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# Integrated and Gender-Affirming Transgender Clinical Care and Research

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# Integrated and Gender-Affirming Transgender Clinical Care and Research

Sari L. Reisner, ScD,\* Asa Radix, MD, MPH,† and Madeline B. Deutsch, MD, MPH‡

## OVERVIEW

Despite the disproportionate burden of HIV infection facing transgender communities, particularly for transgender feminine spectrum people worldwide,<sup>1</sup> transgender individuals continue to represent an underserved, highly stigmatized, and under-resourced population in both general clinical care and HIV prevention services. The aim of this article is to describe and present a model of gender-affirmative and integrated clinical care and community research for transgender people to address and intervene on disparities in HIV infection. To do this, we first define terminology pertaining to transgender people, briefly review the epidemiology of HIV infection and risks in transgender communities, describe exemplar models of gender-affirmative clinical care for transgender people in Boston MA, New York, NY, and San Francisco, CA, and offer suggested “best practices” for integrating clinical care and research in trans health. It is our assertion that any holistic HIV prevention intervention for transgender people will need to address clinical issues and integrate primary concerns of transgender people (eg, gender-affirmative care, management of gender transition, and medical gender affirmation) alongside delivery of HIV-related services (biobehavioral prevention, testing, linkage to care, and treatment). Integration of gender-affirmative clinical care and research represents a holistic and structural approach to intervene on HIV disparities for transgender people.

## TERMINOLOGY

*Transgender* and *gender nonconforming* people (*trans* or *gender minority*) have a gender identity or expression that differs from their assigned sex at birth.<sup>2</sup> Trans people are a diverse group. There is varied terminology used to describe gender minority people in different geographic and cultural contexts and settings; language and terms also continuously evolve and change to describe trans definitions and trans identities over time. In this article, we use the term *trans feminine* to refer to individuals assigned a male sex at birth who identify as women, female, male to female, transgender women, trans women, transfemale, or other diverse culturally or contextually specific gender identities on the trans feminine spectrum. *Trans masculine* denotes individuals assigned a female sex at birth who identify as men, male, female to male, transgender men, trans men, transmale, or another heterogeneous gender identity on the trans masculine spectrum. The terms *trans feminine* and *trans masculine* are used to not only include western definitions of “transgender women” and “transgender men” but also to integrate the diverse and heterogeneous terminologies and conceptualizations of transgender individuals

**Abstract:** Transgender (trans) communities worldwide, particularly those on the trans feminine spectrum, are disproportionately burdened by HIV infection and at risk for HIV acquisition/transmission. Trans individuals represent an underserved, highly stigmatized, and under-resourced population not only in HIV prevention efforts but also in delivery of general primary medical and clinical care that is gender affirming. We offer a model of gender-affirmative integrated clinical care and community research to address and intervene on disparities in HIV infection for transgender people. We define trans terminology, briefly review the social epidemiology of HIV infection among trans individuals, highlight gender affirmation as a key social determinant of health, describe exemplar models of gender-affirmative clinical care in Boston MA, New York, NY, and San Francisco, CA, and offer suggested “best practices” for how to integrate clinical care and research for the field of HIV prevention. Holistic and culturally responsive HIV prevention interventions must be grounded in the lived realities the trans community faces to reduce disparities in HIV infection. HIV prevention interventions will be most effective if they use a structural approach and integrate primary concerns of transgender people (eg, gender-affirmative care and management of gender transition) alongside delivery of HIV-related services (eg, biobehavioral prevention, HIV testing, linkage to care, and treatment).

**Key Words:** HIV, transgender, prevention, models of clinical care, health inequities

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globally, including those who may not fully conform to binary (male/female, man/woman) gender categories and who still may be at risk of HIV acquisition or transmission. We use *nonbinary* to refer to transgender or gender nonconforming people who may not identify with a male/female binary system of gender categorization (eg, genderqueer, bigender, and agender).

