 10 (25%) | |

| Author | Study Type | Recruitment Pool | Enrolled | % GRS | 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<br>116 authorized for GRS.<br>103 completed GRS & 1 yr post-operative.<br>24 excluded | 79 | 79(100%) | - |
| Weyers et al. | Cross-sectional Control: Normative test data | >300 M to F patients had undergone GRS<br>70 eligible patients recruited<br>20 excluded | 50 | 50 (100%) | SF-26 not completed by 1 |
| Wierckx et al. | Cross-sectional except for recall questions Control: Normative test data | 79 F to M patients had undergone GRS & were recruited.<br><br>3 additional non-clinic patients were recruited by other patients.<br>32 excluded initially; 1 later. | 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.<br>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%) | |

| Author | Study Type | Recruitment Pool | Enrolled | % GRS | Completion |
|---|---|---|---|---|---|
| | No control | 254 consecutive eligible patients post GRS identified & sent surveys.<br>135 excluded. | | | Questions regarding the esthetics, functional, and social outcomes of GRS were not answered by 16 to 28 patients. |
| Lawrence | Cross-sectional<br>No control | 727 eligible patients were recruited.<br>495 were excluded | 232 | 232 (100%) | - |
| Salvador et al. | Cross-sectional<br>No control | 243 had enrolled in the clinic<br>82 completed GRS<br>69 eligible patients were identified.<br>17 excluded. | 52 | 52 (100%) | - |
| Tsoi | Cross-sectional<br>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<br>No direct control: Analysis of variance | 200 consecutive patients were recruited.<br>13 declined participation or were excluded for incomplete questionnaires. | 187 | 79 (42.2%) | See prior box. |
| Hepp et al. | Cross-sectional<br>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 |
| Motmans et al. | Cross-sectional<br>No direct control: Analysis of variance & regression | 255 with GD were identified.<br>77 were excluded. | 148 (140) | Not clearly stated. At least 103 underwent some form of GRS. | 8 later excluded for incomplete SF-36 tests.<br>37 w recent GRS or hormone initiation were excluded from analysis of SF-36 results103. |
| Newfield et al. | Internet survey<br>Cross-sectional<br>No direct control: Analysis of variance | Number of incomplete questionnaires not reported<br>446 respondents; 384 U.S respondents<br>62 non-U.S. respondents excluded from SF-36 test results<br>8 U.S. respondents excluded | 376 (U.S.) | 139 to 150 (37.0-39.9%) in U.S. | - |
| Gomez-Gil et al. 2014 | Cross-sectional<br>No direct control: Analysis w regression | The number in the available patient pool was not specified.<br>277 were recruited.<br>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%) | - |

| Author | Study Type | Recruitment Pool | Enrolled | % GRS | 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<br><br>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.)<br>Only facial surgery: 51 (no S.D.)<br>Both types of surgery: 49 (no S.D.)<br>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 | Age (years; mean, S.D., range) | Gender | 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<br>M to F SRS cohort: median age 32<br>F to M applicants for reversal: median age 22<br>M to F applicants for reversal: median age 35 | 767 applicants for legal/surgical reassignment<br>289 (37.7%) F to M, 478 (62.3%) M to F; ratio 1:1.6<br>681 post SRS & legal change<br>252 (37.0%) F to M, 429 (63.0%) M to F; ratio 1:1.7<br>15 applicants for reversal<br>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<br>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<br>(80.7% underwent surgery) | - |
| Kockott | Pre-SRS (continued wish for surgery): 31.7±10.2<br>Post-SRS: 35.5±13.1 | Pre-SRS (continued wish for surgery) 3 (25%) F to M,<br>9 (75%) M to F; ratio 1:3<br>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<br>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<br>Delayed, but completed SRS: 30.9<br>Post-SRS: 30.1 | Pre-SRS: 5 (23.8%) F to M, 16 (76.2%) M to F; ratio 1:3.2<br>Delayed, but completed SRS: 1 (7.1%) F to M, 13 (92.9%) M to F; ratio 1:13<br>Post-SRS: 4 (26.7%) F to M, 11 (73.3%) M to F; ratio 1:2.8 | 86% Caucasian |
| Rakic | All: 26.8±6.9 (median 25.5, range 19-47),<br>F to M: 27.8±5.2 (median 27, range 23-37), M to F: 26.4±7.8 (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±10.42 (but 2 w/o SRS) (13.8±2.8 yrs post legal name change) (long-term follow-up)<br>F to M: 41.2±5.78, M to F 52.9±10.82 | 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)<br>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<br>Post-SRS: 126: 49 (38.9%) F to M, 77 (61.1%) M to F; ratio 1:1.6 | - |
| Udeze 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

**Panel B (Surgical Series: No Concurrent Controls)**

| 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.<br>In study: 38 (48.1%) F to M, 32 (40.5%) M to F w M partner preference, 9 (11.4%)<br>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±8.2 years (range 16 to 49)<br>Time of follow-up: 37.1 ±8.2.4 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<br>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±9 (range 18-70) | 232 M to F | - |
| Salvador et al. | Time of follow-up for post-GRS: 36.28±8.94 (range 18-58)<br>(Duration of follow-up: 3.8±1.7 [2-7]) | 52 M to F | - |
| Tsoi | Time of initial visit: All: 24.0±4.5, F to M: 25.4±4.4 (14-36), M to F: 22.9±4.6 (14-36).<br>Time of GRS: All: 25.9±4.14, F to M: 27.4±4.0 (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%<br>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.<br>W hormone tx: 36 (30.0%) F to M, 84 (70.0%) M to F; ratio 1:2.3.<br>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 |
| Gomez-Gil, et al. 2014 | W & W/O Non-genital GRS: 31.2±9.9 (range 16-67). | | - |

| Author | Age (years, mean, S.D., range) | Gender | 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**<br>*Smilkstein* | Published in 1978<br>Initial data: 152 families in the U.S.<br>A "friends" component was added in 1983.<br>Utility has challenged by many including Gardner 2001 |
| **Beck Depression Inventory**<br>*Beck, Ward, Mendelson, Mock, & Erbaugh* | Published initially in 1961 with subsequent revisions<br>It was initially evaluated in psychiatric patients in the U.S.A.<br>Salkind (1969) evaluated its use in 80 general outpatients in the UK.<br>Itis copyrighted and requires a fee for use |
| **Bem Sex Role Inventory**<br>*Bem* | Published 1974<br>Initial data: 100 Stanford Undergraduates<br>1973 update: male 444; female 279<br>1978 update: 470; female 340 |
| **Body Image Questionnaire**<br>*Clement & Lowe* | Validity study published 1996 (German)<br>Population: 405 psychosomatic patients, 141 medical students, 208 sports students |
| **Body Image Scale**<br>*Lindgren & Pauly*<br>*(Kuiper, Dutch adaptation 1991)* | 1975<br>Initial data: 16 male and 16 female transsexual patients in Oregon |
| **Crown Crisp Experiential Index**<br>(formerly Middlesex Hospital Questionnaire) | Developed circa 1966<br>Manual published 1970 |

