

# SUMMARY OF CLINICAL EVIDENCE FOR GENDER REASSIGNMENT SURGERIES

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## Introduction, Background, and Terminology

Gender Dysphoria (previously named Gender Identity Disorder, sometimes used synonymously with Transsexualism) refers to “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).”<sup>1</sup> Distress can be severe, resulting in higher prevalence of depression and anxiety.<sup>1-5</sup> Global prevalence is difficult to ascertain, but recent estimates approximate that transgender people make up 0.3%-0.5% of the total U.S. population.<sup>6</sup> Treatment for gender dysphoria varies based on individualized assessment for each patient, but generally includes some combination of psychotherapy, cross-sex hormonal therapy, and sometimes surgical intervention.<sup>1,2,7-10</sup> The goals of treatment for Gender Dysphoria are to minimize dysphoria and help patients function in society in their desired gender role.

In the last 10 years, many professional associations, including the American Medical Association, American Association of Family Physicians, the Endocrine Society, American Psychiatric Association, American Psychological Association, American College of Obstetricians and Gynecologists, and the American Public Health Association, have issued statements or guidelines supporting effective treatment protocols and insurance coverage for this care provided to people with Gender Dysphoria.<sup>11</sup> Clinical trials, meta-analyses, and review articles have been published in major peer-reviewed journals such as *the Journal of the American Medical Association*<sup>8</sup>, *Nature*<sup>12</sup>, *British Medical Journal*<sup>13</sup>, the *Journal of Clinical Endocrinology*<sup>5</sup>, *Pediatrics*<sup>14</sup>, and *Archives of Pediatric and Adolescent Medicine*<sup>15</sup>, among others. In addition, the World Professional Association for Transgender Health (WPATH, formerly the Harry Benjamin International Gender Dysphoria Association) has issued global standards of care since 1979; currently, the seventh version is under revision. The WPATH Standards of Care are internationally recognized as the most comprehensive and evidence-based set of recommendations for treating gender dysphoria.

The following summarizes clinical evidence of necessity, effectiveness, and safety for surgical procedures for treatment of gender dysphoria. The essential purpose of transition-related treatment, whether it is genital reconstruction, hormone replacement therapy or any other gender-confirming procedure, is to therapeutically treat Gender Dysphoria, not to improve a person’s appearance. The evaluation of medical necessity must be individualized to each patient and take into account the totality of the patient’s total appearance and transition-related needs. Transgender people have unique clinical needs that are distinct from those of non-transgender people, and individualized assessments should be based on their symptoms, functionality, and the totality of their gendered appearance. As such, an individual may require none, some, or (rarely) all of the surgical procedures described in order to effectively treat their gender dysphoria.

Gender reassignment is the only treatment for gender dysphoria that has shown significant benefits in numerous research trials and meta-analyses over the past half century.<sup>16</sup> Overall, gender reassignment surgeries have been found safe, effective, and necessary in treating gender dysphoria.<sup>1,8,9,16-19</sup> Feelings of regret are extremely rare and, where present, mostly transient.<sup>20-25</sup> Access to transition-related care not only results in reduction of dysphoria and improved psychological outcomes,<sup>26</sup> but is also linked to improved primary care outcomes. Transgender women who accessed transition-related care were less likely to have injected silicone<sup>27</sup> or to have HIV-associated illnesses.<sup>28</sup> HIV-positive transgender women who receive transition-related care are more likely to be engaged in HIV primary care, have higher antiretroviral adherence and achieve undetectable viral loads.<sup>28</sup> Utilization of transition-related medical care has been associated with significantly lower rates of suicide, binge drinking, and non-injection drug use.<sup>29</sup>

## Categories of Gender Reassignment Surgery

The category of Gender Reassignment Surgery (GRS) includes:

1. Breast/chest surgeries;
2. Genital surgeries;
3. Other surgeries.

For the Female-to-Male (FTM) patient, surgical procedures may include the following:

1. Breast/chest surgery: subcutaneous mastectomy, nipple grafts, chest reconstruction;
2. Genital surgery: hysterectomy/salpingo-oophorectomy, metoidioplasty, phalloplasty (employing a pedicled or free vascularized flap), reconstruction of the fixed part of the urethra, vaginectomy, vulvectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;
3. Other: voice surgery (rare), liposuction and lipofilling.

