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Providing Gender-Affirming Care to Transgender and Gender-Diverse Individuals with HIV

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Disclosures

- I have received research grant support from Gilead Sciences, Inc., Abbott Molecular, and the NIH.
- I have served on a scientific advisory board for Scynexis.
- Thanks to Jill Blumenthal (UCSD) for sharing slides
- I am not trained in and do not provide care for minors in this space. This talk focuses on gender-affirming care approaches for adult patients.

The Basics

Gender identity term	Characteristics
Cisgender female or woman	Person assigned female sex at birth whose gender identity is female or woman
Cisgender male or man	Person assigned male sex at birth whose gender identity is male or man
Genderqueer	Person who does not follow gender identity or expression for their sex assigned at birth; they may identify as neither, both, or a combination of binary genders
Nonbinary	Person who does not identify with binary expectations of being strictly a man or a woman
Transgender	Person whose gender identity and sex assigned at birth do not correspond • Transgender female or transgender woman or male-to-female (MTF)[b] • Transgender male or transgender man or female-to-male (FTM)[b]

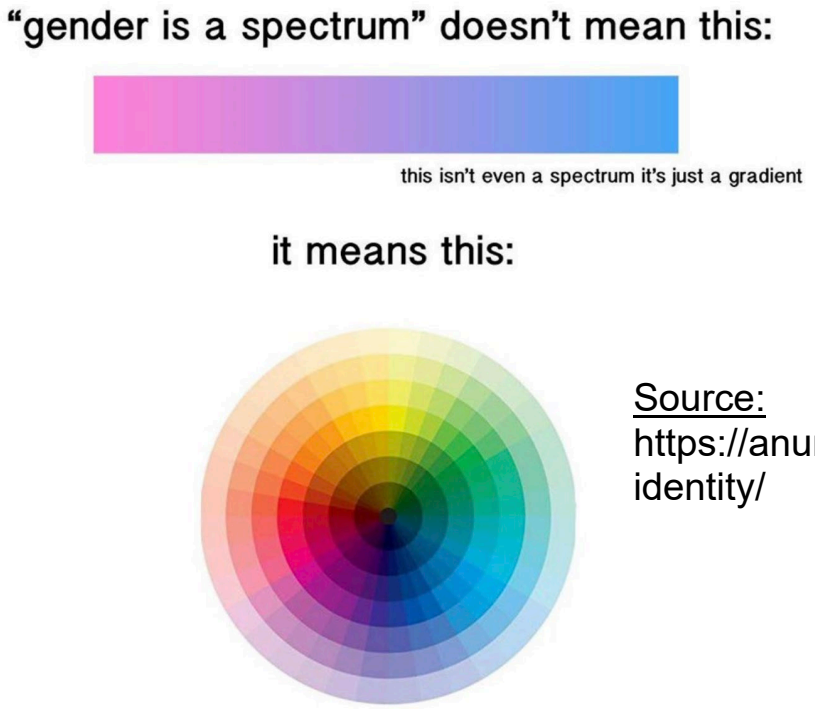
[a] The terms included are the most common, but dozens more are used, and terminology continually evolves.

[b] Medical model terms (not recommended for use unless an individual prefers them).

Top Antivir Med 2023 Mar 31;31(1):3-13.

Gender identity does not equal or predict:

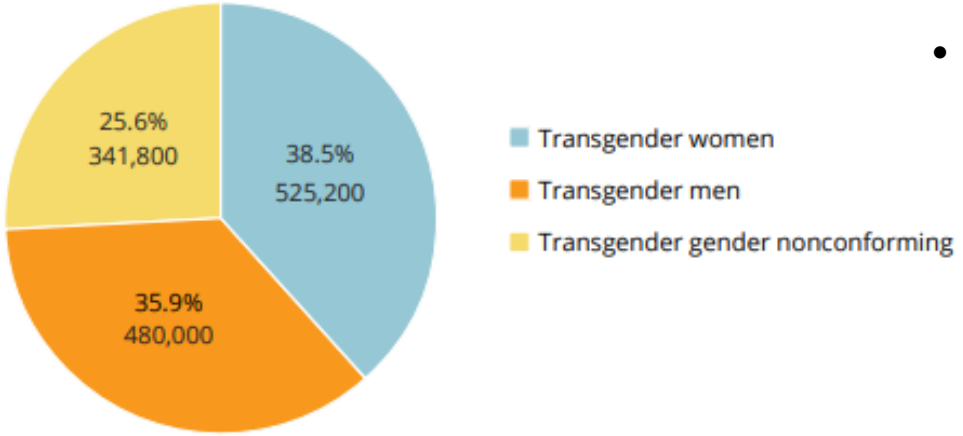
- ***Sexual orientation or identity***
- ***Sexual behaviors***
- ***Genders of sexual partners***



Source: https://anunnakiray.com/2gender-identity/

Demographics

Figure 1. Gender identity of adults who identify as transgender in the U.S.



- 1.6 million individuals based on current U.S. population size.
  - Among adults- **0.5% (over 1.3 million adults)**
  - Among youth ages 13 to 17- **1.4% (about 300,000 youth)**

Table 1. Percent of each age group that identifies as transgender in the U.S.

	PERCENT	NUMBER
13 to 17	1.4%	300,100
18 to 24	1.3%	398,900
25 to 64	0.5%	766,500
65 and older	0.3%	171,700
13 and older	0.6%	1,637,200

Williams Institute, 2022

Gender Affirmation

- The process of recognizing, accepting and expressing one's gender identity
  - Medical – hormones, surgery
  - Social/Emotional – Name, pronoun, dress, coming out to others
  - Psychological - Gender validation, internalized stigma/transphobia
  - Legal – Identity documents (name/gender marker)
- Medicalized with the diagnosis of "gender dysphoria"
  - ICD-10 F64.0. Distress related to incongruence between gender identity and sex assigned at birth

APA 2013; Keatley et al 2014; Sevelius 2013; Lawrence 2003; www.lgbthealtheducation.org;

Treatment Guidance

Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline.

Hembree, et al. 2017

WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.

Coleman, E., et al. 2022.

Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, 2nd edition.

Deutsch, M. et al. 2016

WPATH Recommendations for Assessment of Adults

- Only recommend GAHT for people experiencing "marked and sustained" gender dysphoria
- Identify and exclude other possible causes of apparent gender incongruence prior to initiation of GAHT
- Risk-benefit discussion about mental and physical health conditions that could impact GAHT process
- Assess capacity for consent for the specific treatment prior to initiation
- Consider social transition if appropriate for your patient
- Consider 6 months of GAHT prior to gonadectomy or other irreversible surgical intervention
- Mental health care assessment is not a requisite for initiation of GAHT in all cases (some insurances require it, though)

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Initial Assessment: My Approach

- Ask about their gender journey
  - When they first recognized their identity
  - Past history of hormones, surgeries, etc.
- Support system
  - Biological family
  - Chosen family, network of LGBTQ+ folks
- Mental health
  - Comorbid mental health issues
  - Sources of dysphoria
  - Current therapist/psychiatrist
- Pertinent medical, family, and social history
  - Tobacco use
  - Personal or family history of VTE, clotting disorders, strokes, MI, HTN, gyn cancers, etc.
- Explore their goals and expectations
  - What they expect that hormones can do for them
  - Any interest in surgeries? Which ones? Timeline?
  - Fertility and sexual health
  - Treatment preferences (e.g., drug route, timeline, desire for social transition)

SUMMARY CRITERIA FOR ADULTS

Related to the assessment process

- Health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment should liaise with professionals from different disciplines within the field of trans health for consultation and referral, if required*
- If written documentation or a letter is required to recommend gender affirming medical and surgical treatment (GAMST), only one letter of assessment from a health care professional who has competencies in the assessment of transgender and gender diverse people is needed.

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Criteria for hormones

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
d. Other possible causes of apparent gender incongruence have been identified and excluded;
e. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
f. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

Criteria for surgery

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
d. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
e. Other possible causes of apparent gender incongruence have been identified and excluded;
f. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
g. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).*

*These were graded as suggested criteria

Counseling and Expectations are ESSENTIAL

Table 1. Expected time course of physical changes in response to gender-affirming hormone therapy

Testosterone Based Regimen		
Effect	**Onset**	**Maximum**
Skin Oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	6–12 months	>5 years
Scalp hair loss	6–12 months	>5 years
Increased muscle mass/ strength	6–12 months	2–5 years
Fat redistribution	1–6 months	2–5 years
Cessation of menses	1–6 months	1–2 years
Clitoral enlargement	1–6 months	1–2 years
Vaginal atrophy	1–6 months	1–2 years
Deepening of voice	1–6 months	1–2 years
Estrogen and testosterone-lowering based regimens		
Effect	**Onset**	**Maximum**
Redistribution of body fat	3–6 months	2–5 years
Decrease in muscle mass and strength	3–6 months	1–2 years
Softening of skin/ decreased oiliness	3–6 months	Unknown
Decreased sexual desire	1–3 months	Unknown
Decreased spontaneous erections	1–3 months	3–6 months
Decreased sperm production	Unknown	2 years
Breast growth	3–6 months	2–5 years
Decreased testicular volume	3–6 months	Variable
Decreased terminal hair growth	6–12 months	> 3 years
Increased scalp hair	Variable	Variable
Voice changes	None	

Adapted from Hembree et al., 2017.

Table 2. Risks associated with gender affirming hormone therapy (bolded items are clinically significant) (Updated from SOC-7)

RISK LEVEL	Estrogen-based regimens	Testosterone-based regimens
Likely increased risk	**Venous Thromboembolism** **Infertility** Hyperkalemia[S] Hypertrigyceridemia Weight Gain	**Polycythemia** **Infertility** Acne Androgenic Alopecia Hypertension Sleep Apnea Weight Gain Decreased HDL Cholesterol and increased LDL Cholesterol
Likely increased risk with presence of additional risk factors	Cardiovascular Disease Cerebrovascular Disease Meningioma[C] Polyuria/Dehydration[S] Cholelithiasis	Cardiovascular Disease Hypertriglyceridemia
Possible increased risk	Hypertension Erectile Dysfunction	
Possible increased risk with presence of additional risk factors	Type 2 Diabetes Low Bone Mass/ Osteoporosis Hyperprolactinemia	Type 2 Diabetes Cardiovascular Disease
No increased risk or inconclusive	Breast and Prostate Cancer	Low Bone Mass/ Osteoporosis Breast, Cervical, Ovarian, Uterine Cancer

[C]cyproterone-based regimen
[S]spironolactone-based regimen

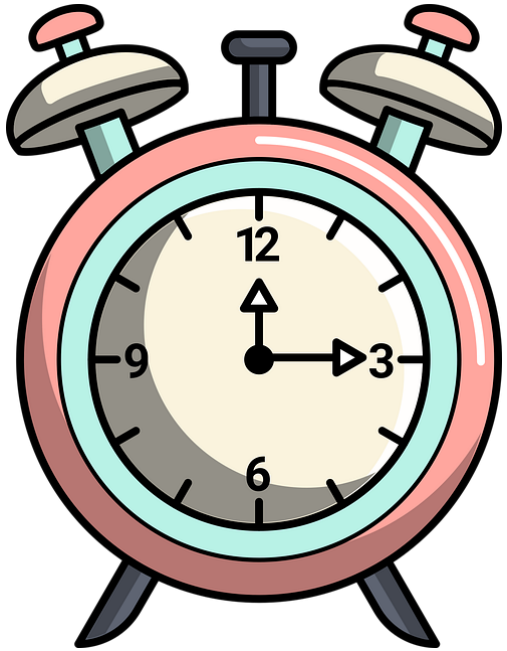

Table 2. Common Gender-Affirming Hormone Therapy Regimens[a]

