

US Guideline Criteria for Human Immunodeficiency Virus Preexposure Prophylaxis: Clinical Considerations and Caveats

Sarah K. Calabrese,¹ Douglas S. Krakower,^{2,3,4} Tiara C. Willie,^{5,6} Trace S. Kershaw,⁷ and Kenneth H. Mayer^{2,3,8}

¹Department of Psychology, George Washington University, Washington, DC; ²Division of Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Harvard University, Boston, Massachusetts; ³The Fenway Institute, Fenway Health, and ⁴Department of Population Medicine, Harvard Medical School, Harvard University, Boston, Massachusetts; ⁵Miriam Hospital and ⁶Warren Alpert Medical School, Brown University, Providence, Rhode Island; ⁷Social and Behavioral Sciences Department, Yale School of Public Health, Yale University, New Haven, Connecticut; and ⁸Department of Global Health and Population, Harvard TH Chan School of Public Health, Harvard University, Boston, Massachusetts

Clinical guidelines for human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) developed by the US Centers for Disease Control and Prevention have been instrumental in the implementation of PrEP in medical practices throughout the country. However, the eligibility criteria contained within may inadvertently limit PrEP access for some patients. We describe the following key considerations and caveats related to these criteria: promotion of a selective vs universal approach to sexual health education involving PrEP; misalignment between criteria stated in the table and text boxes; problematic categorization and confounding of sexual orientation, gender identity, and risk behavior; underemphasis of network/community-level drivers of HIV transmission; oversimplification of serodiscordant risk; and lack of clarity surrounding the relevance of condoms to PrEP eligibility. We offer concrete recommendations to address the identified issues and strengthen future iterations of the guidelines, applying these recommendations in an alternative table of “criteria.”

Keywords. HIV; preexposure prophylaxis; clinical decision-making; patient care.

The US Centers for Disease Control and Prevention (CDC) and the US Public Health Service have pioneered the development of clinical guidelines to support the implementation of human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP). Between 2011 and 2013, in the wake of clinical trials that first demonstrated the efficacy of daily oral tenofovir disoproxil fumarate as PrEP [1–4], these organizations published interim guidance for providing PrEP to men who have sex with men (MSM), heterosexually active adults, and people who inject drugs (PWID) [5–7]. In 2014, they synthesized and expanded the early interim guidance to create a single comprehensive resource [8], recently updated to Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline [9]. This evidence-informed implementation guidance, directed toward clinicians and policymakers, is commonly referred to as the “CDC guidelines” for PrEP. The guidelines summarize evidence of PrEP’s safety and efficacy, provide PrEP eligibility criteria for select populations,

supply recommendations for the provision and discontinuation of PrEP, and offer suggestions for supporting patients’ medication adherence and risk reduction. Publication of the preliminary and present CDC guidelines has coincided with rising rates of PrEP prescription nationally [10]. Both primary and HIV care providers have reported CDC guidelines to be a top resource guiding PrEP service delivery [11, 12]. Additionally, the official state health department websites of 42 of 50 states and Washington, DC, appear to have duplicated, adapted, or linked to CDC guideline criteria [13], further underscoring the potential reach of the guidelines.

Despite the positive and critical role that the CDC guidelines have played in supporting PrEP uptake in the United States, the PrEP eligibility criteria presented within, reproduced in [Table 1](#), and accompanying information surrounding their application require reconsideration if the goal is for *all* people at risk for HIV acquisition to have access to this prevention resource. Here, we describe several clinical considerations and caveats related to the application and contents of the eligibility criteria contained within the current CDC guidelines. We also offer recommendations to address these issues and strengthen future iterations of the guidelines, several of which may be pertinent to PrEP guidelines established by other health authorities as well, such as the World Health Organization [14, 15]. We implement our recommendations in an alternative set of PrEP “criteria,” presented in [Table 2](#).

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Correspondence: S. K. Calabrese, Department of Psychology, George Washington University, 2125 G Street NW, Washington, DC 20052 (skalabrese@gwu.edu).

