Public Comments (Summarized by Topic) and CDC Responses to Public Comments
for the Draft 2021 Update HIV Preexposure Prophylaxis (PrEP) Clinical Practice Guideline and Providers' Supplement

Introduction: CDC is in the process of updating the 2021 draft of the HIV Preexposure Prophylaxis (PrEP) Clinical Practice Guideline and Providers Supplement. As part of this process, CDC conducted public webinars to get feedback from the public on proposed changes to the guideline. CDC conducted a thorough review of the comments received during these public webinars. CDC consolidated and classified the comments by topic and responded to each topic accordingly.[1] These consolidated comments and CDC's response to them are summarized below.

Topic #	Topic (# comments)	Comment	Response
1a.	2-1-1 REGIMEN (n=8)	CDC should adopt the WHO recommendation for use of 2-1-1 -PrEP.	WHO guidelines are developed for low/middle income country settings and do not always align directly with US guidelines/policy. CDC includes guidance for prescribing the 2-1-1 regimen and informs clinicians that 2-1-1 is not an FDA-approved regimen but can be prescribed "off-label".
1b.		Some webinar participants raised objections to guideline statements that "off-label" use may not be covered by some insurers or that its use may inadvertently serve to disclose same-sex behavior to others because it is only recommended for MSM.	CDC did not remove this language, because presenting patients and clinicians with issues that have been raised as concerns for the 2-1-1 regimen is an obligation and necessary for fully informed shared decision making.
1c.		Checklists and other parts of the guideline present daily oral PrEP and 2-1-1 separately but patients may wish to go back and forth between the two regimens.	CDC notes that switching back and forth between regimens without regular HIV testing is not recommended. So, CDC will continue to present the two regimens separately to reinforce the need to confirm HIV-negative status when switching.

[1] For a record of individual comments, see the webinar transcripts at https://www.fcdc.gov/hiv/pdf/programresources/cdc-hiv-PrEPGuideline-Transcript-Webinar-Comments-Chat-24May2021.pdf and https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-PrEPGuideline-Transcript-Webinar-Comments-Chat-25May2021.pdf.

1d.		Clarification is needed about how to define and handle missed doses.	No procedure for handling missed doses is described in reports from the IPERGAY study or observational 2-1-1 studies. So, at this time, CDC is not able to provide additional guidance on defining and handling missed doses in this regimen.
2a.	ADOLESCENT MINORS (n=8)	Adolescents may be covered under their parent's health insurance and be reluctant to discuss PrEP because their parents may become aware through receiving insurance statements. They may also be uninsured and not willing to seek PrEP because of costs of associated clinical care.	CDC understands these concerns. The guidelines encourage clinicians to discuss these issues and potential resources with adolescent minors and their parent/guardians when possible.
2b.		Additional clarifying statements were offered for inclusion in the guideline. Sentence one, "clinicians to explicitly provide assurance of confidentiality and establish limits of confidentiality based on these local laws, regulations and policies." and sentence two: "young people are more likely to disclose sensitive information if consent and confidentiality are clearly explained, which are suggested by the PrEP education for youth serving primary care providers toolkit that was developed in partnership with SIECUS"	CDC will consider inclusion of additional statements designed to improve guideline clarity.
2c.		Some webinar participants objected to the statement that adolescents may have trouble with adherence to daily oral or intermittent (2-1-1) PrEP and wanted it removed.	CDC notes that the data for daily oral PrEP show low adherence rates in adolescents and young adults, particularly over time. There are no data on adherence to the 2-1-1 regimen by adolescents. CDC will retain the statement, because clinicians need to be aware of