| Instrument Name and Developer | Development and Validation Information |
|---|---|
| *Crown & Crisp* | Initial data: 52 nursing students while in class in the UK |
| **(2nd) European Quality of Life Survey** *Anderson, Mikuliç, Vermeylen, Lyly-Yrjanainen, & Zigante,* | Published in 2007<br>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.<br>Additional updates |
| **Female Sexual Function Index**<br>*Rosen, Brown, Heiman, Leiblum, Meston, Shabsigh, Ferguson, D'Agostino*<br>*Wiegel, Meston, & Rosen* | Published in 2000<br>Initial data: 131 normal controls & 128 age-matched subjects with female sexual arousal disorder from 5 U.S. research centers.<br>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**<br>*Strauss* | Published 1996 (German) |
| **Freiberg Personality Inventory**<br>*Fahrenberg, Hampel, & Selg* | 7th edition published 2001, 8th edition in 2009 (Not in PubMed)<br>German equivalent of MMPI |
| **"gender identity disorder in childhood"**<br>*Smith, van Goozen, Kuiper, & Cohen-Kettenis* | 11 items derived from the Biographical Questionnaire for Trans-sexuals (Verschoor Poortinga 1988)<br>(Modified by authors of the Smith study) |
| **Gender Identity Trait Scale**<br>*Altstotter-Gleich* | Published 1989 (German) |
| **General Health Questionnaire**<br>*Goldberg & Blackwell (initial study)*<br>*Goldberg & Williams (manual)* | Initial publication 1970<br>Manual published ?1978, 1988 (Not in PubMed)<br>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.<br>Proprietary test. Now 4 versions. |
| **Hospital Anxiety & Depression Scale**<br>*Zigmond & Snaith* | Published in 1983<br>Initial data: Patients between 16 & 65 in outpatient clinics in the UK<br>>100 patients; 2 refusals. 1st 50 compared to 2nd 50. |
| **Inventory of Interpersonal Problems**<br>*Horowitz* | Published 1988<br>Initial data: 103 patients about to undergo psychotherapy; some patients post psycho-therapy (Kaiser Permanente-San Francisco)<br>Proprietary test |
| **King's Health Questionnaire**<br>*Kelleher, Cardozo, Khullar, & Salvatore* | 1997<br>Initial data: 293 consecutive women referred for urinary incontinence evaluation in London<br>Comparison to SF-36 |
| **Minnesota Multi-phasic Personality Inventory**<br>*Hathaway & McKinley* | Published in 1941<br>Updated in 1989 with new, larger, more diverse sample. |

| Instrument Name and Developer | 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.<br>The test is copyrighted. |
| **Modified Androphia-Gynephilia Index** | Neither the underlying version or the Blanchard modified version could be located in PubMed<br>(Designed by the author of the Blanchard et al. study) |
| **"post-operative functioning 13 items"**<br>*Doorn, Kuiper, Verschoor, Cohen-Kettenis* | Published 1996 (Dutch) (Not in PubMed)<br>(Designed by 1 of the authors of the Smith study) |
| **"post-operative functioning 21 items"**<br>*Doorn, Kuiper, Verschoor, Cohen-Kettenis* | Published 1996 (Dutch) (Not in PubMed)<br>(Designed by 1 of the authors of the Smith study) |
| **Scale for Depersonalization Experiences**<br>*Wolfradt* | Unpublished manuscript 1998 (University of Halle)<br>(Designed by 1 of the authors of the Wolfradt study) |
| **"sex trait function"**<br>*Cohen-Kettenis & van Goozen* | Published 1997<br>Assessed in 22 adolescents<br>(Designed by 1 of the authors of the Smith Study) |
| **Self-Esteem Scale**<br>*Rosenberg* | Published 1965 (Not in PubMed)<br>Initial data: 5,024 high-school juniors & seniors from 10 randomly selected New York schools |
| **Short-Form 36**<br>*RAND*<br>*Ware & Sherbourne1992*<br>*McHorney, Ware, & Raczek 1993* | Originally derived from the Rand Medical Outcomes Study (n=2471 in version 1; 6742 in version 2 1989).<br>The earliest test version is free.<br>Alternative scoring has been developed.<br>There is a commercial version with a manual. |
| **Social Anxiety & Distress Scale**<br>*Watson & Friend* | Initial publication in1969<br>Requires permission for use |
| **Social Support Scale**<br>*Van Tilburg 1988* | Published 1988 (Dutch) (Not in PubMed) |
| **Spielberger State & Trait Anxiety Questionnaire**<br>*Spielberger, Gorsuch, Lushene, Vagg, & Jacobs* | Current format published in 1983<br>Proprietary test |
| **Symptom Checklist-90**<br>*Derogatis, Lipman, Covi*<br>*Derogatis & Cleary* | Published in 1973 & 1977<br>Reportedly with normative data for psychiatric patients (in- & out-patient) & normal subjects in the U.S.<br>Has undergone a revision<br>Requires qualification for use |
| **Tennessee Self-Concept Scale**<br>*Fitts & Warren* | In use prior to 1988 publication.<br>Initial data: 131 psychiatric day care patients.<br>Updated manual published 1996.<br>Update population >3000 with age stratification. No other innformation available.<br>Requires qualification for use |
| **Utrecht Gender Dysphoria Scale**<br>*Cohen-Kettenis & van Goozen* | Published in 1997<br>Initial population: 22 transgender adolescents who underwent reassignment surgery.<br>(Designed by 1 of the authors of the Smith study) |

| Instrument Name and Developer | Development and Validation Information |
|---|---|
| **WHO-Quality of Life** (abbreviated version)<br>*Harper for WHO group* | Field trial version released 1996<br>Tested in multiple countries. The Seattle site consisted of 192 of the 8294 subjects tested). Population not otherwise described.<br>The minimal clinically important difference has not been determined.<br>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**<br>More elements in earlier paper |
| Beatrice | - | MMPI form R, TSCS | - | - | Demographic | Education, Income, Relationships |
| Haraldsen | - | SCL-90/90R | - | - | Demographic | |

| Author | National Data | Instrument w Substantive Normative Data | Instrument w/o Substan-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 | Instrument 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 (2nd) | - | - | 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 |