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Table 1. Overview of 2 Versions of Criteria Contained Within the US Centers for Disease Control and Prevention Guidelines

Version of Criteria	Population		
	MSM	Heterosexual Women and Men ^a	PWID
Summary of guidance	<ul style="list-style-type: none"> • HIV-positive sexual partner • Recent bacterial STI (gonorrhea, chlamydia, or syphilis) • High number of sex partners • History of inconsistent or no condom use • Commercial sex work 	<ul style="list-style-type: none"> • HIV-positive sexual partner • Recent bacterial STI (gonorrhea or syphilis) • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • In high-prevalence area or network 	<ul style="list-style-type: none"> • HIV-positive injecting partner • Sharing injection equipment • ... • ... • ... • ...
Recommended indications	<p>Adult man Without acute or established HIV infection Any male sex partners in past 6 months (if also has sex with women, see recommended indications for heterosexually active men and women) Not in a monogamous partnership with a recently tested, HIV-negative man AND 1+ of the following:</p> <ul style="list-style-type: none"> • Any anal sex without condoms (receptive or insertive) in past 6 months • A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months 	<p>Adult person Without acute or established HIV infection Any sex with opposite sex partners in past 6 months Not in a monogamous partnership with a recently tested, HIV-negative partner AND 1+ of the following:</p> <ul style="list-style-type: none"> • Is a man who has sex with both women and men (behaviorally bisexual; see also recommended indications for MSM) • Infrequently uses condoms during sex with 1+ partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner) • Is in an ongoing sexual relationship with an HIV-positive partner • A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months 	<p>Adult person Without acute or established HIV infection Any injection of drugs not prescribed by a clinician in past 6 months AND 1+ of the following:</p> <ul style="list-style-type: none"> • Any sharing of injection or drug preparation equipment in past 6 months • Risk of sexual acquisition (see also recommended indications for MSM and heterosexually active men and women) • ... • ... • ...

US Centers for Disease Control and Prevention, US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 update: a clinical practice guideline. Available at: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Accessed 10 October 2018.

Abbreviations: HIV, human immunodeficiency virus; MSM, men who have sex with men; PWID, people who inject drugs; STI, sexually transmitted infection.

^aLabeled instead as “Heterosexually Active Men and Women” for the corresponding recommended indications text box.

Consideration/Caveat 1

The guidelines promote a selective (vs universal) approach to PrEP education and provision, which will limit the access of potential beneficiaries.

Within the guidelines, PrEP provision is presented as discretionary and predicated on provider assessment of patient risk. The guidelines do recommend that sexual history-taking be routinely performed with all patients, warning against a selective (vs universal) approach to sexual history-taking “because new HIV infections and STIs [sexually transmitted infections] are occurring in all adult and adolescent age groups, both sexes, and both married and unmarried persons” [9] (p. 33). However, they do not extend the same logic to sexual health education involving PrEP. Instead, provider-initiated discussion of PrEP is contingent upon patients’ self-disclosure of sensitive information and providers’ judgment of patient risk. This is problematic because patients may not be fully forthcoming about their sexual and injection histories, especially when unaware of the benefits to disclosing stigmatized risk behaviors to their providers. Moreover, providers’ judgment of patient risk is imperfect, even when risk prediction tools or standard criteria are used, and vulnerable to social biases, which inevitably results in missed opportunities and could potentially jeopardize access for racial minorities, MSM, and other key populations in particular [16]. Previous research has suggested that CDC guideline criteria fail to consistently identify individuals at risk for HIV [13, 17, 18]. For example, in a cohort study of 300 young black

MSM, 48% of the 33 who seroconverted did not qualify for PrEP according to criteria derived from CDC guidelines [18]. Although continued evaluation and refinement of criteria may improve their sensitivity and reduce disparities in sensitivity, no criteria will ever capture the full range of patients who could benefit from PrEP.

Recommendation

We recommend that the guidelines promote a universalized approach to sexual health education that consistently includes PrEP and is not predetermined by criteria. Specifically, providers in primary care and other preventive and behavioral health settings should engage all patients in conversations about sexual health, regardless of patients’ sexual orientation, gender identity, or self-disclosed risk behavior, and routinely mention PrEP among the HIV prevention strategies available. Assessment of risk and consideration of PrEP should be a shared endeavor between patient and provider, a standard that aligns with the shared and patient-driven decision-making approaches preferred by many specialists and generalists [19–21]. While we encourage a universalized approach to PrEP education, we recommend that the guidelines continue to include specific criteria related to PrEP prescription because abolishing criteria altogether could inadvertently discourage prescription; providers have previously expressed a preference for specificity in clinical guidance surrounding identification of PrEP candidates [22]. However, the criteria, perhaps more accurately labeled