			adherence concerns, so they can provide any indicated support.
3a.	ACUTE HIV INFECTION (n=1)	Some participants suggested that encouraging all PrEP patients to seek early HIV testing if they have symptoms associated with acute HIV infection seems inappropriate, since if they are taking PrEP as prescribed, they are very unlikely to acquire HIV.	CDC notes that for people with low adherence or who stop and restart PrEP between clinician visits, HIV infection does occur and in several published cases was accompanied by these symptoms, leading to need for an interim HIV test. For this reason, CDC will retain this guidance.
4a.	MEDICATION ADHERENCE (n=2)	Participants suggested replacing adherence "monitoring" with "testing."	CDC notes that assessing medication adherence is more commonly done by asking the patient rather than testing for medication levels, so CDC will retain the term monitoring.
4b.		Participants suggested that the guidelines need to emphasize the importance of persistence and adherence for both oral and injection PrEP.	CDC will add this language to the CAB injection section.
4c.		Guideline should recommend assessing interest in discontinuing PrEP at every follow-up visit.	CDC will consider adding guidance asking about desire to stop PrEP every 6 months and every 12 months, at a minimum.
5a.	CONDOMS (n=21)	Participants suggested that condom messaging in the guidelines could undermine the overarching message about PrEP protection. Participants noted that there should be a way to note how condoms provide an extra benefit that doesn't infer that PrEP does not offer the maximum protection if people are not using condoms.	The guidelines currently emphasize the efficacy of PrEP in preventing HIV. CDC will revise the condom discussion sections to clarify the following extra benefits of condoms: protection against bacterial STIs, additional HIV protection if pills are missed (which is more common than we would like), protection against unintended pregnancy when more effective contraceptive methods are not being used.

5b.		The supplement neglects to include people who want PrEP so they can stop using condoms.	CDC notes that patients taking PrEP will make choices about whether or not and when to use condoms. The guideline will continue to recommend condom use, because of the public health benefits they provide, including that they protect against bacterial STIs, provide additional HIV protection if pills are missed, and protect against unintended pregnancy.
6a.	SUPPLEMENT (n=5):	Participants suggested that CDC include a 2-3 page summary on prescribing PrEP in the supplement.	CDC notes that the tables 1a and 1b serve this purpose in the guideline document, and the checklists serve a similar function in the supplement.
6b.		Participants suggested that throughout the patient information sheets change "doctor" or "pharmacist" to "provider".	CDC will change doctor or pharmacist to "health care provider' or "clinician".
6c.		Some participants don't understand the purpose of the checklists and worry it creates a barrier.	CDC notes that the checklists are intended to be guides to a complete PrEP discussion and to ensure that patients have understood what PrEP involves. They are optional documents that only some clinicians will choose to use. There is no signature involved for either patient or clinician, so that the checklist is not perceived as a formal agreement, requiring consent, or formal contract. CDC will retain the checklist as a tool for providers, if they choose to use it.
7a.	COST (n=5)	Several participant comments reflected on the cost of PrEP medication and clinical care.	CDC notes these comments, but CDC will not make changes to the guidelines based on this comment, because the guidelines do not consider costs in the

			recommendation. We do provide information on financial coverage resources in the guideline.
8a.	DIAGNOSIS CODES (n=1)	Participants noted that some listed ICD diagnostic codes are stigmatizing and alienating.	ICD diagnosis codes are established by WHO for worldwide use , so CDC will not be changing the related content in the guideline. CDC notes that ICD diagnostic codes are not intended to be presented to patients. If there is concern about ICD codes reinforcing stigma that patients may experience from healthcare office staff, there are resources to help raise staff awareness about patient-centered communication. For example, best practices for communication strategies and scripts at https://www.cdc.gov/hiv/clinicians/transforming-health/health-care-providers/affirmative-care.html#communicationstrategies.
9a.	EVIDENCE TABLES (n=1)	Participants suggested that data sources were missing from evidence tables.	CDC will add new data recently available from the DISCOVER and HPTN 083/084 studies to the guideline.
9b.		Participants identified an error in lbs vs kg.	CDC will correct the error identified.
10a.	FIGURE 1 (n=2)	Participants identified an error in the figure text.	CDC will correct with “unsuppressed” instead of current “suppressed”.
11a.	FINANCIAL CASE MANAGEMENT (n=8)	Participants expressed concern that the guideline did not discuss coverage of ancillary (non-medication) services like STI and other labs, clinic visit charges, counseling.	CDC will add information about the recent HHS USPSTF Grade A determination and related CMS FAQs, which address coverage of ancillary services for people with insurance coverage.