Medication class	Route	Suggested starting dose range	Suggested maximum dose
Feminizing hormone therapy			
Estrogens			
	Oral or sublingual estradiol	2.0 mg daily	8.0 mg daily
	Transdermal estradiol patch	0.1 mg daily	0.4 mg daily
	Parenteral estradiol valerate (IM/SQ)	20 mg every 2 weeks	40 mg every 2 weeks
	Parenteral estradiol cypionate (IM/SQ)	2 mg every 2 weeks	5 mg every 2 weeks
Antiandrogens			
	Oral spironolactone	100 mg daily	200 mg twice daily
	Oral cyproterone acetate[b]	10 mg daily	same as starting dose
	Parenteral GnRH agonists (IM/SQ)	3.75–7.50 mg monthly	same as starting dose
	Parenteral GnRH agonist depot formulation (IM/SQ)	11.25 mg every 3 months or 22.5 mg every 6 months	same as starting dose
Progesterone			
	Oral micronized progesterone	100 mg daily	200 mg daily
Masculinizing hormone therapy			
	Parenteral testosterone enanthate/cypionate (IM/SQ)	50–100 mg weekly or 100–200 mg every 2 weeks	same as starting dose
	Parenteral testosterone undecanoate (IM)	1000 mg every 12 weeks or 750 mg every 10 weeks	same as starting dose
	Transdermal testosterone patches	2.0 mg daily	8.0 mg daily
	Testosterone topical gel 1%	50 mg daily[c]	100 mg daily

Abbreviations: IM, intramuscular; GnRH, gonadotropin-releasing hormone; SQ, subcutaneous.

[a] Adapted from Coleman[11] and Deutch.[12]
[b] Not available in the United States.
[c] 30 mg = 1 pump.

Parenteral estradiol

- Difficult to monitor given variable half-life (patient to patient)
- Frequent supply chain issues

Transdermal estradiol

- >45 years old
- Prior personal history of VTE

Progesterone + estradiol

- Greater breast cancer and cardiac risk in cisgender women
- May enhance breast and areolar growth

Duration of GAHT

- Usually life-long
- Unclear if doses should be adjusted with age
- Discontinuation of hormone therapy may result in bone loss in TGD individuals and will definitely do so in individuals whose gonads have been removed

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Table 5. Hormone monitoring of transgender and gender diverse people receiving gender-affirming hormone therapy (Adapted from the Endocrine Society Guidelines)

Transgender male or trans masculine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and 1 to 2 times per year thereafter to monitor for appropriate physical changes in response to testosterone.
2. Measure serum total testosterone every 3 months (with dose changes) until levels are at goal
   a. For parenteral testosterone, the serum total testosterone should be measured midway between injections. The target level is 400-700 ng/dL. Alternatively, measure peak and trough peaks to ensure levels remain in the range of reference men.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before injection. If the level is < 400 ng/dL, adjust the dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 week of daily application (at least 2 hours after application of product).
3. Measure hematocrit or hemoglobin concentrations at baseline and approximately 3 months (with dose changes) for the first year and then one to two times a year.

Transgender Female or trans feminine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and one to two times per year thereafter to monitor for appropriate physical changes in response to estrogen.
   a. Serum testosterone levels should be less than 50 ng/dL.
   b. Serum estradiol should be in the range of 100-200 pg/mL.
2. For individuals receiving spironolactone, serum electrolytes, in particular potassium, and kidney function, in particular creatinine, should be monitored.
3. Follow primary care screening per primary care chapter recommendations

Monitoring

	E2 ± antiandrogen	Testosterone
Total testosterone	< 55 ng/dl	Mid normal range
Estradiol*	100-200 pg/mL	<50 pg/mL
Electrolytes	spironolactone	
Lipids	✓	✓
Hematocrit		✓
Liver function		Mild and often transient ↑ ALT/AST
Prolactin	Mild ↑	

*Conjugated or synthetic estrogens can not be monitored by blood tests

Feminizing Surgery

Surgery (2-15%)

- Breast augmentation, orchiectomy, chondrolaryngoplasty, facial feminization, vaginoplasty, labioplasty, vulvopasty
- Increasing numbers of transgender women have genital surgery

Fillers (17-40%)

- Loose fillers (industrial silicone, other substances)
- Injected into breasts, face, hips, buttocks for feminization
- Risk of bloodborne pathogens, migration, inflammation, emboli, disfigurement and death

Poteat, T. CROI Plenary 2016; Drinane, J, Urological Care for the Transgender Patient, 2021

International Journal of STD & AIDS
Volume 33, Issue 2, February 2022, Pages 106-113

https://doi.org/10.1177/09564624211046997

Review article

Anatomical and sexual health considerations among transfeminine individuals who have undergone vaginoplasty: A review

Olivia T Van Gerwen [1], Zain Aryanpour [2], John P Selph[3], and Christina A Muzny[2]

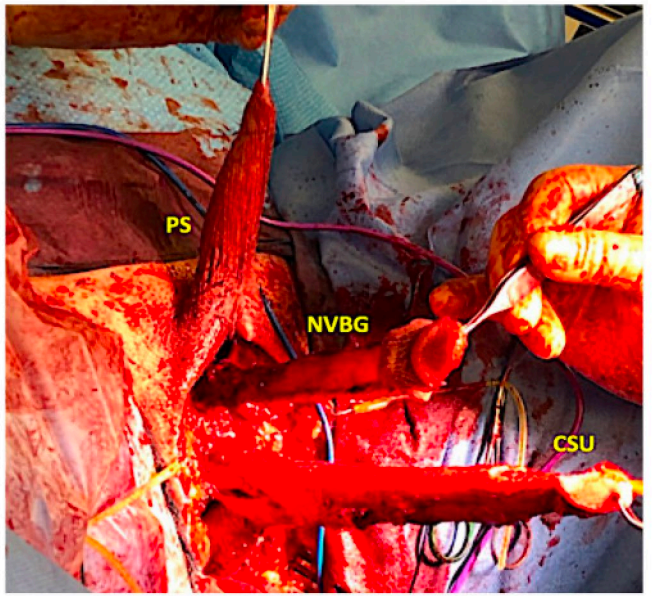


Figure 1. Anatomy of vaginal and vulvar components. PS: penile skin; NVBG: neurovascular bundle and glans; CSU: corpus spongiosum and urethra.