For the Male-to-Female (MTF) patient, surgical procedures may include the following:

1. Breast/chest surgery: mammoplasty;
2. Genital surgery: orchiectomy, penectomy, vaginoplasty, clitoroplasty, vulvoplasty, labiaplasty, urethroplasty, prostatectomy;
3. Other surgeries: reconstructive facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, electrolysis or laser hair removal, and hair reconstruction.

## Summaries of Clinical Evidence for Gender Reassignment Surgeries

### Surgeries for Female-to-Male (FTM) individuals

#### *Breast/Chest Surgery*

Mastectomy for transgender men is necessary for many in order to resolve Gender Dysphoria.<sup>1,8,9,18,30,31</sup> When bilateral (double-incision) mastectomy is performed, nipple grafts are a necessary component of the surgery; when “keyhole” (periareolar incision) is performed, nipple grafts are less likely necessary, but may be required in some cases.<sup>18,31</sup> Both procedures are highly effective, and in either type, reconstruction of the chest to approximate a normal male chest is a necessary component.<sup>18,30–32</sup> In follow-up studies, transgender men who have undergone mastectomy report very low rates of complication and high rates of satisfaction; scarring is generally within expected limits and necrosis of nipple grafts is rare.<sup>1,8,16,22,30,33–37</sup> Chest reconstruction surgery in combination with hormone therapy has been shown to be more effective in alleviating gender dysphoria than hormones alone.<sup>38</sup> Quality of life is higher among transgender men who have undergone chest reconstruction than those who have not.<sup>39,40</sup>

#### *Genital Surgeries*

Three procedures may be indicated for transgender men whose gender dysphoria affects the genitals. Hysterectomy may be performed with or without salpingectomy and oophorectomy; the procedures are safe, with complication rates comparable to the non-transgender population, and effective in reducing gender dysphoria.<sup>18,41–45</sup> If dysphoria related to external genitals is present, patients should receive individualized assessment to determine if metoidioplasty or phalloplasty will be more effective in reducing gender dysphoria.<sup>2,17,18</sup> Both procedures are highly effective in treating gender dysphoria and have acceptable complication rates when weighed against the benefits for some patients; when complications do occur, they are often relatively minor and can be easily treated.<sup>17,18,25,36,40,46,47</sup> Phalloplasty may be safely performed using either a free or pedicled flap technique.<sup>18,46,48–53</sup> Urethral lengthening is required as a component of phalloplasty and is often necessary for metoidioplasty.<sup>18,46,54–58</sup> Scrotoplasty and testicular implants may be necessary components of phalloplasty and metoidioplasty if individualized assessment determines the results would better resolve dysphoria.<sup>47,59</sup>