11b.		Participants requested that financial management information be added to the summary table.	CDC will not make this requested change, as the table would be too complex; clinicians have requested that the summary table be simple and easy to use.
11c.		Participant requested that the guideline reference the Gilead medication assistance program, HHS Ready Set PrEP, and program and state/local PrEP assistance programs.	CDC notes that these programs are already included in the document, including the NASTAD table of state/local programs (which will be updated.)
11d.		Participants requested that CDC remove "when fully implemented" from USPSTF sections, since it is now actively being implemented.	CDC will delete "when fully implemented" per the participants' request.
12a.	ORAL PREP FOLLOW-UP VISITS (n=10)	Participants suggested reducing the frequency of follow-up visits to every 6 months, rather than every 3 months.	CDC notes that quarterly visits are indicated for HIV, before PrEP refill and STI testing. However, CDC will add "virtual, phone, or in-person" to qualify the meaning of "visit".
12b.		Participants suggested that the guidelines allow flexibility with visit frequency for individual patients.	CDC notes that quarterly visits will remain in the guideline as the standard of care. However, CDC will add "virtual, phone, or in-person" to qualify the meaning of "visit". CDC notes that these are guidelines, not regulations or laws, so clinicians have leeway to make flexible decisions when they believe them to be indicated. Increased use of telePrEP, pharmacy PrEP, and same-day PrEP should reduce the burden of quarterly assessments.

13a.	GENERIC MEDS (n=5)	Participants suggested that the guidelines include information about the availability of generic F/TDF and their equivalence to brand name Truvada.	CDC will add text about generic availability. CDC will not list costs, as they are changing rapidly and the list price is not what patients pay.
14a.	GENDER NEUTRAL/SPECIFIC LANGUAGE (n=14)	Participants noted that there are places where the guideline says men and women, where it could say all genders.	CDC will change "men and women" to say either "persons" or "adults and adolescents," when it does not alter the intended meaning or language used in a cited publication.
14b.		Participants suggested that the guideline ask an open-ended question to capture sex partners of all genders, instead of "have you had sex with men, women, or both".	CDC notes that the primary intent of this question is to provide primary care clinicians a non-judgmental way to identify their patients who are MSM, so that PrEP care components that are specific to MSM can be provided (e.g., quarterly STI testing). CDC will not change the question for now but will use the guideline to educate providers by adding a table that provides definitions of the range of genders.
14c.		Participants suggested that CDC consider retitling row in Table 8 that refers to "Women's health".	CDC notes that women's health is a widely understood array of health services, and primary care providers are very familiar with this term. To provide clarity for primary audience for this guideline, CDC will keep this term in table 8 (as well as the term Men's health).
14d.		Participants noted that the guideline currently says that Descovy should only be prescribed for MSM.	CDC will check that section of the guideline and ensure TGW is added to the populations that can be prescribed Descovy.
14e.		Participants suggested that the guideline refer to "cis-MSM" instead of MSM when it excludes transgender men.	CDC notes that to be consistent in the definition, adding cis or cisgender to men in MSM would need to say cis men who have sex with cis men. This is not likely to

			significantly change the current understanding of the term MSM among clinicians, so CDC does not intend to make this change at this time.
14f.		Participants recommended that throughout the guideline, CDC revise outdated and imprecise language around gender identity and sex assigned at birth.	CDC will include a table with sex and gender definitions for provider education. However, CDC will continue to use ‘men" and "women" when indicated for clarity with the non-HIV and non-LGBT provider audience. CDC suggests that the participants see the explanation early in the guideline (page 20). This approach is consistent with other HIV guidelines and with most clinical practice guidelines.
15a.	HARM REDUCTION SERVICES (n=2)	Participants recommended adding harm reduction to list of services to which referral may be indicated.	CDC will add harm reduction to the list of services to which referrals may be indicated.
15b.		Participants recommended that CDC amend language on page 26 that may suggest not prescribing PrEP for persons with substance abuse disorder.	CDC will review language and revise to make the language more clear, and specifically recommend that services should be offered, not that PrEP should be withheld from this population.
16a.	RISK ASSESSMENT (n=29)	Participants noted that leaving arrows with no direction is suboptimal.	CDC will add “discuss PrEP” at the end or currently blank arrows in the Figures 2 and 3 risk assessment flowcharts.
16b.		Participants recommended emphasizing that whether a patient should take PrEP should be a joint decision of the provider and the patient.	CDC notes that PrEP use is always a shared decision. In the flow charts, we use the term “prescribe PrEP,” because provider reluctance is such a common complaint from people seeking PrEP.
16c.		Participants noted that given that exposure to intimate partner violence (IPV) can increase	CDC notes that the guideline recommends IPV screening as part of primary care (Table 8).