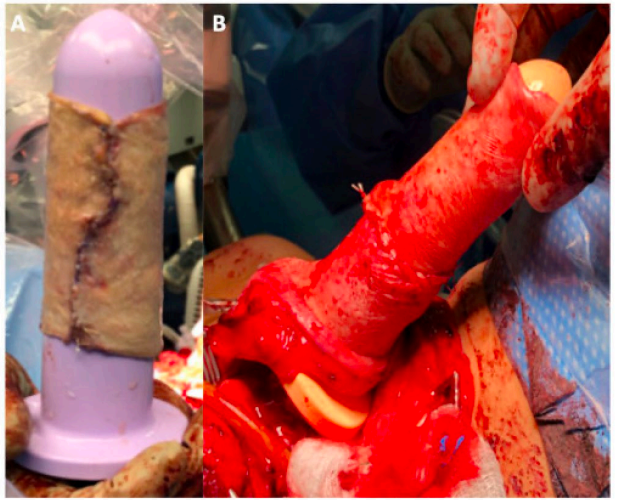


Figure 2. Skin graft in transfeminine vaginoplasty. (A) Skin graft placed on dilator to estimate neovaginal depth. (B) Skin graft sewn into penile skin and overlaid on dilator before inversion into neovaginal cavity.

Masculinizing Surgery

- Chest surgery
  - Breast reduction
  - Chest reconstruction
- Facial masculinization
- TAH/BSO
- Penis
  - Metoidioplasty/Metaoidoplasty (meto/meta)
  - Phalloplasty
- Urethroplasty
- Scrotoplasty

Modified ring metoidioplasty (Dr. Ming Chen)

Agarwal JPRAS 2018; Cleveland Clinic 2021

The Global HIV Burden

- The World Health Organization reports the estimated worldwide prevalence of HIV among transgender women to be 19%.[1]
  - Observational studies in some parts of the world estimate prevalence of up to 49.6% among transgender women.[2]
- Transgender women are 49 times more likely to be living with HIV than other adults of reproductive age. [1]
- While data is limited, 2%-8.3% of transgender men worldwide are estimated to be living with HIV.[2]

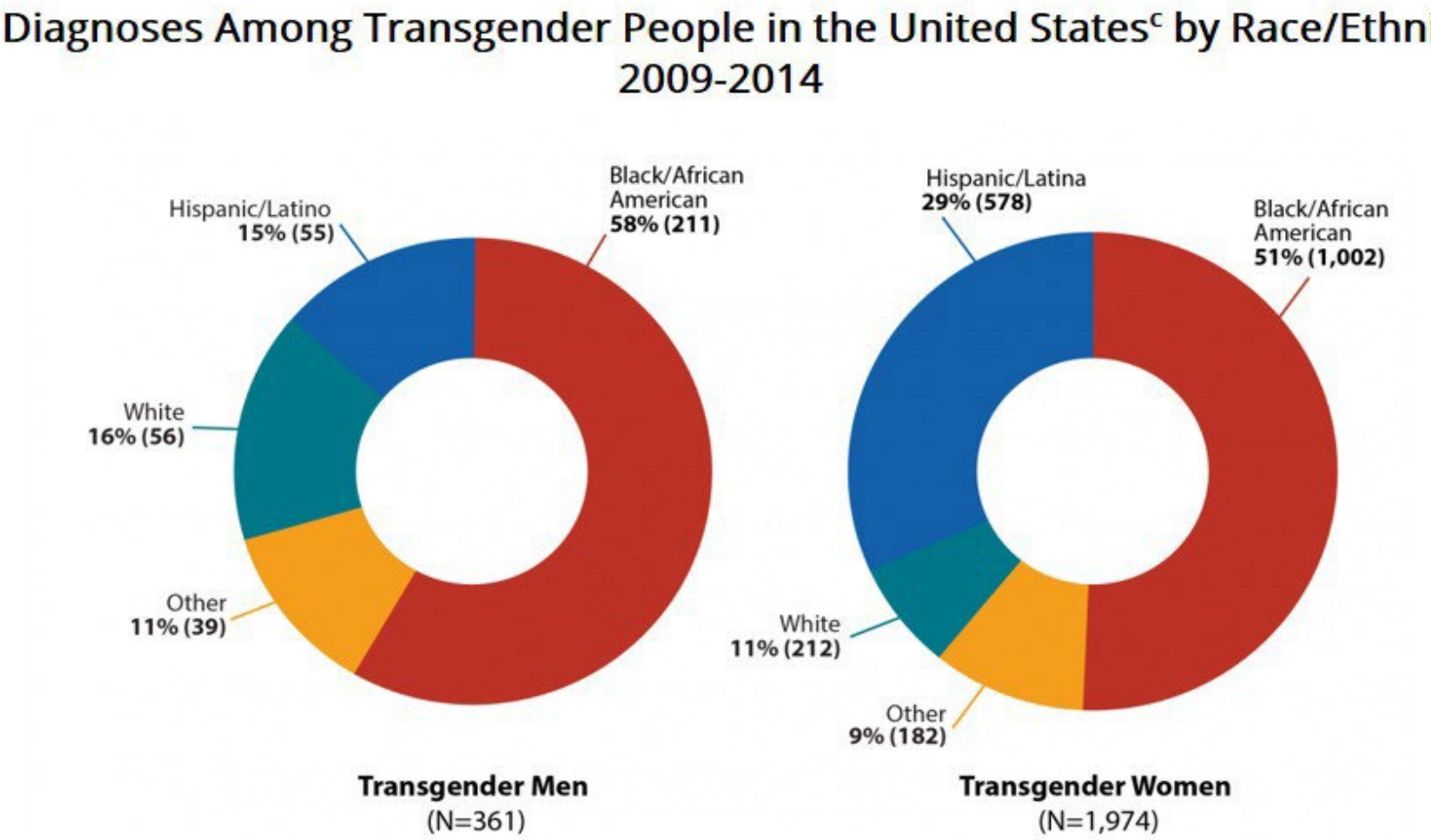
[1]World Health Organization, 2020; [2] Van Gerwen, et al. *Transgender Health*, 2020

HIV Among Transgender People in the U.S.