## Surgeries for Male-to-Female (MTF) individuals

### *Breast/Chest Surgery*

In transgender women who undergo hormone therapy, maximal breast development is generally reached within 2 years; while in some hormone therapy alone is sufficient to achieve breast size appropriate to age and body habitus, in 40-70%, breast reconstruction may be necessary in order for the individual to pass as female and thereby reduce or resolve gender dysphoria.<sup>60-63</sup> Mammoplasty in transgender women serves a primarily therapeutic purpose and should be considered reconstructive rather than cosmetic.<sup>9,24,64</sup> In a recent cohort study, psychosocial wellbeing improved after breast reconstruction, indicating that the procedure is effective in reducing gender dysphoria.<sup>24</sup> Safety is a paramount issue underscoring the necessity of access to breast reconstruction as well, as transgender women who are unable to access safe methods of breast reconstruction sometimes resort to injection of non-medical grade silicone to obtain breast shape and size. In one recent report of complications related to silicone injection, transgender women, who overall represent less than 1% of all women in the general population, accounted for 45% of cases in a recent review article.<sup>65</sup> One argument that is made to deny medically necessary transition services to patients with GD is to state that an specific physical characteristic that requires surgery falls within the “broad range of normal” (BRN) for individuals of the gender to which the patient is transitioning. For example, it is quite obvious that small breasts are within the BRN for cisgender (non-transgender) women. However, perceptions of a person’s gender are not based on a single characteristic but rather look at the totality of a person’s gendered characteristics. It is inappropriate to solely consider individual characteristics such as breast size in isolation: a breast size that may be sufficient to allow a cisgender woman to be perceived as female may not produce the same result in a transgender woman, whose other gendered characteristics may be less likely to fall in the typical range for female appearance. Based on medical standards of care, it is essential that the totality of an individual’s appearance and gendered presentation be considered rather than the individual treatments in isolation.

Adhering to the medical requirement of considering a patient’s overall appearance and social functioning – rather than focusing on specific individual characteristics considered in isolation from one another and from the person’s overall medical needs and treatment goals – is particularly critical in light of the unique challenges faced by transgender women. While transgender men often (but not in all cases) are able to develop a conventionally masculine appearance and be accepted as men in society with access to hormonal treatment and mastectomy, the process for transgender women who transition after undergoing a male puberty is more complicated due to the difficulties of overcoming the physical impact of testosterone. The individual characteristics of many transgender women may fall within the BRN for cisgender women; however, many transgender women are unable to safely live and be accepted as women without the assistance of medical and surgical treatments. The inability to be perceived as women results in disproportionately increased rates of discrimination, job loss and unemployment, interpersonal violence, imprisonment, and suicide among transgender women. A national survey of over 6,454 transgender Americans demonstrated that visual non-conformity (inability to “pass” as male or female) was “a risk factor in eliciting anti-transgender bias and its attendant social and economic burdens.”<sup>66</sup> The authors also demonstrated that visual non-conformers were more likely to attempt suicide (44%) and were less likely to receive medical care at a primary care provider’s office. Subsequent analysis of their data demonstrated that visual non-conformers were more likely to be homeless. They were also more likely to be denied access to a homeless shelter, to be assaulted by shelter staff or residents, and to be forced to leave shelters due to poor treatment and/or unsafe conditions.<sup>67</sup> Another study of young transgender women in Los Angeles found that “[t]ransgender women, particularly those who have difficulty ‘passing,’ or looking like biologic females, report problems obtaining gainful employment because of transgender-related discrimination.”<sup>68</sup> Thus inability to “pass” not only worsens patients’ dysphoria and other mental health symptoms as evidenced by increased suicide rates, but also increases risk for harassment, violence, unemployment, and decreased access to services such as primary care and homeless shelters.

Denial of care based on the assumption that care is purely cosmetic particularly fails to recognize that transgender women can have individual characteristics within the BRN for that specific characteristic, and yet still have an overall gendered appearance that falls far outside of the BRN and that prevents them from living and being accepted by others as women. As the medical framework recognizes, people perceive gender conformity based not on a single characteristic but the totality of a person's appearance. Assuming that individual characteristics like breast size, thyroid cartilage size, jaw size and angle, voice pitch, male pattern baldness, and facial hair fall along a random bell curve in women, it would not be unusual for a woman to have a single characteristic such as very small breasts that places her at the 10th percentile for breast size – meaning that 10% of women would have the same or a smaller breast size. But if one considers what percentage of women would randomly fall at the 10th percentile for all six characteristics, the number would be 0.0001% (or one in a million) – well outside of even a very broad range of normal variation. So while it might well be within the BRN for a woman to have small breasts, it would be decidedly outside of that range for a woman to be balding, have a deep voice, large jaw, tiny breasts, a protruding thyroid cartilage, and dense beard growth. It is these kinds of odds that many transgender women face when they are unable to access medically necessary procedures designed not to make them look cosmetically flawless but simply to give them the typical appearance associated with women.