		risk for HIV infection, they suggest recommending that clinicians ask questions to determine a patient's exposure to IPV as part of the risk assessment for sexual acquisition.	
16d.		Participants recommended that CDC guidelines encourage education about PrEP prior to sexual debut and offers of PrEP even to people who are not currently sexually active or are currently using condoms all the time.	CDC notes that the first graded recommendation listed is that all sexually active patients be informed about PrEP. CDC notes that the guideline does not recommend PrEP for all sexually active adolescents and adults, because all are not at significant risk for HIV acquisition. CDC is concerned that a broader recommendation would risk credibility of the guideline and reduce health care provider willingness to adopt the current recommendation.
16e.		Participants recommended that the CDC consider changing the language, so that it's not recommending PrEP for all sexually active adolescent and adults, but it informs everyone about PrEP regardless of sexual activity.	CDC notes that the guidelines recommend PrEP for persons with current risk for HIV acquisition and people who request it regardless of risk assessment. The latter guidance should allow prescription to persons who anticipate future need.
16f.		Participants recommended moving language toward sexual health assessment as opposed to risk assessments.	CDC wants to communicate clearly with clinicians that PrEP is about HIV prevention. Among primary care clinicians, sexual health assessment is not commonly understood as synonymous with sexual risk assessment for HIV acquisition. Also, it does not include injection risk assessment. So CDC will continue to use the language most commonly used by primary care clinicians to ensure they understand the guideline.
16g.		Participants requested that CDC add a textbox at the bottom of each the flow chart	CDC will add this guidance to both risk assessment flow charts.

		saying explicitly that PrEP should be provided to patients if they ask for it, even if they don't disclose specific risk.	
16h.		Participants noted that communicating the benefits of PrEP, beyond just HIV risk reduction, is critical for successful PrEP implementation. Participants recommended that the patient-facing FAQ highlight the following benefits: reduced HIV anxiety, increased sexual satisfaction, and increased pleasure and intimacy.	CDC acknowledges that there may be ancillary benefits for some patients, but the most common reason given for discontinuation is a patient perception (often inaccurate) that their risk for HIV has decreased. CDC will not make this change, because the intended use of PrEP is to reduce the risk of HIV acquisition.
16i.		Participants noted that conducting follow-up visits to assess HIV risk behavior and to provide counseling support for risk reduction practices is a very stigmatizing practice that will alienate people from PrEP care and will not improve HIV prevention.	CDC notes that the guideline will continue to recommend risk reduction and adherence support at routine visits. Not all PrEP patients are fully adherent and therefore maximally protected from HIV acquisition when engaging in sexual or injection practices that may result in HIV exposure. These conversations can help clinicians determine prevention needs as patients stop or restart or transition between PrEP modalities. CDC will add a revised risk counseling supplement section to guide clinicians in providing nonjudgmental, minimally intrusive counseling in these areas.
16j.		Participants noted that the guideline should include partner, network, and community-level considerations, not just individual-level behavior.	CDC notes that consideration of community prevalence was removed from this guideline, because it was not understood or used by clinicians.
17a.	PWID RISK ASSESSMENT (n=1)	Participants noted that the injection drug flow chart does not include information on sexual partners.	CDC will add instruction in the guideline to also assess sexual risk in PWID.

18a.	HCV (n=1)	Participants recommended more frequent HCV testing.	The CDC guideline recommends annual HCV screening for MSM/TGW/PWID who use PrEP based on existing data for these populations. No data are yet available to recommend annual or frequent screening for women on PrEP.
19a.	HIV TESTING (n=16)	Participants suggested that the lead sentence on page 31 should be corrected to reflect the minimal occurrence of acquiring HIV after initiating PrEP.	CDC will review and consider revising this sentence.
19b.		Participants suggested that CDC use consistent language about testing throughout.	CDC will review the guideline for consistency.
19c.		Participants suggested that CDC clarify which tests may have an "indeterminate" result.	CDC will consider clarifying which tests may have an "indeterminate" result.
19d.		Participants suggested that Figure 4 include initiation of nPEP for very recent exposure.	CDC notes that the algorithm is intended to document HIV status for PrEP initiation. Adding screening for <72 hours exposure would make the figure too complex. CDC notes that this suggestion is covered in the accompanying text; specifically, the guidelines state that persons within 3 days (72 hours) of most recent exposure should be provided PEP, and then transition to PrEP if HIV status remains negative. For these reasons, Figure 4 will not be changed.
19e.		Participants recommended adding a discussion of the window period and possible	CDC notes that the guideline recommends a testing algorithm to rule in/out acute infection. CDC notes that delaying initiation could result in a recurring period of