## SOCIAL EPIDEMIOLOGY OF HIV INFECTION AMONG TRANS PEOPLE

Globally, HIV infection is devastatingly high among trans feminine people. A meta-analysis of global studies with laboratory-confirmed HIV infection data and at least 50 participants documented an HIV prevalence of 19% among trans feminine individuals and a 49-fold increased odds of HIV infection compared with cisgender (ie, nontransgender) adults of reproductive age.<sup>1</sup> HIV infection data are scarce for trans masculine individuals.<sup>3</sup> A 2016 review found only 10 quantitative studies (all in North America) with laboratory-confirmed HIV serostatus among trans masculine people; among these, documented HIV seroprevalences were 0%, 2.2%, 3.0%, and 4.3% (1 of 23 individuals).<sup>4</sup> There exist few HIV infection data about nonbinary trans people; these individuals are underrepresented in current clinical and epidemiologic research.

As with other key populations, risk for HIV acquisition or transmission in trans people is complex. HIV risk for trans people has been attributed to intersecting syndemics of biopsychosocial factors (eg, biological, psychological, social, and structural) occurring across multiple levels of influence, ranging from the individual, interpersonal, community and network, and societal levels.<sup>4-8</sup> A core driver of HIV risk for trans people is pervasive stigma which leads to HIV-related vulnerabilities through pathways of social and economic exclusion and marginalization, particularly for trans feminine individuals.<sup>1,9</sup> For example, social marginalization and employment discrimination can lead trans feminine populations to engage in transactional or survival sex (ie, sex work) with higher economic incentives offered by clients for condomless anal sex acts.<sup>10</sup> Trans masculine individuals, particularly those who are gay, bisexual, same-gender loving, queer, or have sex with cisgender males are also an at-risk group, potentially exposed to the double stigma of being both sexual and gender minorities.<sup>11</sup> Attending to the trans-specific biological, social, and behavioral factors which drive HIV vulnerabilities will be crucial to HIV prevention interventions that seek to curb HIV incidence in transgender people.<sup>12</sup>

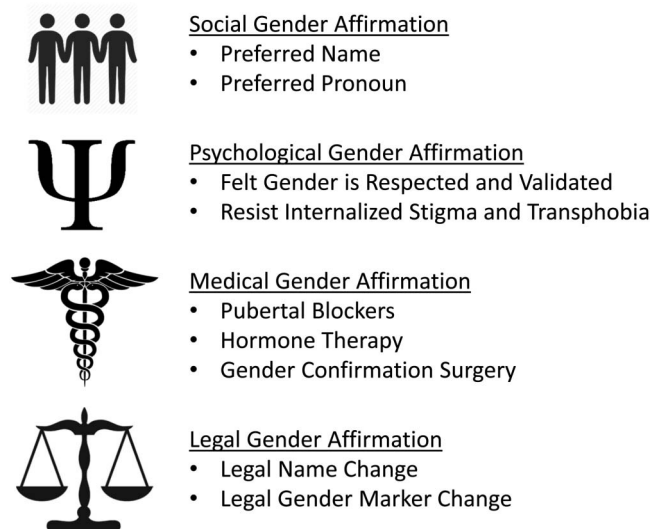
## GENDER AFFIRMATION AS A KEY SOCIAL DETERMINANT OF TRANS HEALTH

In 2013, the *Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5)* was revised and *gender identity disorder (GID)* was changed to *gender dysphoria*, a diagnostic criteria reflecting the psychological distress that occurs due to gender and sex discord.<sup>13</sup> Gender dysphoria is characterized by clinically significant distress or impairment in social, occupational, or other important areas of functioning associated with having a gender identity or expression different than that sex assigned at birth and/or gender roles typically associated with

that sex. Alleviation of symptoms of clinically significant distress resulting from gender dysphoria (ie, “treatment”) focuses on *affirming* the person’s felt and/or expressed gender. Gender affirmation is thus a critical component of the health and well-being of trans individuals and communities.