*Listed as San Francisco-36 in manuscript
** From medical charts & verdicts ?=Possibly self-designed
AG=Androphilia-Gynephilia Index (investigator designed 1985) (used more for classification)
APGAR=Family Adaptability, Partnership growth, Affection, and Resolve
BDI=Beck Depression Inventory
BIQ=Body Image Questionnaire
BIS=Body Image Scale
BSRI=Bem Sex Role Inventory
CCEI=Crown Crisp Experiential Index
Cohen-Kettenis'= Sex trait function (An author helped design)
Dorn's x2= Post-operative functioning 13 items (An author helped design)
Post-operative functioning 21 items (An author helped design)
EQOLS (2nd)=2nd European Quality of Life Survey
FBeK=Fragebogen zur Beurteilung des eigenen Korpers
FPI-R=A version of the Freiberg Personality Inventory
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

IIP=Inventory of Interpersonal Problems
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 | 90 applicants for SRS were recruited.<br>•8 (8.9%) declined participation.<br>•12 (13.3%) excluded b/c GID-NOS dx.<br>•12 (13.3%) did not complete the treatment sequence b/c of psychiatric/physical co-morbidity, personal decision for no tx, or personal decision for only hormone tx.<br>•1 (1.1%) committed suicide during follow-up.<br>57 (63.3% of recruited) entered the study.<br>•1 (12.2% of initial recruits) had not yet received SRS by study close.<br>**46 (51.1% of recruited) underwent serial evaluation**<br>•The test was not completed by 1 at t=0, 10 at t=1 (after hormone tx), & 4 at t=2 (after SRS)<br>**missing data for another 1.1% to 11.1%.** | 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.<br><br>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. | |

| Author | | Test | Patient and Data Loss | Results |
|---|---|---|---|---|
| | | | 140 received recruitment letters.<br>•2 (1.4% of those with recruitment letters) had died.<br>•1 (0.7%) was institutionalized.<br>•5 (3.6%) were ill.<br>•8 (5.7%) did not have time.<br>•8 (5.7%) stated that GD was no longer an issue.<br>•8 (5.7%) provided no reason.<br>•28 (20.0%) declined further contact.<br>•9 (6.4%) were lost to follow-up.<br>**71 (50.7%) agreed to participate.**<br>**•2 (1.4%) had not undergone SRS**<br>•The test was not completed by 9.<br>**missing data for another 6.4%.** | At t=0, the "global severity index "SCL-90R score was 0.53±0.49. At post-SRS follow-up the score had decreased to 0.28±0.36.<br><br>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.<br><br>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±0.67 at t=0 and 0.26±0.34 post-SRS. |
| Smith et al.<br>Holland<br>2005 | | MMPI<br>SCL-90 | The number in the available adult patient pool was not specified.<br>325 adult & adolescent applicants for SRS were recruited.<br>•103 (31.7%) were not eligible to start hormone tx & real-life experience.<br>•34 (10.7%) discontinued hormone tx<br>162 (an unknown percentage of the initial recruitment) provided pre-SRS test data.<br>**•36 to 61 (22.2%-37.6% of those adults w pre-SRS data) did not complete post-SRS testing.** | Most of the MMPI scales were already in the normal range at the time of initial testing.<br><br>At t=0, the global "psychoneuroticism" SCL-90 score, which included the drop-outs, was 143.0±40.7.<br>At post SRS-follow-up, the score had decreased to 120.3±31.4.<br><br>The scores were statistically different from one another, but are of limited biologic significance given the range of the score for this scale: 90 to 450, with higher scores consistent with more psychological instability. |
| Udeze, et al.<br>2008<br>Megeri, Khoosal<br>2007<br>UK | | SCL-90R | The number in the available patient pool was not specified.<br>40 subjects were prospectively selected.<br>•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.<br>At post-SRS follow-up, the mean score was 49.15. |

| Author | Test | Patient and Data Loss | Results |
|---|---|---|---|
| | | | There were no statistically significant changes in the global score or for any of the subscales. |
| | **National Databases** | | |
| Dehjne Sweden 2011 | Swedish National Records | 804 with GID in Sweden 1973 to 2003 were identified.<br>•480 (59.7%) did not apply or were not approved for SRS 324 (40.3%) underwent SRS.<br>•All were followed.<br><br>3240 controls of the natal sex and 3240 controls of the reassigned gender were randomly selected from national records | 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]).<br><br>Suicide attempts were more common ( n= 29 [9%]) than in controls (adjusted H.R. 4.9 [2.9–8.5]).<br><br>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<br>Landén et al. 1998<br>Sweden | Swedish National Registry | 767 applied for SRS/legal status (1960-2010)<br>•25 (3.3%) applications denied.<br>•61 (8.0%) not granted full legal status<br>681 (88.7%) underwent SRS.<br>•All were followed. | 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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# Exhibit H

# Health Data on Active Duty Service Members with Gender Dysphoria

## Comparison health care data with statistical analysis, deployment, treatment plan, surgical recovery times, separation data and cost data

December 13 2017

# Gender Dysphoria (GD) Medical Utilization Comparisons Methodology

- Reviewed select medical utilization (i.e., mental health visits/admissions, hormones, surgical and other procedures) for the Study Group of 994 TG service members with GD
  - Limited the group studied to those in an Active Duty or Activated Guard status for the entire period of time from FY16 to current (July 2017)
- Final GD Study Group = 691
  - Study Period: Oct 2015 to July 2017 (22 months)

# Medical Utilization Comparisons Methodology

Created two control groups:

- **"MH+ Control Group"** - Matched 5:1 with non-TG service members by:
  - Major Depressive Disorder (Yes/No)
  - Anxiety (Yes/No)
  - Adjustment Disorder (Yes/No)
  - Matching included gender, age group (<25, 25-40, 40+), rank group, Service
  - MH+ Control Cohort = 3,455
- **"AG Control Group"** - Matched 5:1 with non-TG service members by:
  - Matching included age group (<25, 25-40, 40+) and gender
  - AG Control Cohort = 3,455
- Study Period Oct 2015 – July 2017