		repeat testing one month after initial screening.	possible acute infection based on recent exposure. CDC will remove the "retest in 1 month" option in Figure 4.
19f.		Participants recommended that CDC include a caveat about the frequency of detected K65R mutation.	CDC has not included a discussion of resistance mutations in seroconverters on PrEP, because it does not inform PrEP prescribing practice, which is the focus of the guideline. For this reason, CDC will not add the requested caveat.
19g.		The participant recommended that CDC reconsider the viral load cut-off for considering a "false positive" result. The participant noted that it may be too high.	CDC notes that the DHHS panel is reconsidering the cutoff; CDC will reconsider after hearing the HHS determination.
19h.		Participants recommended that CDC clarify and provide reasoning for the frequency of HIV testing for persons receiving CAB injections, the assay(s) to be used, and in what sequence.	CDC is discussing these topics with FDA, ViiV, APHL, and others. CDC will revise the testing algorithm based on the conclusions of these discussions.
20a.	HPV VACCINE (n=5)	Participants suggested that CDC consider recommending HPV vaccine for persons older than 26 in Table 8.	CDC will consult the 2021 STD guidelines and ACIP recommendation and revise if indicated.
21a.	INTIMATE PARTNER VIOLENCE (n=2)	Participants suggested that CDC consider adding IPV screening for MSM and TG persons.	CDC will add IPV screening to Table 8.
22a.	LIPID TESTING (n=2)	Participants recommended that CDC consider whether lipid testing will be feasible in STD clinics providing PrEP without primary care clinicians on staff.	CDC notes that laboratory tests are listed as indicated for monitoring patient safety, and that the recommendations are not tailored to match common practices at various types of clinics.

22b.		Participants noted that lipid testing every 6 months may be too frequent and that it could be age- or risk-based.	CDC notes that the current recommendation is based on DISCOVER trial data. As more observational data become available, CDC will consider changing the recommendation. In the meantime, CDC agrees that it is likely safe to do a lipid screen every 12 months.
23a.	LANGUAGE AND TERMINOLOGY (n=7)	Participants suggested that CDC consider changing "primary care physicians" to "primary care clinicians" on page 23.	CDC will make the suggested change from "physicians" to "clinicians".
23b.		Participants suggested that CDC consider deleting "who provide care to persons at risk of acquiring" on page 23.	CDC is not making this change, because clinicians providing care to persons at risk for HIV acquisition are those who should be offering PrEP.
23c.		Participants suggested that CDC say "Black persons" rather than "Blacks" on page 22.	CDC will change "Blacks" to "Black persons".
23d.		Participants suggested that CDC replace language in patient info sheet "why take PrEP" language that refers to communities that have more HIV with more sex positive language that focuses on control, intimacy, reduced anxiety, and increased sexual pleasure.	CDC will review the patient-facing language. CDC notes, however, that PrEP is used to lower the risk of acquiring HIV infection, and the guideline must communicate its intended purpose.
23e.		Participants suggested that CDC define PrEP as medication plus the wrap around services.	CDC notes that the PrEP guideline contains all these components and that PrEP specifically refers to the prescribed medication. CDC notes that HIV, STI screening, medical monitoring, and sexual health counseling without medication are not PrEP.