- From 2009 to 2014, 2,351 transgender people received an HIV diagnosis in the U.S.
  - 84% (1,974) were transgender women
  - 15% (361) were transgender men
  - Less than 1% (16) had another gender identity
  - Around half of transgender people (43% transgender women and 54% of transgender men) who received an HIV diagnosis lived in the South.

AIDS Behav 2017;21(9):2774-2783

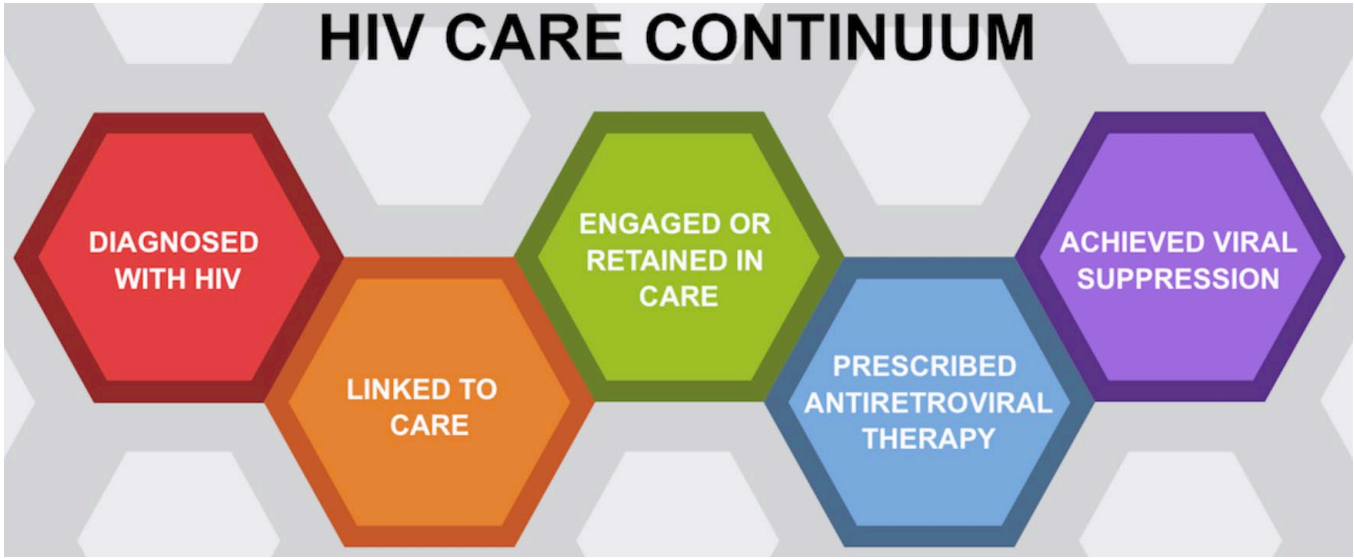
People of Color are Disproportionately Affected



HIV Treatment Outcomes

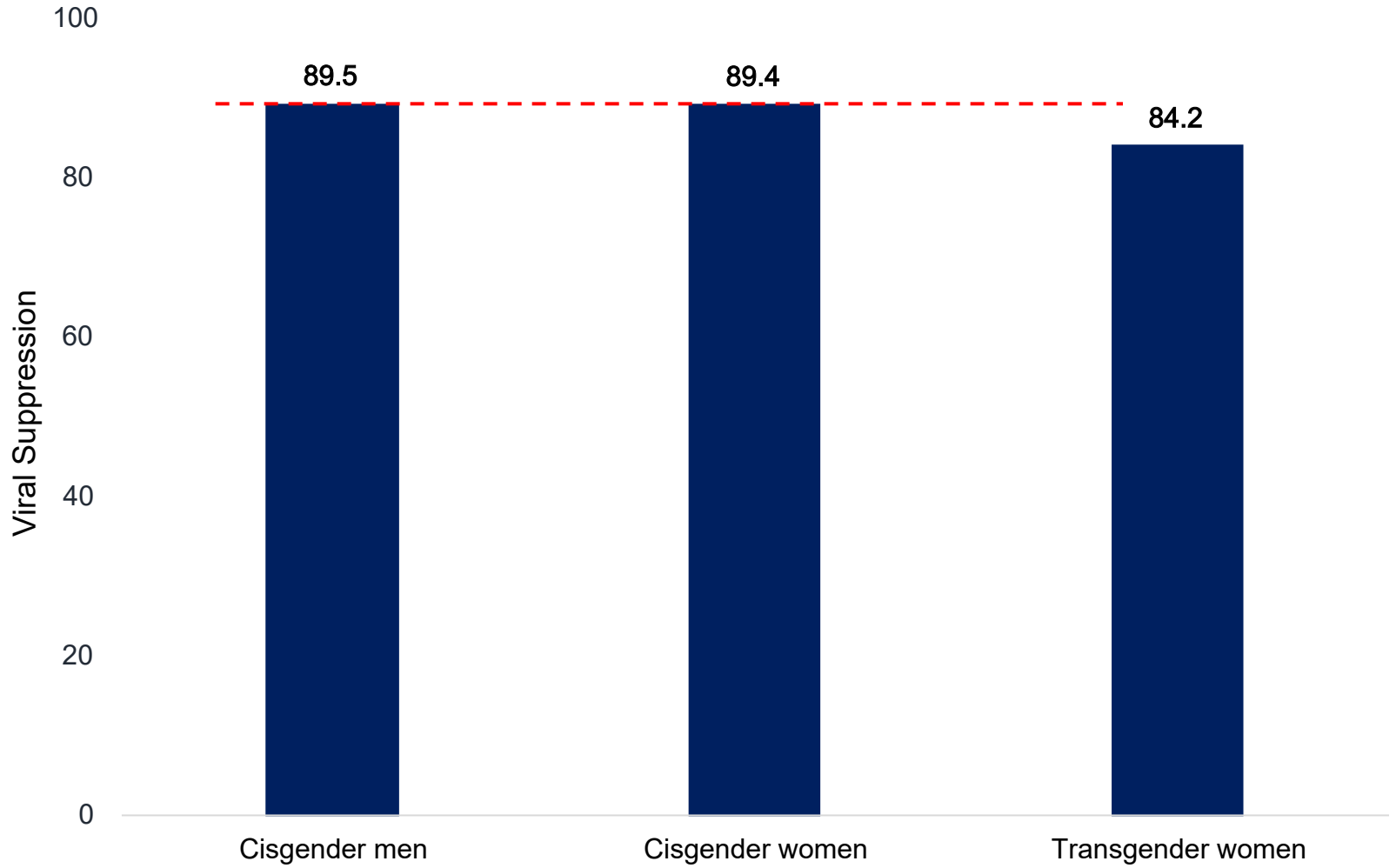
Studies show transgender women living with HIV have less access to HIV care across the care cascade, including:

- Lower retention in care
- Lower ART use
- Lower ART adherence
- Lower rates of viral suppression



Baguso et al., 2016; Dowshen et al., 2016; Melendez et al., 2006; Mizuno et al., 2015; Mugavero et al., 2013;Sevelius et al., 2010, 2014; Weiwel et al., 2014; Yehia et al., 2013

Viral Suppression among Adults and Adolescents Served by the Ryan White HIV/AIDS Program, 2020

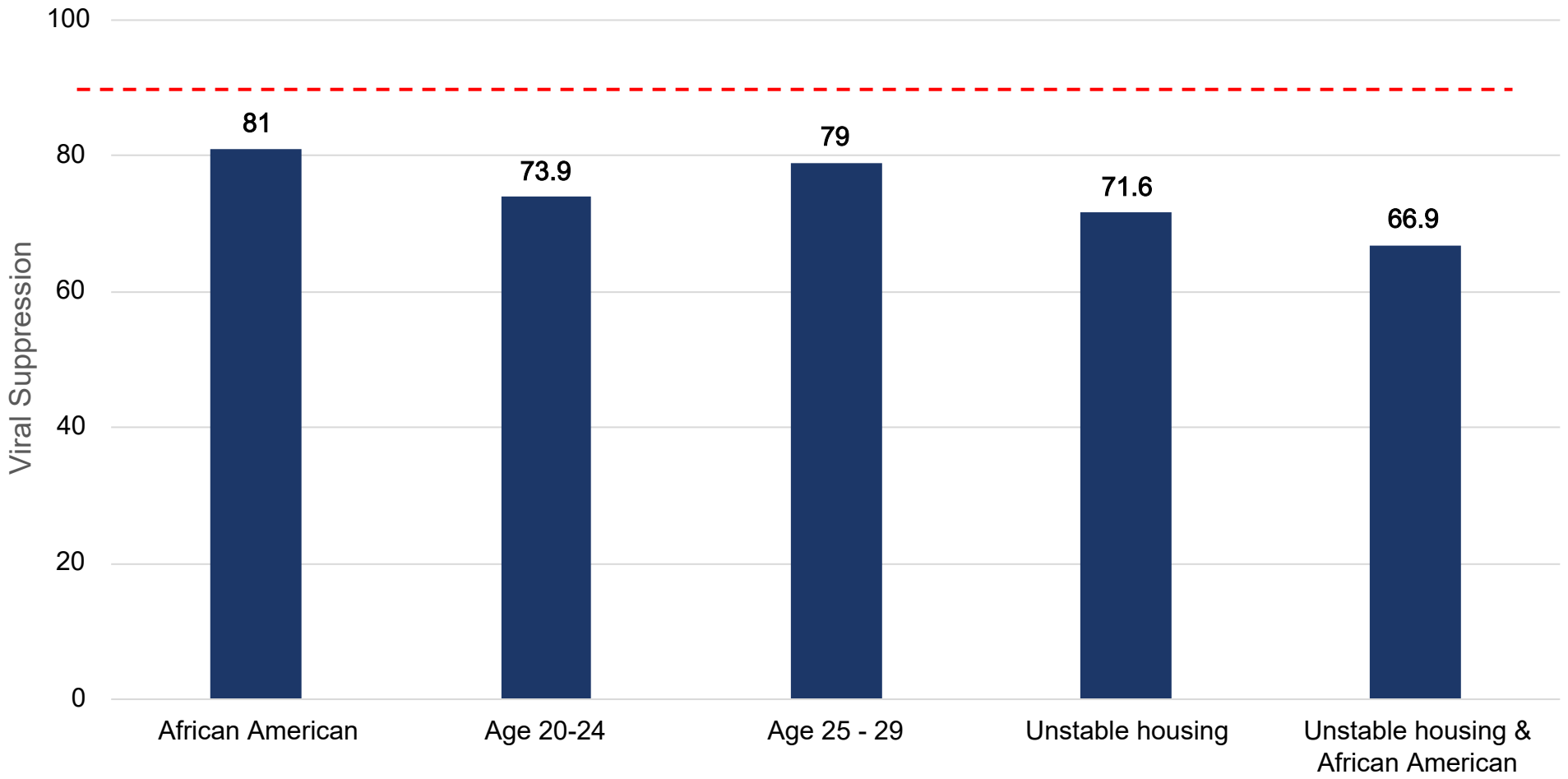


RWHAP
N= 561,416
89.5%

Includes data for adults and adolescents aged 13 and over
Viral suppression: ≥1 OAHS visit during the calendar year and ≥1 viral load reported, with the last viral load result <200 copies/mL.