# Study Group Descriptive Data

| | | STUDY GROUP Count | STUDY GROUP Percentage |
|---|---|---|---|
| **Study Group Size** | **N** | **691** | **100%** |
| **Age Group** | <25 | 281 | 41% |
| | 25-40 | 388 | 56% |
| | 40> | 22 | 3% |
| **Gender** | Female | 349 | 51% |
| | Male | 342 | 49% |
| **Sponsor Service** | Army | 226 | 33% |
| | Air Force | 188 | 27% |
| | Marines | 38 | 5% |
| | Navy | 216 | 31% |
| | Other | 23 | 3% |
| **Rank Group** | Jr Enlisted | 354 | 51% |
| | Sn Enlisted | 293 | 42% |
| | Officer | 44 | 6% |

# Descriptive Data (continued)

| | | STUDY COHORT Count | STUDY COHORT Percentage |
|---|---|---|---|
| **Study Group Size** | **N** | **691** | **100%** |
| **Major Depressive Disorder** | No | 529 | 77% |
| | Yes | 162 | 23% |
| **Adjustment Disorder** | No | 488 | 71% |
| | Yes | 203 | 29% |
| **Anxiety Disorder** | No | 543 | 79% |
| | Yes | 148 | 21% |

- The Age-Gender matched 'AG Control Group' - Major Depressive Disorder, Anxiety, and Adjustment were not very prevalent

# Regression Analysis

- Multiple regression models were run for both control groups to assess if there is significant difference between the study and control groups regarding psychotherapy and any mental health utilization.
- Dependent Variables of Interest
  - Psychotherapy visits
  - Any mental health visits
- Regressions controlled for combinations of the following independent variables:
  - Age Group
  - Gender
  - Rank (officer vs. enlisted)
  - Service
  - Presence of MH Conditions
    - Major Depressive Disorder, Anxiety or Adjustment

# Summary of Results: Psychotherapy Encounters

| | STUDY GROUP (n=691) | | MH+ CONTROL GROUP (n=3455) | | AG CONTROL GROUP (n=3455) | |
|---|---|---|---|---|---|---|
| | Outpatient (Oct 2015-July 2017) | | Outpatient (Oct 2015-July 2017) | | Outpatient (Oct 2015-July 2017) | |
| | Avg. Encounters per service member | Total Encounters | Avg. Encounters per service member | Total Encounters | Avg. Encounters per service member | Total Encounters |
| **Psychotherapy** | **20.4** | **14,088** | **7.9** | **27,237** | **1.99** | **6,864** |

- After controlling for age, sex, rank, service, and presence of any of the three mental health disorders (MDD, Anxiety, Adjustment), there is a **statistically significant** effect in psychotherapy utilization between study group and both control groups.
  - Individuals in the Study Group (GD) on average generate **13 more psychotherapy encounters** over a **22 month period**.
  - The Study Group had 2.5 x the number of psychotherapy visits than the MH control group and 10 x the number of visits than the age and gender matched control group

# Summary of Results: Any Mental Health Encounters

| | STUDY GROUP (n=691) | | MH+ CONTROL GROUP (n=3455) | | AG CONTROL GROUP (n=3455) | |
|---|---|---|---|---|---|---|
| | Outpatient (Oct 2015-July 2017) | | Outpatient (Oct 2015-July 2017) | | Outpatient (Oct 2015-July 2017) | |
| | Avg. Encounters per service member | Total Encounters | Avg. Encounters per service member | Total Encounters | Avg. Encounters per service member | Total Encounters |
| Any Mental Health | **28.1** | 19,379 | **10.7** | 36,818 | **2.69** | 9,297 |

- After controlling for age, sex, rank, service, and presence of any of the three mental health disorders (MDD, Anxiety, Adjustment), there is a **statistically significant** effect in mental health utilization between study group and both control groups.
  - Individuals in the Study Group (GD) on average generate **18 more mental encounters** over a **22 month period**.
  - The Study Group had 9 x the number of MH visits than the age and gender matched group
  - The Study Group had over 2.5 x as many MH visits as the MH control group

# Summary of Results: Suicidal Ideation

| | STUDY GROUP (n=691) | | MH+ CONTROL GROUP (n=3455) | | AG CONTROL GROUP (n=3455) | |
|---|---|---|---|---|---|---|
| | **(Inpatient and Outpatient) (Oct 2015-July 2017)** | | **(Inpatient and Outpatient) (Oct 2015-July 2017)** | | **(Inpatient and Outpatient) (Oct 2015-July 2017)** | |
| | Individuals Receiving Treatment | Percentage | Individuals Receiving Treatment | Percentage | Individuals Receiving Treatment | Percentage |
| Suicidal Ideation | **81** | 12% | **235** | 7% | **52** | 1.5% |

- Also ran multiple logistic regressions to calculate the odds ratio of suicidal ideation while controlling for age and gender.
  - Only 12% of our Study Group reported suicidal ideation compared to the 25% reported in one civilian sector study.
  - The Study Group had an 8 x higher rate of suicide ideation than age and gender matched AD SMs over a 22 month period.
    - **Result is statistically significant**
    - Note: The AG Control Group did not have sufficient suicidal ideation prevalence for analysis.

# DEPLOYMENT DATA

# Study Group Deployment History

994
- Service members with a primary diagnosis of gender dysphoria – FY2016 to July 2017

393
- Deployed in support of OEF/OIF/OND (OCONUS)

114
- Deployed following a primary diagnosis of gender dysphoria

69
- Deployed following a primary diagnosis of gender dysphoria AND after July 1, 2016

# Cohort Deployment History

**114**

- Deployed following a primary diagnosis of gender dysphoria

**6**

- Were medically evacuated from CENTCON following a primary diagnosis of gender dysphoria
- 4 had a mental health diagnosis identified as the reason for evacuation

**69**

- Deployed following a primary diagnosis of gender dysphoria AND after July 1, 2016