Gender affirmation refers to the social process of being recognized or affirmed in one’s gender identity, expression, and/or role.<sup>14</sup> Although gender affirmation can be theorized as an inherently social process,<sup>14</sup> it must necessarily also be conceptualized as multidimensional with at least 4 core constructs: social (choice of name and pronoun, interpersonal and institutional acknowledgment and recognition), psychological (internal felt sense of self-actualization, validation of gendered self, internalized transphobia), medical (pubertal blockers, hormones, surgery, other body modification), and legal (legal name change, legal change of gender marker designation) (Fig. 1).<sup>11</sup> There is no one single path to gender affirmation—no “one size fits all” approach describes how trans people affirm their felt or expressed gender.<sup>15</sup> Some trans individuals pursue social but not medical gender affirmation, some pursue medical but not legal gender affirmation, and so on. Gender affirmation sometimes, but not always, conforms to binary categories of being female or male. Furthermore, gender affirmation does not require linearly following a discrete series of “transition” events—it is conceptualized as an ongoing process throughout the lifecourse.

Gender affirmation is a unique social determinant of health that affects trans people’s lives. Lack of social and psychological gender affirmation has been shown to adversely impact health care utilization behaviors among transgender people, including delaying preventive health care screenings or avoiding needed clinical care when sick or injured.<sup>16,17</sup> Medical gender affirmation (eg, hormones) has been shown to reduce mental health risks<sup>18,19</sup> and improve quality of life for transgender people.<sup>20,21</sup> Although the impact of gender affirmation on overall health has not been studied,



**FIGURE 1.** Gender affirmation: process of being affirmed in one’s gender identity. Four dimensions: social, psychological, medical, and legal.

provider anecdotes include reports of improvements in a variety of health conditions including obesity and diabetes after gender-affirming care and interventions, as patients gain a sense of self-worth and self-efficacy and become more invested in achieving and maintaining health.

In many countries and geographic contexts, medical gender affirmation is excluded from mainstream delivery or primary care services for transgender people and thereby relegated outside of the health care system. Lack of knowledgeable health care providers combined with transphobia and stigma in health care delivery systems may lead transgender people to procure gender-affirmative medical care through informal peer or community networks,<sup>22–24</sup> which may increase risk of health complications (eg, lack of routine monitoring of hormone levels, using higher than recommended dosages of hormones). Inability to legally affirm gender through legal documents (eg, government-issued identification) that match one's gender identity can be a barrier to accessing and receiving health care services, particularly within socialized government supported and sponsored health care systems. In most countries, transgender people cannot obtain appropriate legal gender affirmation documents and/or are required to have genital surgery to be able to do so.<sup>25</sup> This lack of legal recognition leads to social, economic, and political marginalization and economic exclusion which can increase vulnerability to HIV.<sup>26</sup>

Gender affirmation has been further implicated in HIV-related outcomes. Lack of social gender affirmation has been shown to increase sexual risk for HIV acquisition or transmission in both trans feminine<sup>14,27</sup> and trans masculine individuals.<sup>11,27</sup> Medical mistrust due to previous experiences of gender invalidation and transphobic-stigma in health care settings is linked to low pre-exposure prophylaxis (PrEP) acceptability among HIV-uninfected trans feminine individuals,<sup>28</sup> to challenges with engagement and retention in HIV treatment and care among trans feminine people living with HIV,<sup>29,30</sup> and with participation in HIV research trials.<sup>31</sup> Prioritization of hormones for medical gender affirmation over other health concerns influences all aspects of the HIV continuum of care, including PrEP acceptability,<sup>28</sup> engagement and retention in HIV treatment, and care.<sup>29,30</sup> Adherence to hormones has been shown to positively correlate with increased viral load among transgender women living with HIV providing further evidence that trans communities prioritize medical gender affirmation in daily life.<sup>32</sup> Concerns regarding adverse interactions between antiretroviral medications and hormones are frequently cited barriers to PrEP acceptability and engagement and retention in HIV treatment and care.<sup>28,29</sup>