Table 2. Recommended Alternative to US Centers for Disease Control and Prevention Preexposure Prophylaxis Eligibility Criteria

Indicators of PrEP Candidacy	
Individual level	Recent or anticipated condomless oral, anal, or vaginal sex Recent or anticipated sharing of injection equipment Biomarkers of recent condomless sex (eg, sexually transmitted infection ^a or pregnancy) Reported desire to use PrEP
Partner ^b level	Sexual or injecting partner with unknown HIV status and/or perceived to be at risk for acquiring HIV Sexual partner living with HIV who has a clinically detectable viral load or unknown viral suppression status ^c Injecting partner living with HIV Partner-related barriers to using other forms of protection (eg, intimate partner violence, economic incentive)
Network/Community level	Multiple partners Partner concurrency Partner network known to have high HIV prevalence Neighborhood/community known to have high HIV prevalence

Key Considerations for Applying Indicators

These indicators of PrEP candidacy are intended to guide conversations about PrEP with patients and to support patients in making informed decisions about whether to use PrEP.

- The indicators are *not* intended to be used as screening criteria to determine whether a patient should be educated about or offered PrEP.
- The indicators listed may not identify all individuals at risk for HIV or all HIV risk factors affecting a single individual.
- All patients should be educated about PrEP as part of routine sexual healthcare, irrespective of sexual orientation, gender identity, or self-disclosed risk behaviors.
- The indicators vary in their strength of association with population-level HIV incidence, and the magnitude of risk posed by any single indicator will vary according to individual-level circumstances.
- Patients who express a desire for PrEP but do not report specific HIV risk factors should still be offered PrEP. Patients may choose not to disclose private and potentially stigmatizing sexual behavior or injection practices but wish to mitigate the risk associated with these activities.

PrEP can be used alone or in combination with other methods (eg, condoms) to protect against HIV.

- Patients should be informed that PrEP is highly effective in preventing HIV during sexual acquisition when used as a standalone prevention method and that use in combination with condoms offers added protection against other sexually transmitted infections and pregnancy.
- Further guidance on counseling patients about PrEP and condom use can be found here: <https://www.ncbi.nlm.nih.gov/pubmed/26895239>.

Abbreviations: HIV, human immunodeficiency virus; PrEP, preexposure prophylaxis.

^a“Sexually transmitted infection” is not further specified since all sexually transmitted infections may suggest condomless sex. However, certain sexually transmitted infections are more frequently associated with subsequent HIV infection than others, in part, because of the biological susceptibility that they confer, which may be a point of discussion with patients.

^b“Partner” includes any person whose blood, semen, preseminal fluid, rectal fluids, or vaginal fluids come into direct contact with the patient.

^cPartners whose HIV viral load is durably suppressed will not transmit the virus. However, PrEP may still offer value to HIV-negative patients whose partners are virally suppressed because partner viral suppression status may change, other partners/behaviors may pose a risk, and psychosocial benefits may be gained (eg, reduction in anxiety).

as potential “indicators of PrEP candidacy,” should be accompanied by a clear statement of their purpose and limitations. Specifically, the following should be expressly affirmed: the indicators are intended to guide conversations about PrEP with patients and to support patients in making informed decisions about whether to use PrEP. Furthermore, the indicators may not identify all individuals at risk for HIV or all HIV risk factors affecting a single individual. Patients who do not report specific risk factors but nonetheless report a desire for PrEP may still be at risk for HIV (because they have chosen not to disclose such risk factors or because they have other risk factors) or may otherwise benefit from PrEP.

Consideration/Caveat 2

Within the CDC guidelines, there are inconsistencies between the PrEP eligibility criteria stated in the summary of guidance table [9] (p. 13) and recommended indications text boxes [9] (pp. 36–38), which may foster confusion and lead to discrepant assessments of PrEP candidacy.

For example, as shown in Table 1, women at risk due to heterosexual activity could qualify for PrEP based on their own risk behavior alone according to the summary of guidance criteria,

whereas to qualify for PrEP according to the recommended indications criteria, they would need to know their partner’s HIV risk or recognize a potentially asymptomatic STI [13, 23]. This discrepancy has meaningful implications for assessing PrEP candidacy. In a sample of 679 women recently engaged in care at Planned Parenthood health centers, 82% of the sample qualified for PrEP based on the summary of guidance criteria, whereas less than 2% of the same sample qualified based on the recommended indications criteria [13]. Thus, the 2 sets of criteria presented in the guidelines yield vastly different eligibility estimates and could lead to variable clinical standards and practices enacted by healthcare professionals.