**3**

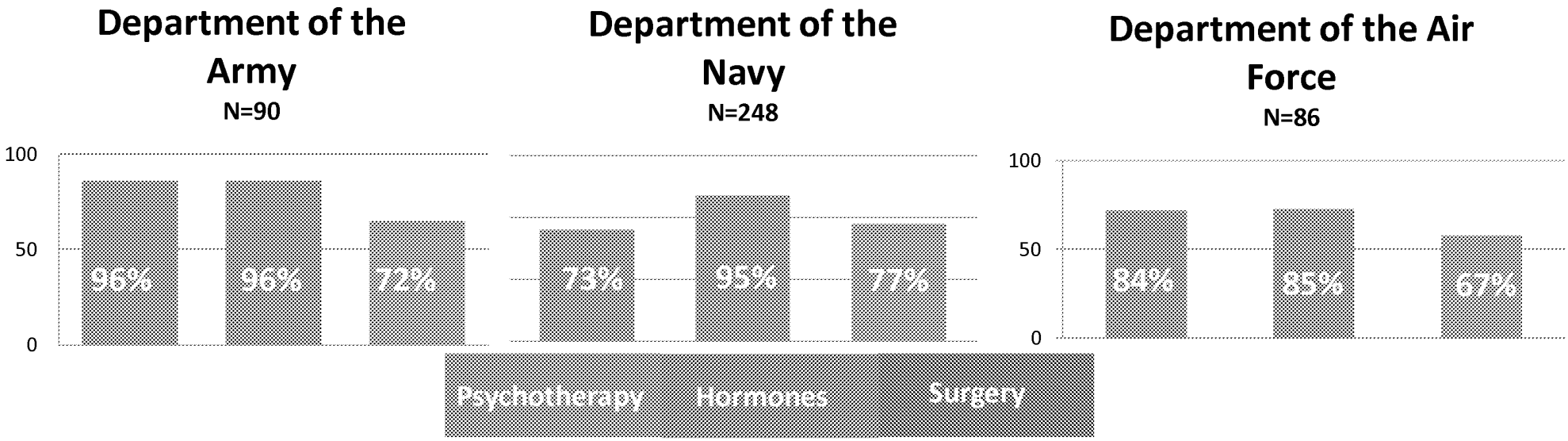
- Were medically evacuated from CENTCOM following a primary diagnosis of gender dysphoria AND after July 1, 2016
- 1 had a mental health diagnosis identified as the reason for evacuation

# TREATMENT PLAN DATA

# Service Data Request

- Data collection will cover the time period from **September 1, 2016, to August 31, 2017**
- Data request included:
  - Number of SMs with approved treatment plans
  - Number of SMs receiving psychotherapy and cross-sex hormones as part of the treatment plan
  - Number of SMs with sex reassignment surgery as part of the treatment plan
  - Total number of profiles/LIMDUs and days on restricted duty for each transitioning SM
  - Total number of days on profile/LIMDU/restricted duty
- Army, Navy and Air Force coordinated definitions and methodologies of collection for data elements

# Service Data – Approved Treatment Plans*




| | ARMY | NAVY | AIR FORCE |
|---|---|---|---|
| Number of Service Members with surgeries as part of treatment plan^ | 65 | 190 | 58 |
| Percent of Treatment Plans with surgery included | 72% | 77% | 67% |

**Services only had access to treatment plans submitted to their TG care teams (TGCT/MMDT)*
*^A Civilian study shows that 23% of MtF and 2% FtM TG individuals initially wanting surgery actually have surgery.*

# SERVICE DATA – Types of Surgeries Included in Treatment Plans

| | ARMY | NAVY | AIR FORCE |
|---|---|---|---|
| Hysterectomy/Oophorectomy | ** | 97 | 14 |
| Orchiectomy | ** | 61 | 12 |
| Mastectomy/Augmentation | ** | 113 | 38 |
| Genital Reassignment | ** | 118 | 19 |
| Other | - | - | 27 |

* An individual service member may have more than one surgical procedure in their treatment plan
** Army responded this level of detail is not consistently provided or individualized in proposed medical treatment plans on file.

# SERVICE DATA – Profiles/LIMDUs/Restricted Duty

| | ARMY* | NAVY** | | AIR FORCE*** |
|---|---|---|---|---|
| Number of Service Members with a diagnosis of Gender Dysphoria on Profile/LIMDU/Restricted Duty | 87 (90) | 22 (248) | | 52 (86) |
| Average Number of Profiles/LIMDUs/Restricted Duty per transitioning SM | 3.4 | 0.1 | | 1.9 |
| Average number of days a transitioning Service Member is in a Profile/LIMDU/Restricted Duty status | 167.4 | 1-90 | 3 | 159 |
| | | 90-180 | 12 | |
| | | 180-270 | 3 | |
| | | 270-360 | 2 | |
| | | >360 | 2 | |
| Range of Days on Profile | 0 - 537 | 1 - 360+ | | 1 - 365 |

* **Army** – profiles for SMs with GD; indication for profile not known; could be for transition or for other indications.
** **Navy** - policy dictates no LIMDU for gender transition. All LIMDUs are for non-transition indications. SMs undergoing transition are non-deployable for the first 3 to 6 months of hormone therapy but not put on LIMDU. Navy provided Avg. Number of days on LIMDU in block times.
*** **Air Force** - profiles are for transition.

# SURGICAL RECOVERY TIME DATA

# Estimated Recovery Times, by Surgery*

| Selected Surgical Procedure | Average Recovery Time (assumes no complications) | Notes |
|---|---|---|
| Hysterectomy*/** (laparoscopic approach, recommended) | 4 weeks desk job<br>6-8 weeks unrestricted activity | (data for all indications)<br>Major complication = 9.5%<br>Minor complication = 28% |
| Hysterectomy* (abdominal approach) with or w/o Oophorectomy | 6-8 weeks | (data for all indications)<br>Major complication = 6%<br>Minor complication = 27% |
| Chest masculinization* (Mastectomy) | 2-4 weeks (desk job)<br>4-6 weeks (physically demanding job) | Low complications |
| Orchiectomy* | 3-4 weeks desk job<br>6 weeks unrestricted activity | Very low complications |
| Vaginoplasty** | 6 weeks desk jobs (some restrictions)<br>6-8 weeks resume physical activity<br>3 months for unrestricted activity | • Recommend stay in area of hospital where procedure performed for up to 2 weeks<br>• Major complications 1.5%-10%<br>• Minor complications ~25%,self limiting |
| Phalloplasty** (2 stages, 2nd surg 9-12 mos later) | 6 weeks desk job<br>8-12 weeks return to activity<br>3 months unrestricted | • Recommends stay in area of hospital where procedure performed for up to 3 weeks/complications 10-80% |
| Metoidioplasty** (2 stages, 2nd stage performed >/=3 mos later) | 3 weeks desk job<br>6 weeks return to activity<br>8 weeks unrestricted | • Recommends stay in area of hospital where procedure performed for up to 3 weeks<br>• <5% complication rate |

*From Mayo Clinic, UCSF Center of Excellence for Transgender Health websites and **Dr. Loren Schechter

# Estimated Recovery Time for Vaginoplasty from Two SHCP Waiver Requests*,**

| PROCEDURE | CENTER | RECOVERY TIMES | | | | |
|---|---|---|---|---|---|---|
| | | Inpatient | Post-op Bedrest | Con leave | Light duty | Non-deployable |
| **Vaginoplasty** | Papillon Center New Hope, PA | 6 days | 3 days | 6 weeks | 2-3 months | 6 months |
| | | | | | | |
| **Vaginoplasty** | Papillon Center | 6 days | 3 days | 6 weeks | 2-3 months | 6 months |