Ryan White HIV/AIDS Program, 2020

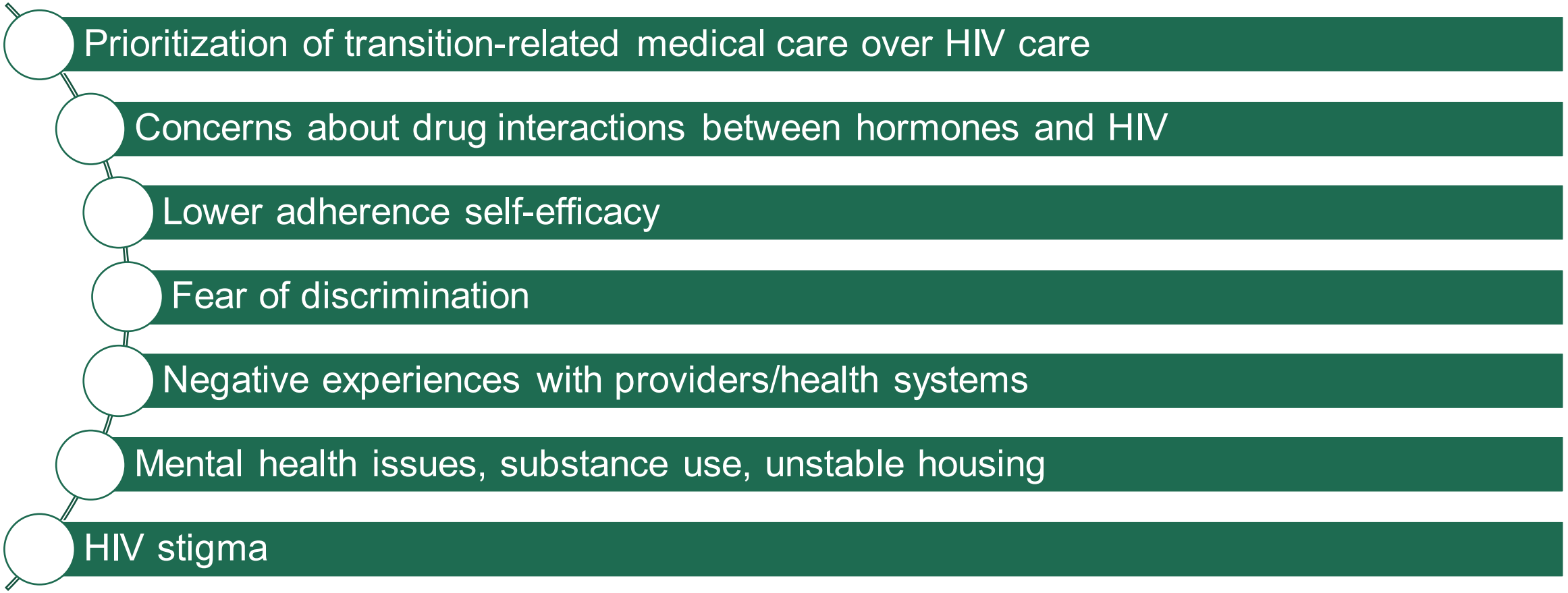
Viral Suppression among Transgender Adults and Adolescents Served by the Ryan White HIV/AIDS Program, 2020



Includes data for all transgender people aged 13 and over.
Viral suppression: ≥1 OAHS visit during the calendar year and ≥1 viral load reported, with the last viral load result <200 copies/mL.

Ryan White HIV/AIDS Program, 2020

Factors Associated with Viral Suppression



Sevelius J, et al. J Assoc Nurses AIDS Care. 2010. 21(3): 256–264; Sevelius J, et al. AIDS Care. 2014 August. 26(8): 976–982; Chung, et al. 2016. Transgender Law Center; Reback CJ 2019; Reback CJ 2018

2022 DHHS Guidelines

Transgender People with HIV

Panel's Recommendations Regarding Transgender People with HIV

Panel's Recommendations
• Antiretroviral therapy (ART) is recommended for all transgender people with HIV to improve their health and to reduce the risk of HIV transmission to sexual partners **(AI).** • HIV care services should be provided within a gender-affirmative care model to reduce potential barriers to ART adherence and to maximize the likelihood of achieving sustained viral suppression **(AII).** • Prior to ART initiation, a pregnancy test should be performed for transgender individuals of childbearing potential **(AIII).** • Some antiretroviral drugs may have pharmacokinetic interactions with gender-affirming hormone therapy. Clinical effects and hormone levels should be routinely monitored with appropriate titrations of estradiol, testosterone, or androgen blockers, as needed **(AIII).** • Gender-affirming hormone therapies are associated with hyperlipidemia, elevated cardiovascular risk, and osteopenia; therefore, clinicians should choose an ART regimen that will not increase the risk of these adverse effects **(AIII).**

Rating of Recommendations: *A = Strong; B = Moderate; C = Weak*

Rating of Evidence: *I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

Drug-Drug Interactions (GAHT and ART)

- ART with least potential to impact gender affirming hormone therapy (GAHT)
  - **All NRTIs**
  - **Unboosted INSTIs**
  - **NNRTIs: RPV, DOR**
- ART that may increase GAHT
  - EVG/c, PI/r & PI/c increase testosterone, finasteride and dutasteride levels
- ART that may decrease GAHT
  - PI/r decreases estradiol
  - EFV, ETR, NVP decrease estradiol, testosterone, finasteride
- ART with unclear effect on GAHT
  - EVG/c and PI/c on estradiol

Monitor dose of GAHT based on desired clinical effects, adverse effects and hormone concentrations.

Table 17, DHHS ART Guidelines 2022

Medical Comorbidities: Weight Gain

- HIV: ART meds (eg, **INSTI, TAF**)
- GAHT
  - Can cause weight redistribution and changes in muscle mass
  - Although muscle mass reduction can occur with feminizing HT, **estrogens known to cause weight gain**
  - Increased body mass typically results from testosterone therapy, but weight gain can vary
- Life stressors

Considerations:

- **ART**: Switching ART is **not recommended** by current guidelines, could consider switch to NNRTI-based regimen
- **GAHT**: Reduce estrogen dose, if patient amenable
- **Lifestyle**: Diet and exercise
- **Other**: If diabetic or prediabetic, consider GLP-1 agonist

Bansi-Matharu. Lancet HIV 2021. 8:e711. transcare.ucsf.edu/guidelines; transcare.ucsf.edu/patients/information-testosterone-hormone-therapy; Block. Am J Epidemiol. 2009;15:181; DHHS Adult and Adolescent ART Guidelines. Sept 2022; Kumar. AIDS 2020. Abstr OAB0605; Monroe. Clin Infect Dis. 2015. 60:453.