Recommendation

The criteria stated in the summary of guidance table and recommended indications text boxes should be brought into alignment or reduced to a single set of criteria.

Consideration/Caveat 3

The 3 risk categories for which separate criteria have been established, MSM, heterosexual women and men, and PWID, are unnecessary and confound sexual orientation, gender identity, and

risk behavior. These 3 categories likely arose from the protocols and entry criteria established for participant sampling in PrEP clinical trials, which themselves reflect classification paradigms used in other health contexts. These trials yielded different bodies of evidence and led to the staggered release of CDC interim guidance across categories [5–7]. However, these categories do not necessarily represent how at-risk people identify and are not inclusive of people of all sexual orientation and gender identities (all lesbian, gay, bisexual, transgender, questioning, queer + individuals). The criteria related to sexual risk are limited to “men” and “women.” Although PrEP for transgender people is now recommended for consideration in the main text of the guidelines [9], transgender people and people who otherwise identify their gender as something besides “man” or “woman” (eg, nonbinary, genderqueer, 2-spirit) are not clearly represented in the table and text box criteria despite the high HIV prevalence found among transgender women [24] and their active participation alongside MSM in foundational PrEP research [1]. Exclusion also occurs based on sexual orientation. For example, women who sexually identify as something other than “heterosexual” (eg, bisexual, queer, pansexual) are implicitly excluded from the 2 sexual risk categories, MSM and heterosexual (also referred to as “heterosexually active”) women and men, despite potentially engaging in behavior that confers HIV risk. Division by gender identity and sexual orientation is unnecessary when people of all genders and sexual orientations are at risk for HIV if they engage in behaviors known to transmit infection.

Recommendation

A simpler and more inclusive approach to organizing PrEP eligibility criteria would facilitate more equitable access to PrEP. We recommend a single set of criteria that pertain to all populations, relabeled as indicators of PrEP candidacy. These indicators would incorporate both sex- and injection-related risk factors.

Consideration/Caveat 4

The guidelines’ criteria underemphasize network- and community-level factors that drive HIV transmission.

The criteria are particularly insensitive to risk factors outside of individual-level behavior and partner characteristics. There is preliminary evidence to suggest that black MSM are less likely than white MSM to meet CDC-based criteria [17, 25], which may be because network and neighborhood dynamics, including assortative mixing (eg, same-race partnering among black MSM), are not captured by the guideline criteria despite being primary drivers of HIV transmission among black MSM in some communities [17]. Epidemiological context is an acknowledged consideration in the main text of the CDC guidelines and in the summary of guidance criteria specified for heterosexual men and women. However, epidemiological

context is absent in the summary of guidance criteria for MSM and PWID and in the recommended indications criteria for all 3 populations.

Recommendation

Epidemiological context (eg, network and community HIV prevalence) should be incorporated as a relevant indicator of PrEP candidacy for all individuals. Additionally, indicators should be presented in a way that gives comparable emphasis to indicators at the network/community level vs indicators at the individual and partner levels.

Consideration/Caveat 5

Presenting “HIV-positive partner” as a sexual risk criterion without further qualification by viral suppression status is misleading and perpetuates social misunderstanding.

Currently, HIV-positive sexual partners are listed among the summary of guidance criteria for MSM and heterosexuals and among the recommended indications criteria for the latter. However, we are now in an era where sufficient evidence has accumulated to assert more definitively that people with sustained HIV suppression cannot sexually transmit the virus [26–29], an assertion that the CDC itself has endorsed [30], and this ought to be clearly communicated within the criteria. Although the guidelines do summarize several clinical trials that demonstrate no sexual transmission of HIV between male–female and male–male serodiscordant couples when the HIV-positive partner was virally suppressed, this information is presented in the main text rather than in the summary of guidance table or recommended indications text boxes. Therefore, the information could be easily overlooked by busy clinicians. Additionally, while the information in the main text is accompanied by a statement that a partner with HIV may not be virally suppressed (due to lack of treatment, type of treatment, inadequate adherence, or other reasons) and that partner viral suppression status may not be verifiable absent medical record access, direct acknowledgment that an HIV-negative individual whose partner is virally suppressed may also benefit from taking PrEP is warranted. Individuals with virally suppressed partners may benefit because their other behaviors pose a risk (eg, sex with outside partners, unsafe injection practices) or because the added layer of protection and its user-controlled nature alleviate anxiety about HIV acquisition.