## GENDER-AFFIRMATIVE HEALTH CARE FOR TRANS PEOPLE

Gender-affirmative health care refers to care that is sensitive, responsive, and affirming to trans patients' gender identities and/or expressions (Fig. 2). Several US centers (eg, Fenway Health in Boston, MA; Callen-Lorde Community Health Center in New York City, NY; and the University of California, San Francisco, CA) specialize in transgender clinical care (Appendix 1). Through serving large numbers

of trans patients, these organizations have developed and refined models of gender-affirmative care to meet trans patients' needs. Gender-affirmative models are rooted in a strength-based depathologization of human gender diversity (transgender as "identity"), rather than a pathological perspective (transgender as "disorder"). These programs exemplify an approach to transgender clinical care, research, and public health that can and should be implemented everywhere, no matter how many or how few transgender patients a clinic or hospital or community center may see. In reality, effective transgender care systems can be developed in any setting, as long as this development is supported by institutional will and is incorporated into the organization's mission.

The bedrock of gender-affirmative health care, including HIV prevention and care services to address the HIV continuum of care for trans people, is affirming trans patients across social, psychological, medical, and legal dimensions. Within the social and psychological domains, referring to trans people respectfully, and with the appropriate pronoun and name, is a key construct in the provision of gender-affirming care. "Misgendering" involves referring to a trans person using an incorrect pronoun or name, and represents one of the most common microaggressions experienced by trans people in clinical and research settings.<sup>33,34</sup> One way to prevent misgendering is rely on gender-neutral language, such as "How may I help you today?" instead of "How may I help you, sir?" or "Dr. Hope's 11:30 a patient is here" rather than "he is here for his appointment." Staff can also use neutral "they" pronouns instead of "she" or "he"; for example, "they are here for their 3:00 PM appointment." While some may perceive this use as grammatically incorrect, some language authorities and officials are beginning to formally recognize neutral pronouns.<sup>35</sup> Under no circumstances should any person ever be referred to as "it."

Registration or intake forms and electronic health records that routinely collect gender identity using a 2-step method<sup>36,37</sup> (current gender identity and assigned sex), as well as chosen name and pronoun ("he/him/his," "she/her/hers," "they/them/theirs"), are recommended. The 2-step method for gender identity, as well as collection of sexual orientation information, has been incorporated into the "Meaningful Use" guidelines for electronic medical records published by the US Department of Health and Human Services.<sup>38</sup> Health care systems should integrate this information into clinical care from the moment a patient walks into the door. Name and gender on government-issued identification may or may not be able to be changed, depending on the country and context. Legal documents may have implications for health insurance billing and claims, as well as ability to access certain medical services. For example, medical services may be needed that conflict with legal gender markers which can complicate health insurance billing (eg, a female-to-male trans masculine individual having a legal male gender marker and needing a Pap test to screen for cervical cancer). Consultation with local state laws and experts is recommended for solutions to specific incidents as they arise. In the United States, a "code 45" modifier can be used in cases of mismatch between legal sex and a needed service.<sup>39</sup>

Medical gender affirmation may include any combination of hormones, surgery, and other procedures such as hair

<p>Use patient's preferred name and pronoun:</p> <ul style="list-style-type: none"> <li>• If not sure, politely ask</li> <li>• Document in patient chart</li> <li>• If having trouble, use gender neutral language ("they," "them," "their")</li> <li>• Never refer to someone as "it"</li> </ul> <p>The patient may or may not want to medically affirm their gender:</p> <ul style="list-style-type: none"> <li>• No "one size fits all" approach</li> <li>• Many types of surgical procedures</li> <li>• Medical affirmation does not necessarily include gender confirmation surgery</li> <li>• Screen for silicone</li> </ul> <p>Only ask questions that are required:</p> <ul style="list-style-type: none"> <li>• Avoid invasive questions driven by curiosity</li> <li>• What do I know now? What do I need to know? How can I ask in a sensitive way?</li> </ul>	<p>"If you have it, check it" approach:</p> <ul style="list-style-type: none"> <li>• Anatomy inventory</li> <li>• Screen bioanatomy as appropriate (e.g., Pap test for transgender men who retain a cervix)</li> <li>• Ask patient permission before physically touching them</li> </ul> <p>Referrals for transgender patients to other services:</p> <ul style="list-style-type: none"> <li>• Specialists</li> <li>• Social services (e.g., housing, employment)</li> <li>• Family or spousal support and services</li> </ul> <p>Consult Standards of Care and Primary Care Protocols for Transgender People as needed:</p> <ul style="list-style-type: none"> <li>• World Professional Association for Transgender Health (WPATH): <a href="http://www.wpath.org/">http://www.wpath.org/</a></li> <li>• Center of Excellence for Transgender Health, University of California San Francisco: <a href="http://transhealth.ucsf.edu">http://transhealth.ucsf.edu</a></li> </ul>
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**FIGURE 2.** Gender-affirmative health care: health care that holistically attends to transgender people's physical, mental, and social health needs and well-being while respectfully affirming their gender identity.