***Times are not cumulative; total non-deployable = 6 months***
****Information from the Defense Health Agency***

# Surgeries in Study Group, FY2016 to Present
# Includes Direct Care and Purchased Care

| SERVICE | | Resection of Uterus/ Hysterectomy | Mastectomy | Excision Procedures on the Testes | Totals |
|---|---|---|---|---|---|
| Air Force | Active Duty | 3 | | | 3 |
| Army | Active Duty | 6 | 5 | 2 | 13 |
| | Guard/Reserve | | 1 | | 1 |
| Marine Corps | Active Duty | 1 | 6 | | 7 |
| Navy | Active Duty | 4 | 3 | 2 | 9 |
| | Guard/Reserve | 1 | | | 1 |
| Totals | | **15** | **15** | **4** | **34** |

33 procedures were performed in MTFs, 1 in Purchased Care.
Of the 34 procedures performed, 25 were for an indication of GD

# Time to Return to Full Duty After Transition Surgery in MTFs

- The Services and NCR were requested to provide actual recovery times (times to return to full duty) for gender transition surgeries performed in the MTFs
- Surgeries performed included mastectomies, hysterectomies, orchiectomies and facial feminization
- Recovery times were available for 36 procedures performed in 13 different MTFs
  - 6 Army
  - 4 Navy
  - 1 Air Force
  - 2 NCR

# MASTECTOMY

## CPT Code 19303-19304

| | Primary Procedure Code | # Days to Full Duty | Comments |
|---|---|---|---|
| Army | 19303 | 30 | |
| Army | 19303 | 14 | |
| Army | 19304 | 75 | |
| Army | 19394 | 42 | |
| Army | 19304 | 28 | |
| Army | 19304 | 27 | |
| Navy | 19303 | 42 | **Average # Days = 39** |
| Navy | 19303 | 42 | **Range 14 - 75** |
| Navy | 19303 | 42 | |
| Navy | 19303 | 42 | |
| Navy | 19304 | 42 | |
| Navy | 19303 | 42 | |
| Navy | 19303 | 42 | |
| Navy | 19303 | 42 | |
| Navy | 19304 | 42 | |
| NCR | 19304 | 30 | |

# HYSTERECTOMY

## CPT Code OUT9FZZ

| | Primary Procedure Code | # Days to Full Duty | Comments |
|---|---|---|---|
| Army | OUT9FZZ | 68 | Average # Days = 67<br>Range 30 – 237<br><br>(Avg # days w/o AF = 55) |
| Army | OUT9FZZ | 42 | |
| Army | OUT9FZZ | 42 | |
| Army | OUT9FZZ | 87 | |
| Army | OUT9FZZ | 96 | |
| Navy | OUT9FZZ | 56 | |
| Navy | OUT9FZZ | 56 | |
| Navy | OUT9FZZ | 56 | |
| Navy | OUT9FZZ | 56 | |
| Navy | OUT9FZZ | 60 | |
| Navy | OUT9FZZ | 45 | |
| Navy | OUT9FZZ | 45 | |
| Air Force | OUT9FZZ | 237 | |
| NCR | OUT9FZZ | 31 | |
| NCR | 58262 | 30 | |

# ORCHIECTOMY

## CPT Code 54520

| | Primary Procedure Code | # Days to Full Duty | Comments |
|---|---|---|---|
| Army | 54520 | 45 | Average # days = 38.3<br>Range 35-45 |
| Navy | 54520 | 35 | |
| Navy | 54520 | 35 | |

# OTHER PROCEDURES

| | Procedure (s) | # Days to Full Duty | Comments |
|---|---|---|---|
| Army | Facial Feminization | 42 | 1 case |
| Army | Hysterectomy & Mastectomy | 89 | Procedures performed two months apart |

# SEPARATION DATA

# Separation Data

| | |
|---|---|
| **Cohort members** | 993* |
| **Cohort members that are continuously AD 10/1/2015-7/1/2017** | 691 |
| **Cohort members who may have separated** | 302 |
| **Cohort members who may have separated in separation file** | 194 |
| **Unknown** | 108 |

*1 of the original 994 was not found in DEERS

# Reason for Separation

## High to Low Comparison

## Study Cohort

| | Frequency | Percent |
|---|---|---|
| Expiration of term of service | 74 | 38.14 |
| Temporary disability retirement | 19 | 9.79 |
| Permanent disability retirement | 12 | 6.19 |
| Unqualified for active duty, other | 9 | 4.64 |
| Disability, severance pay | 8 | 4.12 |
| Retirement, 20 to 30 years of service | 8 | 4.12 |
| Drugs | 8 | 4.12 |
| Early release, in the national interest | 7 | 3.61 |
| Character or behavior disorder | 7 | 3.61 |
| Officer commissioning program | 6 | 3.09 |
| Failure to meet weight or body fat standards | 5 | 2.58 |
| Military service academy | 4 | 2.06 |
| Pattern of minor disciplinary infractions | 3 | 1.55 |
| Commission of a serious offense | 3 | 1.55 |
| Failure to meet minimum qualifications for retention | 3 | 1.55 |
| Other | 3 | 1.55 |
| Alcoholism | 2 | 1.03 |
| Court-martial | 2 | 1.03 |
| Juvenile offender | 2 | 1.03 |
| Erroneous enlistment or induction | 2 | 1.03 |
| Condition existing prior to service | 1 | 0.52 |
| Discreditable incidents, civilian or military | 1 | 0.52 |
| Unfitness, reason unknown | 1 | 0.52 |
| Unsatisfactory performance (former Expeditious Discharge program) | 1 | 0.52 |
| Entry level performance and conduct (former Trainee Discharge program) | 1 | 0.52 |
| Secretarial authority | 1 | 0.52 |
| Breach of contract | 1 | 0.52 |
| Total | 194 | |