Recommendation

Conveying the nuance that surrounds serodiscordant transmission risk in the phrasing of the criterion would help patients and providers to more accurately assess a patient’s likelihood of benefiting from PrEP. We recommend modifying the sexual risk criterion “HIV-positive partner” to “sexual partner living with HIV who has a clinically detectable viral load or unknown viral suppression status.” A footnote could explain reasons why

PrEP may still offer added value despite partner viral suppression (eg, partner viral suppression status may change, other partners/behaviors may pose a risk, and psychosocial benefits may be gained).

Consideration/Caveat 6

The relevance of condoms to PrEP eligibility is unclear.

The guidelines convey mixed messages about how patients' condom practices influence their initial and ongoing eligibility for PrEP. For example, the guidelines include condomless sex among the PrEP eligibility criteria for MSM and heterosexuals and suggest that PrEP use is unwarranted if consistent and correct condom use can be achieved. At the same time, the guidelines report that PrEP was approved for use "in combination with safer sex practices" and that PrEP patients should be counseled to use condoms.

Recommendation

It is important to clarify PrEP's value as a standalone form of HIV prevention and to communicate acceptance of patients' decision to forgo and/or inability to use condoms while taking PrEP. Providers should be encouraged to educate patients about the added protection that concurrent condom use offers with respect to preventing pregnancy and STIs but to also acknowledge that, when taken as prescribed, PrEP alone is highly effective in preventing HIV. Linkage to resources specifically designed for counseling patients about condom decision-making in the context of PrEP [31] could help providers to navigate these conversations.

CONCLUSIONS

The CDC guidelines have been instrumental in promoting PrEP access, offering a rich resource to guide policy and practice around PrEP service delivery. Additionally, they have positioned PrEP as a gateway to other forms of preventive healthcare by promoting vaccination, STI testing, risk reduction counseling, and behavioral health screening (eg, for alcohol abuse) as part of the PrEP care package [32]. Creating a resource that is both comprehensive and digestible is no easy task, and reducing the complexity of PrEP candidacy to a limited set of bullet points inevitably requires compromise. Nonetheless, concrete changes to the eligibility criteria and accompanying text could help to ensure that the overarching objective of the guidelines, that is, to support PrEP use for the prevention of HIV, is not thwarted by the recommendations contained within.

Notes

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References

1. Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* **2010**; *363*:2587–99.
2. Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* **2012**; *367*:399–410.
3. Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* **2013**; *381*:2083–90.
4. Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* **2012**; *367*:423–34.
5. US Centers for Disease Control and Prevention. Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men. *MMWR* **2011**; *60*:65–8.
6. US Centers for Disease Control and Prevention. Interim guidance for clinicians considering the use of preexposure prophylaxis for the prevention of HIV infection in heterosexually active adults. *MMWR* **2012**; *61*:586–9.
7. US Centers for Disease Control and Prevention. Update to interim guidance for preexposure prophylaxis (PrEP) for the prevention of HIV infection: PrEP for injecting drug users. *MMWR* **2013**; *62*:463–5.
8. US Centers for Disease Control and Prevention, US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. Available at: <https://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>. Accessed 10 October 2018.
9. US Centers for Disease Control and Prevention, US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 update: a clinical practice guideline. Available at: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Accessed 10 October 2018.
10. Sullivan PS, Giler RM, Mouhanna F, et al. Trends in the use of oral emtricitabine/tenofovir disoproxil fumarate for pre-exposure prophylaxis against HIV infection, United States, 2012–2017. *Ann Epidemiol* **2018**; *28*:833–840.
11. Smith DK, Mendoza MC, Stryker JE, Rose CE. PrEP awareness and attitudes in a national survey of primary care clinicians in the United States, 2009–2015. *PLoS One* **2016**; *11*:e0156592.
12. Krakower D, Ware N, Mitty JA, Maloney K, Mayer KH. HIV providers' perceived barriers and facilitators to implementing pre-exposure prophylaxis in care settings: a qualitative study. *AIDS Behav* **2014**; *18*:1712–21.
13. Calabrese SK, Willie TC, Galvao RW, et al. Current US guidelines for prescribing HIV pre-exposure prophylaxis (PrEP) disqualify many women who are at risk and motivated to use PrEP. Under review.
14. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, 2nd ed. Available at: <http://www.who.int/hiv/pub/arv/arv-2016/en/>. Accessed 10 October 2018.
15. World Health Organization. WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: module 1 (clinical). Available at: <http://apps.who.int/iris/bitstream/handle/10665/255889/WHO-HIV-2017.17-eng.pdf>. Accessed 10 October 2018.
16. Calabrese SK, Krakower DS, Mayer KH. Integrating HIV preexposure prophylaxis (PrEP) into routine preventive health care to avoid exacerbating disparities. *Am J Public Health* **2017**; *107*:1883–9.