removal or voice modification. In addition to specific gender-affirming interventions, transgender people require the full range of primary and specialty care. Because transgender people may have a variety of organ configurations (someone may have both a prostate and breasts, or ovaries but no uterus or breasts), clinicians and researchers should take an organ-based approach rather than relying on natal sex or gender identity to define anatomy.

## CLINICAL MANAGEMENT OF MEDICAL GENDER AFFIRMATION

The most recent clinical and medical aspects of transgender care have been outlined in version 7 of the Standards of Care by the World Professional Association for Transgender Health (WPATH).<sup>15,40</sup> Transgender people seeking gender affirmation through the acquisition of secondary sex characteristics of their identified gender may seek hormonal interventions. The proportion of transgender people who opt to undergo medical transition varies based on access and cost. In the United States and Canada, hormone utilization among trans feminine individuals is reported to be 43%–73%,<sup>24,41–43</sup> with as high as 70% accessing hormones outside of the medical system.<sup>43–46</sup> Nonbinary individuals are less likely to use hormonal therapy or undergo gender-confirming surgeries.<sup>41,47</sup> Hormonal therapies seem to be associated with improved quality of life and mental health functioning; however, there have been no clinical trials or long-term prospective studies.<sup>21,48,49</sup>

For trans feminine individuals, hormonal therapy usually consists of estrogens and androgen blockers. Estrogen therapy typically includes an oral, transdermal, or injected 17-beta estradiol.<sup>15,50</sup> Ethinyl estradiol (a common component of oral contraceptives) is associated with high incidence of venous thromboembolism<sup>51</sup> and is no longer recommended in feminizing regimens, but may be used by trans feminine individuals outside of medical settings. There are many different androgen blockers used for transition care. Spironolactone, an aldosterone receptor antagonist, is frequently used in the United States, whereas cyproterone acetate, a synthetic steroidal antiandrogen with prostatic properties, is predominantly outside of the United States. Other blockers include

gonadotropin-releasing hormone analogs, eg, leuprolide acetate; 5 alpha-reductase inhibitors, eg, finasteride; and progestins. Trans masculine individuals who seek virilization typically use injected or topical testosterone regimens. The choice of hormones and route of administration are often based on personal preference, age, and concurrent medical issues. There have been no clinical trials to evaluate comparative safety and efficacy of hormones in transgender people. For trans feminine people who have significant cardiovascular risk factors, including smoking and older age, transdermal estrogens are recommended. There are no evidence-based recommendations for the frequency or type of laboratory monitoring. Existing guidelines for laboratory monitoring are based on expert opinion and range from every 3 months to once a year, depending on the length of time an individual has been receiving hormones and concurrent medical conditions.<sup>50</sup>