23f.		Participants requested CDC replace “HIV infection” with “HIV status” when discussing HIV testing,	CDC will make this suggested change.
24a.	MEDICATION ADHERENCE MONITORING (n=3)	Participants suggested that CDC mention a specific commercial lab that can quantify PrEP medication in biologic specimens for monitoring adherence.	CDC has included language about the availability of this kind of adherence testing, but CDC will not recommend specific commercial laboratories.
24b.		Participants suggested that CDC changing “therapeutic drug management” to “objective adherence testing”.	CDC will consider changing “therapeutic drug management” to “laboratory measures of medication adherence”.
25a.	NPEP (n=1)	Participants recommend that CDC drop “repeatedly seek nPEP” as an indication for PrEP.	CDC will consider changing “repeatedly seek nPEP” to having "one or more" courses of nPEP. CDC notes that some PEP users do not have ongoing exposure risk and do not necessarily need PrEP (e.g., sexual assault survivors).
26a.	PREGNANCY TESTING (n=1)	Participants noted that not all persons with childbearing potential are at risk of getting pregnant, especially if using contraception.	CDC will reconsider whether to recommend regular pregnancy testing, since current data show safety of tenofovir-based PrEP during pregnancy and breastfeeding.
27a.	PRESCRIBING ORAL PREP (n=1)	Participants recommended that CDC consider including information about legislation in some states permitting community pharmacists to dispense PrEP without prescription.	CDC notes that the legislation is beyond the scope of the guideline. CDC included pharmacists in the list of clinicians, and pharmacists would follow the clinical practice guidelines. All programs are able to follow guidelines if prescribing PrEP, including pharmacists.
28a.	PRESCRIBING CABOTEGRAVIR INJECTIONS (n=10)	Participants noted that there was no mention of the oral cabotegravir lead-in in table 1B.	CDC notes that in the text section, oral lead-in is listed as optional. CDC notes that no safety issues were identified during the oral lead in HPTN 083 and 084.

28b.		Participants noted that indication should be placed in table 1B for oral F/TDF or F/TAF, when CAB injections are discontinued to cover the "tail".	CDC will add these recommended indications to table 1B.
28c.		Participants noted that the CAB summary chart does not say what to do if doses need to be taken early, are late, or are missed. When is another loading dose schedule needed?	CDC will add content to the text section on prescribing CAB, but CDC does not plan to change table 1B.
28d.		Participants noted that some recent data from HPTN 083 and 084 are not included.	CDC will update the text and evidence tables with the most recent data (including publications expected in the next few weeks).
28e.		Participants asked what treatment regimen is recommended for person who acquire HIV while receiving CAB injections?	CDC will refer clinicians to the HHS ARV treatment guidelines for guidance on appropriate regimens for people who seroconvert while on PrEP.
28f.		Participants asked how often do persons receiving CAB injection for PrEP need to be HIV tested?	CDC notes that the guideline recommends HIV testing at each injection visit (i.e., every 2 months).
29a.	PRESCRIBING PREP BY TELEHEALTH (n=3)	Participants asked why is home oral testing recommended in this section but advised against elsewhere in the guideline?	CDC will clarify language related to this topic. This language is a remnant of the COVID PrEP guidance and is only to be used during lockdown or other emergency situations were lab or clinic HIV tests cannot be obtained.
30a.	PREP FOR PWID (n=10)	Participants noted that encouraging clinicians to discuss drug treatment with PWID may alienate them because they are pushed toward treatment in so many settings.	CDC continues to recommend that clinicians offer drug treatment; CDC is not recommending that clinicians pressure patients to enter drug treatment.

30b.		Participants did not understand why TAF/FTC and cabotegravir are both recommended forms of PrEP for PWID, given that studies have not been conducted with those regimens among PWID.	CDC notes that the recommendation for PWID, who usually have both sexual and injection exposure risk, was made by experts, given that PEP was not ever proven in RCTs, that an RCT in PWID with only TDF showed substantial efficacy, that F/TAF and F/TDF are equivalent or more active against HIV then TDF alone, and given that CAB is even more effective as PrEP.
30c.		Participants noted that the PrEP checklists in the supplement do not mention PrEP for injection drug use, only for sexual behavior.	CDC will revise the checklists to include PWID, where indicated. Most checklist items refer to risk behaviors without specifying sexual or injection.
30d.		Participants noted that in a recent outbreak investigation among PWID, the majority of infections were attributed to injection, and few to sexual behavior. Participants noted that they did not agree with CAB for PrEP in PWID.	CDC notes that in most PWID outbreaks, both sexual and injection risk are identified. Because CDC uses a hierarchy to attribute risk of infection, IDU will supercede sexual risk. In checking with the investigator teams for the outbreak referred to, they reported high levels of STI among the PWID, which strongly supports sexual risk as a factor.
30e.		Participants suggested that CDC add a recommendation for PrEP for PWID who currently do not share injection equipment but may in the future.	CDC does not make recommendations for people who are not currently engaging in behaviors that risk HIV exposure. However, CDC now recommends PrEP for all who request it, regardless of reported HIV exposure risk behavior.
31a.	RACIAL/ETHNIC DISPARITY (n=8)	Participants asked what specific culturally-relevant strategies are addressed to enable	CDC notes that this is an important implementation issue but is beyond the scope of the clinical practice guideline,