Medical Comorbidities: Cardiovascular Risk

- HIV
  - Impact of viremia/inflammation
  - ART meds (protease inhibitors, abacavir)
- GAC
  - Increased venous thromboembolic risk with transgender individuals taking estrogens
  - Possible increased risk for HTN, dyslipidemias, and stroke
- CV risk factors and life stressors

Considerations:

- **ART**: Consider avoiding PIs (except ATV) and ABC; TAF in patients with hyperlipidemia
- **GAC**: Use estrogen injectables or patches instead of pills for patients ≥ 45 years old
- **Lifestyle**: Smoking cessation

Hsue. J Infect Dis. 2012;205:S375. Lundgren. Curr Opin Infect Dis. 2018;31:8; DAD. Lancet. 2008;371:1417; Vehkavaara. Thrombo Haemost. 2001;85:619; Canonico. Circulation. 2007;115:840; cdc.gov/heartdisease/risk_factors.htm; Block. Am J Epidemiol. 2009;15:181; DHHS Adult and Adolescent ART Guidelines. Sept 2022; Patel. IDWeek 2021. Abstr 822.

Medical Comorbidities: Bone Health and Renal Impairment

- Bone health
  - TGW at increased risk for osteoporosis
    - Risk factors: underutilization of hormones after gonadectomy or use of androgen blockers with insufficient estrogen
- Renal impairment
  - Changes of body composition and lean body mass may impact creatinine levels

Considerations:

For bone health

- **ART**: Consider switch TDF to TAF
- **Lifestyle**: light weights and exercise

For renal impairment

- **ART**: Consider switch TDF to TAF
- **Dosing Considerations:** CrCl and IBW calculations should be based on gender identity after patient has been on hormone therapy for >6 months

transcare.ucsf.edu/guidelines/bone-health-and-osteoporosis; Collister. Can J Kidney Health Dis. 2021;8; Tao. Int J Infect Dis. 2020;93:108; Stevenson. Endocrinol Metab Clin North Am. 2019;48:421; Webb. Am J Health Syst Pharm. 2020;77:427.

Facilitating HIV Care Engagement

Gender Affirmation

- Having HIV care providers that affirm their gender (e.g., use chosen name and pronouns) were **more likely** to be virally suppressed.
    - Making access to GAHT contingent upon ART adherence associated with **lower likelihood** of viral suppression.

Integration of HIV Care with Gender Care

- Associated with higher rates of viral suppression
- Decreases the number of provider visits
- Makes it easier to discuss important concerns about HIV and gender health care

Peer Navigation

- Having visible transgender staff in the clinic facilitates engagement in care.

Trauma-Informed

- Recognizing and interacting with TPLW as women
- Accounting for various forms of violence, stigma and discrimination affecting TPLW

Chung C, Transgender Law Center, 2016; Dowshen N, Trans Health, 2017; Lacombe-Duncan, Health and Social Care, 2020.

HIV Prevention in Gender Diverse Patients

- Daily oral FTC/TDF
  - All genders
- Daily oral FTC/TAF
  - One for use in people assigned male at birth
  - Limited data on people having receptive neovaginal sex
- Long-acting injectable CAB (every 1-2 months)
  - All genders
  - Avoid in patients with buttock silicone injections or fillers

*****Data suggest little to no concern for drug-drug interactions between PrEP and GAHT*****

Top Antivir Med 2023 Mar 31;31(1):3-13

Best Practices in Meeting (ALL) Patients and Collecting Gender Health Data

- Start by introducing yourself, consider using your pronouns, then asking:
  - “What is your name/how would you like to be addressed here?”
  - ”What pronouns do you use?”

- Use the two-step method
  - Ask about current gender identity
  - Ask about sex assigned at birth

- Use less gendered language
  - Try to use neutral and inclusive terminology to avoid patient discomfort

- Maintain an up-to-date organ inventory

Deutsch et al. 2013

Create a Welcoming and Affirming Environment

Assess and change current clinical environment

- Intake forms and EMRs inclusive of multiple gender identities and sexualities
- Use patient chosen names and pronouns
- Knowledgeable providers
- Wrap around services
- Include transgender images on education materials, brochures, website
  - Hire trans-identified staff
  - Gender neutral/inclusive bathrooms

Cahill S, *PLoS ONE*. 2014

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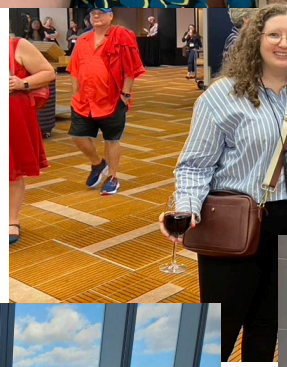
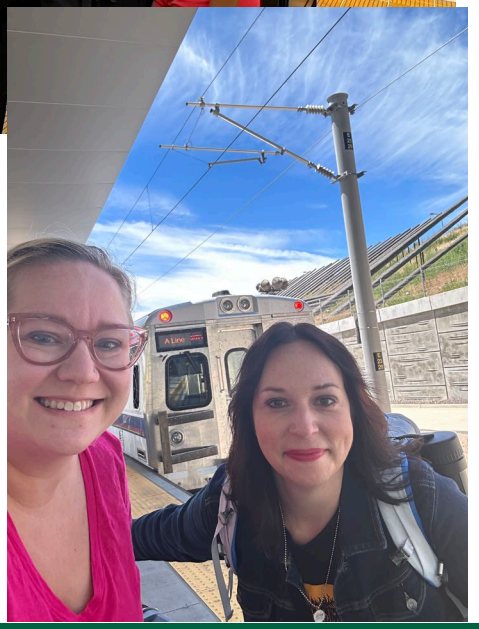
- Brianna Patterson, MPH
- Emma Kay, MSW, PhD
- Mahogany Toney
- Saralyn Richter
- Angela Pontius
- Alex Sherman
- Aiesha Gentry
- Katie White
- Peggy Olney

Countless other family, friends, colleagues, patients, and participants





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Invited Review

Providing Gender-Affirming Care to Transgender and Gender-Diverse Individuals With and at Risk for HIV

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