## Percentages of all Separations for the Same reasons from 10/1/2015 - 7/1/2017

(not matched, taken from entire set of 408,409 SMs separated)

| | Frequency | Percent |
|---|---|---|
| Expiration of term of service | 197,959 | 48.47 |
| Retirement, 20 to 30 years of service | 39,925 | 9.78 |
| Unqualified for active duty, other | 18,979 | 4.65 |
| Disability, severance pay | 11,480 | 2.81 |
| Permanent disability retirement | 10,801 | 2.64 |
| Temporary disability retirement | 10,408 | 2.55 |
| Officer commissioning program | 9,691 | 2.37 |
| Entry level performance and conduct (former Trainee Discharge program) | 9,176 | 2.25 |
| Unsatisfactory performance (former Expeditious Discharge program) | 9,061 | 2.22 |
| Drugs | 8,836 | 2.16 |
| Early release, in the national interest | 8,603 | 2.11 |
| Commission of a serious offense | 6,979 | 1.71 |
| Failure to meet weight or body fat standards | 6,064 | 1.48 |
| Other | 5,147 | 1.26 |
| Erroneous enlistment or induction | 4,105 | 1.01 |
| Discreditable incidents, civilian or military | 3,538 | 0.87 |
| Juvenile offender | 2,618 | 0.64 |
| Character or behavior disorder | 2,480 | 0.61 |
| Failure to meet minimum qualifications for retention | 2,386 | 0.58 |
| Pattern of minor disciplinary infractions | 1,508 | 0.37 |
| Court-martial | 1,216 | 0.3 |
| Military service academy | 1,213 | 0.3 |
| Alcoholism | 1,081 | 0.26 |
| Unfitness, reason unknown | 692 | 0.17 |
| Secretarial authority | 624 | 0.15 |
| Condition existing prior to service | 475 | 0.12 |
| Breach of contract | 135 | 0.03 |

# Reason for Separation

## Alphabetical Comparison

## Study Cohort

| | Frequency | Percent |
|---|---|---|
| Alcoholism | 2 | 1.03 |
| Breach of contract | 1 | 0.52 |
| Character or behavior disorder | 7 | 3.61 |
| Commission of a serious offense | 3 | 1.55 |
| Condition existing prior to service | 1 | 0.52 |
| Court-martial | 2 | 1.03 |
| Disability, severance pay | 8 | 4.12 |
| Discreditable incidents, civilian or military | 1 | 0.52 |
| Drugs | 8 | 4.12 |
| Early release, in the national interest | 7 | 3.61 |
| Entry level performance and conduct (former Trainee Discharge program) | 1 | 0.52 |
| Erroneous enlistment or induction | 2 | 1.03 |
| Expiration of term of service | 74 | 38.14 |
| Failure to meet minimum qualifications for retention | 3 | 1.55 |
| Failure to meet weight or body fat standards | 5 | 2.58 |
| Juvenile offender | 2 | 1.03 |
| Military service academy | 4 | 2.06 |
| Officer commissioning program | 6 | 3.09 |
| Other | 3 | 1.55 |
| Pattern of minor disciplinary infractions | 3 | 1.55 |
| Permanent disability retirement | 12 | 6.19 |
| Retirement, 20 to 30 years of service | 8 | 4.12 |
| Secretarial authority | 1 | 0.52 |
| Temporary disability retirement | 19 | 9.79 |
| Unfitness, reason unknown | 1 | 0.52 |
| Unqualified for active duty, other | 9 | 4.64 |
| Unsatisfactory performance (former Expeditious Discharge program) | 1 | 0.52 |
| Total | 194 | |

## Percentages of All Separations for the Same Reasons from 10/1/2015 - 7/1/2017 (not matched, taken from entire set of 408,409 SMs separated)

| | Frequency | Percent |
|---|---|---|
| Alcoholism | 1,081 | 0.26 |
| AWOL or desertion | 284 | 0.07 |
| Breach of contract | 135 | 0.03 |
| Character or behavior disorder | 2,480 | 0.61 |
| Civil court conviction | 267 | 0.07 |
| Commission of a serious offense | 6,979 | 1.71 |
| Condition existing prior to service | 475 | 0.12 |
| Court-martial | 1,216 | 0.3 |
| Disability, severance pay | 11,480 | 2.81 |
| Discreditable incidents, civilian or military | 3,538 | 0.87 |
| Drugs | 8,836 | 2.16 |
| Early release, in the national interest | 8,603 | 2.11 |
| Entry level performance and conduct (former Trainee Discharge program) | 9,176 | 2.25 |
| Erroneous enlistment or induction | 4,105 | 1.01 |
| Expiration of term of service | 197,959 | 48.47 |
| Failure to meet minimum qualifications for retention | 2,386 | 0.58 |
| Failure to meet weight or body fat standards | 6,064 | 1.48 |
| Juvenile offender | 2,618 | 0.64 |
| Military service academy | 1,213 | 0.3 |
| Officer commissioning program | 9,691 | 2.37 |
| Other | 5,147 | 1.26 |
| Pattern of minor disciplinary infractions | 1,508 | 0.37 |
| Permanent disability retirement | 10,801 | 2.64 |
| Retirement, 20 to 30 years of service | 39,925 | 9.78 |
| Secretarial authority | 624 | 0.15 |
| Temporary disability retirement | 10,408 | 2.55 |
| Unfitness, reason unknown | 692 | 0.17 |
| Unqualified for active duty, other | 18,979 | 4.65 |
| Unsatisfactory performance (former Expeditious Discharge program) | 9,061 | 2.22 |