		the African American gay community to access PrEP?	which applies to all persons seeking or with indications for PrEP.
31b.		Participants asked what specific communication strategies are there for African American gay men?	CDC notes that this is an important implementation issue but is beyond the scope of the clinical practice guideline, which applies to all persons seeking or with indications for PrEP.
31c.		Participants recommended that CDC encourage providers to address the disparity in PrEP use by Black women, including the possibility of personal bias in screening.	CDC notes that this is an important implementation issue but is beyond the scope of the clinical practice guideline, which applies to all persons seeking or with indications for PrEP.
31d.		Participants recommended that because African Americans' kidney function may be more of a concern, the change in frequency of renal function testing needs clear justification to avoid medical mistrust.	CDC notes that the guideline recommends renal function be regularly monitored in all PrEP patients; this practice should benefit African Americans.
32a.	RENAL FUNCTION TESTING (n=2)	Participants requested that CDC include more specific guidance about when to monitor more frequently is needed.	CDC notes that the current recommendation is to monitor people at higher risk of significant declines in estimated creatinine clearance (comorbidities that affect renal function, age, marginal baseline function) at 6 month intervals, based on the results of recent studies with PrEP patients over time.
33a.		Participants requested that CDC add that medication coverage options may be available to those without insurance who are being considered for same-day PrEP on page 36.	CDC will add the suggested language regarding coverage options for the uninsured. CDC notes that some of these programs do not provide immediate medication availability.

33b.		Participants asked if unstable housing is a disqualification, how is it being measured?	CDC did not disqualify homeless persons from PrEP in this guideline. The guideline does state that if there is no way to contact a person for follow-up, then same-day PrEP "may not be appropriate". For example, it would be concerning if a person provided same-day start PrEP had their laboratory tests return an HIV-positive result, and there was no way to contact them, inform them to stop taking PrEP, and to link them to appropriate HIV care.
34a.	STI (n=8)	Participants noted that there is data to support STI testing every 3 months for MSM.	CDC notes that the guidelines do recommend STI testing every 3 months for MSM on oral PrEP, because of the current evidence base and every 4 months for MSM on cabotegravir injections.
34b.		Participants recommended that CDC consider recommending more frequent STI testing for MSM who have “extreme risk” rather than at follow-up visit intervals.	CDC notes that clinicians are free to test more frequently, if indicated by their experience. Also, CDC notes that there are no broadly applicable data that would allow for this type of tiered recommendation. For this reason, CDC will not make this recommended change.
34c.		Participants asked why is every three/four month STI testing not recommended for all PrEP patients?	CDC notes that we do not have data from PrEP populations other than MSM that indicate a need for routine quarterly STI testing.
34d.		Participants asked why is more frequent chlamydia testing not recommended for women?	CDC is suggesting more frequent testing and in a wider age range of populations than the current STD guidelines. CDC notes that there is not yet data from PrEP studies to suggest that women need chlamydia screening more frequently than annual, so for this reason, CDC will not recommend more frequent chlamydia screening in women at this time.

35a.	Table 1a (n=1)	Participants recommended that CDC spell out estimated creatinine clearance in a full footnote to make it clear.	CDC will review and consider this change.
36a.	Table 4 (n=1)	Participants suggested that CDC update the guideline to include the available gender affirming hormone therapy drug-drug interaction data.	CDC will review and consider.
37a.	TABLE 5 (n=1)	Participants suggested baseline HCV screening for all, not just PWID and MSM.	CDC notes that HCV screening for other populations are covered in the primary care considerations in Table 8.
38a.	TAF EVIDENCE REVIEW (n=1)	Participants suggested that CDC include bone mineral density data from DISCOVER trial.	CDC notes that these data are included in the section on "bone health."
39a.	U=U (n=3)	Participants were concerned that the wording about HIV discordant couples denies U=U.	CDC notes that some persons with recent undetectable viral load, will not sustain it (may fall out of treatment, may develop resistance), so there is some residual risk, although low.
39b.		Participants were concerned that the question in the MSM risk index "…how many partners were HIV positive" denies U=U.	CDC notes that the guideline discusses U=U. CDC also acknowledged that 35,000 HIV transmissions occur each year. CDC will consider amending the index item to say "with an unknown or detectable viral load."
39c.		Participants noted that it is highly stigmatizing to refer to someone as "having HIV infection."	CDC will delete the word "infection" and review language to clarify the U=U concept.
40a.	TIME TO PROTECTION (n=5)	Participants noted that the statement that there is no scientific consensus on the start-	CDC notes that there are differing interpretations of the available data with respect to time to protection with daily