In the context of coadministration of gender-affirming hormones and antiretroviral therapy (ART) either for treatment or PrEP for HIV, no direct studies have been conducted. Studies of interactions of oral contraceptives containing synthetic ethinyl estradiol and various ART medications suggest that negative effects of hormones on ART are limited to amprenavir, unboosted fosamprenavir, and stavudine.<sup>52–55</sup> Positive or negative effects of ART on ethinyl estradiol levels may be more common and might represent a barrier to adherence because trans feminine individuals who perceive a negative impact on their gender transition may exhibit reduced adherence or total discontinuation of ART therapy<sup>29,56</sup>; pill burden may represent another factor which leads to adherence to hormones, but not ART. The authors of a recent subanalysis of trans feminine individuals in the iPrEx study of PrEP opined that an observed association of hormone therapy with lower drug levels was as a result of such behavioral factors, rather than a pure biological interaction.<sup>57</sup>

With respect to gender-affirming surgeries, for trans feminine people may opt to undergo gonadectomy (orchiectomy) and creation of a vagina, clitoris, and labia. The most common vaginoplasty procedure uses penile and scrotal tissue to create a skin-lined vaginal vault and vulva (penile inversion vaginoplasty); much less common is an approach using sigmoid colon to create a self-lubricating neovagina, with drawbacks of higher rates of complication and a more invasive

procedure. Gender-affirming surgeries for trans masculine people include breast reduction, eg, bilateral double incision or periareolar mastectomy, hysterectomy, and oophorectomy. There are several procedures to construct the external genitalia, including creation of a phallus (phalloplasty or metoidioplasty) and/or scrotum (scrotoplasty with testicular implants). In general, levels of satisfaction after gender-affirming surgeries are high,<sup>58,59</sup> although trans feminine individuals who have undergone vaginoplasty are more likely to meet criteria for hypoactive sexual desire disorder than both nontransgender women and transgender women who have not undergone vaginoplasty.<sup>60,61</sup> Trans masculine individuals experience higher rates of sexual desire after starting testosterone.<sup>60,62</sup> No studies have been conducted to determine changes in behavior after genital surgery, for example, to assess whether trans feminine individuals are more likely to have vaginal rather than anal receptive sex after vaginoplasty.

Because the majority of vaginoplasties use the penile inversion technique which results in a penile skin-lined vagina, risk of transmission of HIV or of acquisition of genital lesions is unknown,<sup>10</sup> although infections with gonorrhea and human papillomavirus (condyloma acuminata) have been reported.<sup>63–67</sup> Trans masculine individuals may engage in receptive anal or vaginal sex and may continue to engage in receptive anal sex even after genital reconstruction. The cervical epithelium changes with administration of testosterone.<sup>68</sup> It remains unknown whether hormone-mediated changes to the genital tract in either trans feminine or trans masculine individuals could impact risks for HIV or other sexually transmitted infections.

## CONNECTING TRANS CLINICAL CARE AND RESEARCH

In the absence of solid evidence to inform “best practices” for improving and connecting clinical care and research programs in transgender health and medicine, we propose the below framework of recommendations:

### Ask the 2-Step Method (Gender Identity and Assigned Sex at Birth) on Intake Forms and in Electronic Health Records

Collect gender identity and assigned sex at birth data on intake forms and electronic health records to promote gender-affirmative health care. Capturing gender identity data can inform quality improvement efforts and create basic research opportunities (ie, chart review studies to characterize the patient population, prevalence, and distribution of patient populations retained in care).

### Co-Locate Services, Including Access to Hormones and HIV Prevention, Testing, and Linkage to HIV Care and Treatment Services

Wrap-around services are ideal in trans health care provision, minimizing loss to follow-up and simplifying service delivery. Integrating HIV-related services into gender-affirmative care is an especially effective clinical

strategy. For example, routine HIV testing can be implemented as part of routine blood work for monitoring and management of cross-sex hormones.

### Partner With and Engage Local Trans Communities

Engaging and involving trans communities in health care delivery, programs, and interventions is critical to ensure that services are gender affirmative and responsive to community health care needs. A local community involvement process (eg, community advisory boards) should be used to tailor clinical and research tools to local demographics (ie, monolingual Spanish speaking trans feminine people in Los Angeles have different concerns and approaches than Black trans feminine people in Atlanta). Community members should be involved in the formulation of research questions and methods. The opportunity for community feedback at all junctures (eg, grievance procedures, etc.) will build trust.