# COST DATA

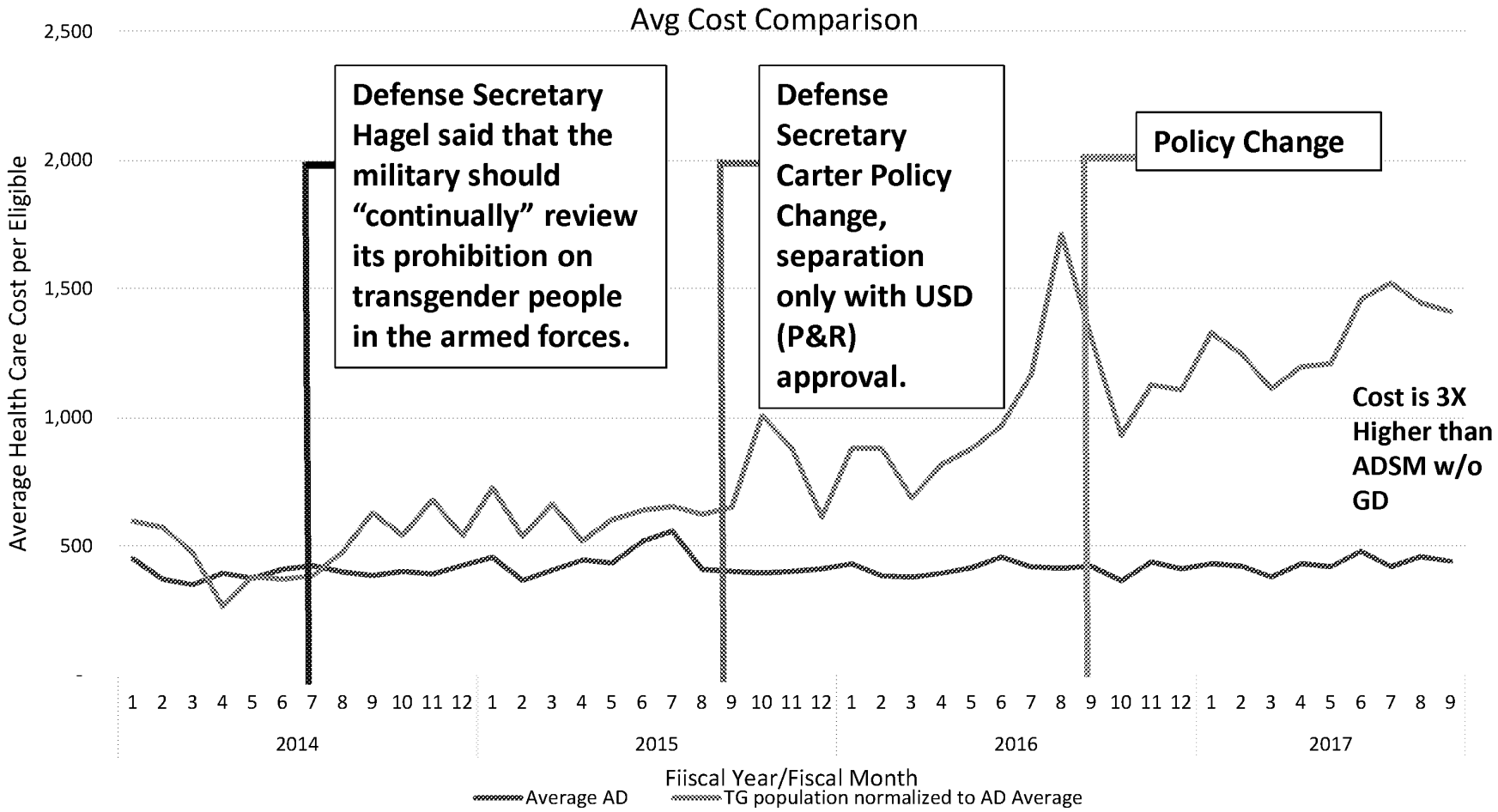
# Cost of Services for Gender Dysphoria

## (Purchased Care Paid Costs; Direct Care Estimated Costs)

| | FY14 | FY15 | FY16 | FY17 | TOTAL |
|---|---|---|---|---|---|
| Direct Care | $ 82,558 | $ 83,563 | $ 650,492 | $ 2,172,849 | $ 2,989,462 |
| Purchased Care | $ 5,421 | $ 3,884 | $ 10,094 | $ 16,509 | $ 35,908 |
| Pharmacy | $ 1,264 | $ 2,693 | $ 3,406 | $ 6,130 | $ 13,493 |
| TOTAL | $ 89,243 | $ 90,140 | $ 663,992 | $ 2,195,488 | $ 3,038,863 |

# Average Health Care Expenditures:

## Transgender Active Duty (TRICARE Prime) vs Average Active Duty




*Source: M2 (Purchased Care: Inpatient (TED-I); Professional (TED-NI)); (Direct Care: Inpatient (SIDR); Professional (CAPER)); Pharmacy (PDTS); Population (DEERS)*

# Exhibit I

**WPATH Timeline Guide for United States Armed Service Members Going Through Transgender Hormonal or Surgical Transition**

This guide is intended to assist in determining relative deployability of transgender service members during hormonal and surgical transition. Customization of the specific treatment plan should be discussed by the medical provider and the service member informed by duty requirements and the below timeline guidance.

The timelines for transgender surgical interventions and recovery should be expected to mirror similar procedures with existing guidelines. Therefore, timelines for recovery from surgical procedures are not different for transgender service members relative to non-transgender service members. Existing guidelines for chest reconstruction surgeries and major pelvic surgeries in general should be referenced when determining the timeline of the treatment plan.

During medical transition, determination of deployability can be aided by recognizing treatment and monitoring needs along with anticipated changes in function attributable to hormones.

For transgender men and women the key needs during transition are simple and straightforward. When initiating cross-sex hormone therapy, transitioning transgender service members will require access to laboratory testing approximately every 3 months along with access to providers appropriately trained in hormone care approximately every 3 months. For those who have initiated hormonal treatment prior to enlistment, a baseline laboratory assessment should be obtained, and retesting done annually.

For transgender men, the timeline for monitoring hormonal transition can be anticipated to range from 6 to 12 months. It is during that period that the every-3-month monitoring and medical provider access would be required.

For transgender women, the timeline for monitoring hormonal transition can be anticipated to range from 6 to 18 months. It is during that period that the every-3-month monitoring and medical provider access would be required.

Subsequent to achieving steady state hormone levels, the monitoring requirement for both transgender men and transgender women should be anticipated to decrease to annual laboratory testing along with annual access to providers appropriately trained in hormone care.

Hormone therapy is not known to be associated with changes in cognitive function. Similarly, behavioral function is not known to vary when levels of circulating sex steroids are in the normal ranges for either men or women.

Strength does correlate with testosterone levels such that there is risk that some transgender women might require accommodation for decreasing strength during the period between the initiation of treatment but prior to the formal shift to female physical standards.

Quick Reference: Timing of Medical Interventions for Transgender Service Members

| Intervention | Transgender Men | Transgender Women | Notes |
|---|---|---|---|
| Initiating hormones | Baseline lab report | Baseline lab report | |
| Monitoring hormones | 3 month intervals for first 6 to 12 months (2 to 4 iterations of lab reports), to achieve normal male levels of testosterone. | 3 month intervals for first 6 to 18 months (2 to 6 iterations of lab reports), to achieve normal female estrogen levels, and monitor testosterone suppression. | |
| Monitoring after steady state hormone levels are achieved | Annually | Annually | |
| Monitoring when hormones were initiated before enlistment | Baseline lab report; annually thereafter. | Baseline lab report; annually thereafter. | |
| Surgical interventions | Chest reconstruction may be done any time; if hormones are initiated first, optimal timing is 6 months after hormone initiation. Genital reconstruction earliest time is 12 months after hormone initiation. | Breast surgery should not be done before 18-24 months of hormone use, to first establish maximum breast growth using hormones alone. Genital reconstruction earliest time is 12 months after hormone initiation. | Timing of these procedures should be determined on an individualized basis, in consultation with the patient and in consideration of duty requirements |