		up time (for oral PrEP) is not true. WHO has reached consensus.	oral PrEP for women (receptive vaginal sex). CDC suggest that participants see this link provided in the guideline https://www.youtube.com/watch?v=5WfNqJPIIH8
40b.		Participants noted that the statement that PK data for F/TAF are not yet available is inaccurate.	CDC will revise the statement and add the references provided. CDC notes that while there are PK data, there are not sufficiently robust data on which to estimate time to protection (see FDA package insert).
40c.		Participants suggested that the new guidelines state that cisgender men should start TDF/FTC with a 2-pill loading dose 2-24 hours before sex with daily doses afterward.	This suggestion is extrapolated from the 2-1-1 studies and is not FDA-approved for daily oral PrEP. CDC notes that the guideline will not make this change for MSM for these reasons. CDC notes that clinicians may, however, choose to prescribe this way based on other guidelines.
41a.	TRANSGENDER PERSONS (n=18)	Participants suggested that CDC include data from the iBreath study regarding drug-drug interactions with F/TDF and gender affirming hormones/androgen blockers.	CDC will update references and include content on gender affirming hormones.
41b.		Participants asked why do the guidelines say there are no data available on administering CAB PrEP with feminizing HRT when 12% of HPTN 083 participants were transgender women?	CDC will revise and update this section with HPTN 083 data, which were recently published.
41c.		Participants asked if non-sterile injections occur uniquely among transgender persons who inject medications.	CDC notes that this is not unique to transgender women. CDC will consider how to be clearer about this behavior as an HIV risk factor.

41d.		Participants requested that the section on transgender people state that there is no reason to believe that F/TDF PrEP is less effective for preventing HIV among transgender people.	CDC will separate the clinical trial data for transgender women from those for MSM in the evidence table, so that the efficacy data for TGW are more clearly presented. CDC will update the table to include data from HPTN 083 on efficacy in transgender women and revise the text accordingly.
41e.		Participants noted that the section on transgender individuals only discussed transgender women.	CDC notes in the guideline that there are no efficacy data yet on PrEP for transgender men.
42a.	PHARMA/TDF/TAF (n=17)	Participants requested that CDC re-evaluate the language around a client's need to switch from F/TDF to F/TAF to say that the CDC recommends the use of whichever HIV prevention medication is deemed medically necessary.	CDC notes that the guidelines are intended to provide information for clinicians to determine which medications are safe for an individual patient. CDC will review and clarify the language about relative advantages and disadvantages of these two oral PrEP medications.
42b.		Participants pointed out a few errors/typos in Table 3.	CDC will review the package inserts, re-review the content to ensure accuracy, and make any indicated corrections in Table 3.
42c.		Participants noted that the recommendation for F/TAF based on renal markers is important and will be helpful here. Participants also noted that having something similar for bone demineralization and frailty fracture risk would also be helpful.	CDC notes that because BMD measurement is not recommended for all oral PrEP patients, clinicians do not usually have these data. CDC notes that no increased risk of fragility fractures has yet been documented in HIV-negative patients on tenofovir-based PrEP. CDC notes that we do not want to raise anxiety about a laboratory finding without demonstrable clinical impact.
42d.		Participants noted that CDC should update Table 1a and other relevant sections to make	CDC will review and make any indicated revisions (e.g., ≥30 ml rather than >30 ml).

		clear the renal requirements for both F/TAF and F/TDF.	
43a.	Hepatitis b (n=1)	Participants asked about whether viral hepatitis testing should be featured in the summary somewhere?	CDC notes that viral hepatitis testing was moved , because clinicians were considering HBV tests to be required before initiating PrEP and sometimes considered a contraindication to PrEP use although neither are correct.