### Use a Multidisciplinary Team Approach to Clinical Care and Research

Multidisciplinary team approaches to clinical care and research are an integrated model of gender-affirmative service delivery for trans people. Regular team meetings that integrate clinical and research teams will help to ensure coordination and integration of trans health care and the goal of achieving health equity.

### Design all Clinical Tools and Research Assessments to be Gender Affirming

Clinical tools (eg, registration forms) and research assessments (eg, surveys) should be gender affirming. Care should be taken to ensure that all tools and assessments are culturally responsive for trans people. Having trans community members be part of the design of tools and assessments, review before implementation, and pilot test is critical. Always give participants the opportunity to provide feedback on clinical care and research, including instruments and surveys (eg, use an open-ended feedback field at end of survey for participants to provide feedback).

### Ensure that Clinical Care and Research are Responsive to the Social Contexts and Lived Realities of Local Trans Populations

Trans communities face social and economic exclusion. Gender-affirmative health care that is contextually informed will be most responsive to community needs. This includes flexible scheduling and hours; trans staff and providers so trans people “see themselves” in clinical and research staff; multiple contacts to help retain trans individuals in clinical care and research (eg, friends and family contacts); multiple modes of communication for contacts (eg, phone, text, social media, and e-mail).

## Use Peer-to-Peer Methods to Recruit and Retain Participants in Clinical Care and Research

Clinical care infrastructures can be used as a foundation for other services. For example, wrap-around services such as peer health navigation, patient advocacy, and case management can improve patient engagement and retention in care and research.

## Create a Pipeline of Trans Clinicians and Researchers

Clinical and research training opportunities in transgender medicine, epidemiology, and public health (eg, residency programs, postdocs, grad student mentors) are greatly needed. Although transgender clinicians and researchers encounter numerous professional barriers and biases, a transgender identity is not currently recognized by the US National Institutes of Health (NIH) as an under-represented minority for the purposes of accessing funding and training programs. Increased recognition of nontraditional investigator career paths will also expand the range of opportunities for transgender-identified clinicians and investigators.

## THE WAY FORWARD: INTEGRATION FOR GENDER AFFIRMATION

Gender affirmation is a key ingredient to address the needs of transgender people who are at risk for HIV worldwide. Health care systems and clinical settings should consider social, psychological, medical, and legal constructs of gender affirmation in clinical care and research. Holistic and culturally responsive HIV prevention interventions must be grounded in the lived realities faced by the transgender community to reduce disparities in HIV infection, particularly the need for gender-affirmative medical care. Addressing structural factors facing transgender people, particularly stigma and transphobia in health care settings, is necessary to increase uptake of the full HIV continuum of care (eg, prevention, testing, and linkage to care) for the transgender population. Training of health care providers in medical gender affirmation and improving systems of health care delivery to be gender affirmative will be integral components of any strategy to mitigate HIV incidence.

Meaningful engagement of local, national, and global transgender communities will be paramount to ensure responsiveness of interventions and programs, as well as to increase trust and reciprocity between clinicians, researchers, patients, and participants. Addressing disparities in HIV infection and achieving health equity for transgender people necessitate an integrated and gender-affirming model of clinical care and research that uses a participatory population perspective<sup>69</sup> to work “with” not “on” communities.<sup>70</sup> This means involving transgender people in all aspects of clinical care and research. Implementation science research<sup>71</sup> may be well suited to implement and test biobehavioral interventions, such as PrEP and early antiretroviral medication initiation, as part of a comprehensive package of evidence-based prevention interventions linked to gender-affirmative care for transgender

people. Such interventional efforts will be maximally responsive if they attend to the multiple health care needs of transgender people outside of HIV infection.