17. Sullivan PS, Rosenberg ES, Sanchez TH, et al. Explaining racial disparities in HIV incidence in black and white men who have sex with men in Atlanta, GA: a prospective observational cohort study. *Ann Epidemiol* **2015**; 25:445–54.
18. Lancki N, Almirol E, Alon L, McNulty M, Schneider JA. Preexposure prophylaxis guidelines have low sensitivity for identifying seroconverters in a sample of young black MSM in Chicago. *AIDS* **2018**; 32:383–92.
19. Krakower DS, Ware NC, Maloney KM, Wilson IB, Wong JB, Mayer KH. Differing experiences with pre-exposure prophylaxis in Boston among lesbian, gay, bisexual, and transgender specialists and generalists in primary care: implications for scale-up. *AIDS Patient Care STDS* **2017**; 31:297–304.
20. Krakower DS, Beekmann SE, Polgreen PM, Mayer KH. Diffusion of newer HIV prevention innovations: variable practices of frontline infectious diseases physicians. *Clin Infect Dis* **2016**; 62:99–105.
21. Calabrese SK, Magnus M, Mayer KH, et al. Putting PrEP into practice: lessons learned from early-adopting U.S. providers' firsthand experiences providing HIV pre-exposure prophylaxis and associated care. *PLoS One* **2016**; 11:e0157324.
22. Mullins TL, Lally M, Zimet G, Kahn JA; Adolescent Medicine Trials Network for HIV/AIDS Interventions. Clinician attitudes toward CDC interim pre-exposure prophylaxis (PrEP) guidance and operationalizing PrEP for adolescents. *AIDS Patient Care STDS* **2015**; 29:193–203.
23. Raifman J, Sherman SG. US guidelines that empower women to prevent HIV with preexposure prophylaxis. *Sex Transm Dis* **2018**; 45:e38–9.
24. Baral SD, Potat T, Strömdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. *Lancet Infect Dis* **2013**; 13:214–22.
25. Hoots BE, Finlayson T, Nerlander L, Paz-Bailey G; National HIV Behavioral Surveillance Study Group. Willingness to take, use of, and indications for pre-exposure prophylaxis among men who have sex with men—20 US Cities, 2014. *Clin Infect Dis* **2016**; 63:672–7.
26. Bavinton BR, Pinto AN, Phanuphak N, et al; Opposites Attract Study Group. Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study. *Lancet HIV* **2018**; 5:e438–47.
27. Cohen MS, Chen YQ, McCauley M, et al; HPTN 052 Study Team. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* **2016**; 375:830–9.
28. Rodger A, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: the PARTNER2 Study extended results in gay men [Abstract WEAX0104LB]. In: 22nd International AIDS Conference. Amsterdam, **2018**.
29. Rodger AJ, Cambiano V, Bruun T, et al; PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA* **2016**; 316:171–81.
30. McCray E, Mermin J; US Centers for Disease Control and Prevention. Dear colleague: information from CDC's division of HIV/AIDS prevention. Available at: <https://www.cdc.gov/hiv/library/dcl/dcl/092717.html>. Accessed 10 October 2018.
31. Corneli A, Yacobson I, Agot K, Ahmed K. Guidance for providing informed-choice counseling on sexual health for women interested in pre-exposure prophylaxis in Kenya and South Africa. *AIDS Patient Care STDS* **2016**; 30:106–9.
32. Marcus JL, Levine K, Grasso C, et al. HIV preexposure prophylaxis as a gateway to primary care. *Am J Public Health* **2018**; 108:1418–20.