### *Genital Surgeries*

Genital surgeries for transgender women generally fall into two types: orchiectomy, performed alone or as part of vaginoplasty, and procedures associated with vaginoplasty (penectomy, vaginoplasty, clitoroplasty, vulvoplasty, labiaplasty, urethroplasty, and rarely prostatectomy). Whether or not assessment indicates vaginoplasty is necessary to resolve an individual's gender dysphoria, orchiectomy may be indicated separately.<sup>1,7,18,69,70</sup>

Vaginoplasty has been shown to be necessary, safe, and effective in treating gender dysphoria. The procedure may be performed using skin grafts or flaps; the most common technique involves inversion of an anteriorly pedicled penile skin flap in combination with a small dorsally based scrotal flap.<sup>9,17–19,71</sup> Follow-up studies indicate high satisfaction, improved sexual, physical, and psychosocial health, and reduction of gender dysphoria.<sup>16,20,21,23,25,35,36,36,37,71–77</sup> Follow-up studies have found complications including dehiscence, prolonged vaginal bleeding, vaginal pain, anorgasmia, rectal-vaginal fistula, vaginal stenosis, urethral stenosis, clitoral necrosis, vaginal prolapse, and vaginal hair; complication rates are acceptable when weighed against the benefits for some patients.<sup>18,19,21,23,25,71</sup> Pre-vaginoplasty electrolysis is necessary to prevent vaginal hair.<sup>21,78</sup>

### *Other Surgeries*

Other surgeries or procedures that may be necessary to resolve gender dysphoria and allow transgender women to navigate the world as women include facial and body hair removal, reconstructive facial feminization surgery, reduction thyroid chondroplasty, vocal surgery, and hair reconstruction.<sup>1,16,18,19</sup> These procedures are not cosmetic, but rather serve a primarily reconstructive purpose by allowing transgender women whose overall physical appearance otherwise prevents them from being perceived as female.

A recent review article defines reconstructive facial feminization surgery as “a broad range of cranio-maxillofacial surgical procedures and techniques with the sole objective of converting a masculine face to a more feminine one. There is no attempt to convert the face into that of a fashion model as all that is usually desired by the individual is to pass as a female in everyday society and to integrate as well as possible into the community.”<sup>79</sup> Facial cues serve as a primary basis for making a determination of gender, and these determinations take just over one hundredth of a second to make.<sup>64,80</sup> As hormone treatment and other surgical interventions provide no significant changes to facial structure,

reconstructive facial feminization is a critical component of transition for many transgender women, in order to participate in society as a woman and avoid gender-based violence and discrimination.<sup>81-85</sup>

Facial feminization is highly effective, with high rates of satisfaction;<sup>64,79,80,82,83,85-88</sup> in one study, it was associated with higher quality of life, compared to transgender women who had undergone no surgery or only genital surgery.<sup>64</sup> In another, participants were asked to determine the gender of a person based on photographs of the upper, middle, or lower regions of the face; participants correctly identified the gender of transgender women who had undergone reconstructive facial feminization more than 80% of the time, compared to expected values of 4% for those who had not undergone the surgery.<sup>80</sup> The same study found that less than 2% of 168 transgender women who had undergone reconstructive facial feminization experienced complications. Another study analyzed the results of 214 transgender women who had undergone reconstructive facial feminization and found no serious complications, no new emergency surgical operations, and no necessity to drain seromas or hematomas; one patient had a fistula along an incision, which resolved on its own.<sup>86</sup> Removal of facial and body hair through electrolysis or laser instruments provides another necessary treatment that allows perceptions of gender based on secondary sex characteristics, and particularly facial cues, to correctly identify transgender women as women.<sup>1,18,19,89</sup> One study noted a mean of 90% hair clearance using an Intense Pulsed Light Source (laser) and that clearance rates did not differ based on whether the individual had undergone any hormone therapy.<sup>89</sup>

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