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## APPENDIX 1. GENDER-AFFIRMATIVE MODELS OF TRANS CARE AND RESEARCH

### Fenway Health, Boston, MA

Founded in 1971 as a grassroots health clinic in Boston, MA, Fenway Health is a federally qualified community health center specializing in lesbian, bisexual, and transgender (LGBT) health care.<sup>69</sup> Fenway offers accessible, patient-centered, gender-affirmative care for transgender individuals philosophically grounded in a model where gender affirmation (eg, cross-sex hormone therapy) is a routine part of primary care service delivery. Fenway uses an informed consent model of care which removes unnecessary barriers to hormone therapy for trans patients, including restrictions specifying prolonged mental health evaluations and “real life tests” (ie, living full-time in one’s self-identified gender) to obtain hormone therapy, that had long been embedded in existing standards of care. Trans patients complete a hormone readiness assessment, but mental health counseling is not automatically required. In 1983, Fenway Health initiated one of the first community-based HIV research programs, and The Fenway Institute (TFI) has continued to grow in scope and broaden its mission: to make life healthier for those who are LGBT, people living with HIV/AIDS, and the larger community through research and evaluation, education and training, and public health advocacy.<sup>70</sup> TFI has more than 12 active biobehavioral and epidemiological research protocols focused specifically on the health of trans people, including HIV prevention studies with trans feminine<sup>72,73</sup> and trans masculine youth.<sup>74</sup>

### Callen-Lorde Community Health Center, New York City, NY

Callen-Lorde Community Health Center is a federally qualified community health center with a mission to provide quality, sensitive medical and related services targeted to New York’s lesbian, gay, bisexual, and transgender (LGBT) communities, including those living with HIV/AIDS. The health center began when 2 volunteer-staffed, grassroots STD clinics that predominantly treated gay men and transgender women, merged in 1983. The health center is likely one of the largest outpatient practices in transgender health in the nation, serving over 3000 transgender and gender nonconforming patients. Callen-Lorde’s facilities are designed for transgender sensitivity, including trans-inclusive registration forms, gender-neutral bathrooms and trans-affirmative signage and imagery, and trans-identified staff. Callen-Lorde pioneered early adoption of a customized electronic health record that allows appropriate documentation of the diversity of identities and anatomy among transgender patients. The Trans Community Advisory Board reviews services to ensure that these are accountable to community-based standards of cultural competence. Transgender health is embedded in a primary care model. All primary care providers provide comprehensive transgender health care, including hormone therapy, using the Informed Consent Model that removes unnecessary restrictions (eg, real life experience and mandatory mental health evaluations) to hormone access. The center has onsite care coordination and legal services to assist with name changes, housing, and insurance navigation to address structural barriers to care. The center provides low cost or free hormones and education programs, such as Hormone 101, self-injection education, groups for trans feminine and trans masculine youth and adults, and community health forums “Trans Out Loud.” Callen-Lorde also provides LGBT trainings to external health facilities, with the goal to increase provider knowledge and clinical skills caring for transgender communities.<sup>75</sup> Since 2010, the center has participated in clinical research, mainly focusing on behavioral and biomedical HIV prevention interventions among MSM and transgender populations.

### Transgender Care Navigation Program, University of California, San Francisco (UCSF), San Francisco, CA

The University of California, San Francisco is a world-recognized leader in biomedical research and academic medicine. The Transgender Care Navigation Program represents a collaboration between the UCSF National Center of Excellence in Women’s Health and the Center of Excellence for Transgender Health. The program was launched in 2015 as a multidisciplinary network of primary care and specialty providers who provide a range of medical, surgical, and vocal health care to children and adults. A dedicated transgender care navigator serves as a central hub for new patients and referrals between specialties. The navigator oversees insurance authorizations and assists with preoperative assessments and preparation. Providers collaborate on individual cases to optimize care and preparation for surgeries. A program website provides information for both patients and referring providers. As a large tertiary referral center, UCSF draws patients from within a several hundred mile radius; hormone therapy can be provided by telemedicine. Patients seeking hormone therapy can also receive HIV care and general primary care from the same provider; others who have outside primary and/or HIV care can be seen specifically for hormone therapy consultations. In the first 6 months of operation, the program received inquiries from more than 400 transgender individuals seeking care.