Transcript of Public Comment Webinar
PrEP Guideline and Providers Supplement – 2021 Update
24 May 2021

CDC Presentation by Dr. Dawn K. Smith and Dr. Gema Dumitru

Dawn Smith: We're glad to have you here. Dr. Gema Dumitru is going to start us off with a few orientation slides.

Gema Dumitru: Hello everyone I'm Gemma to meet your health scientist on the rehab guidelines team. And I would like to welcome you all to our webinar to discuss the 2021 draft clinical practice prep guideline and clinical supplement. Gema Dumitru: Next slide please.

Gema Dumitru: The next slide we are sharing our agenda. So after the introductory slides. Dr. Dawn Smith will present an overview of the PrEP guideline changes and additions, followed by an opportunity for public comments from the audience. And similarly, after the overview of the clinical supplement changes and additions. We will welcome your comments for the clinical supplement. Next slide please.

Gema Dumitru: So, the purpose of the webinars is to provide public comment opportunity for our stakeholders in particular clinicians who provide care to persons at risk of acquiring data HIV infection, being the primary target audience for the plan guideline and clinical supplement Each webinar will present both the guideline and supplement changes for comments and each webinar will be audio day to provide complete and accurate record of the comments made and upload or comments provided by you. During the webinars will be considered, but there is no return comment outside the webinars. Next slide please.

Gema Dumitru: This is some instructions for providing comments so all participants can make comments either verbally by unmuting themselves and you probably all now this but just a refresher, or by entering comments in the chat. So for verbal comments. We try to keep things organized and we will invite participants to participate in groups alphabetically by last name and I will let you know when our turn comes by group and we also asked commenters to identify themselves by last name and organization and to keep verbal comments short, if possible, no longer than three minutes to give everybody a chance to comment. And also to please not repeat comments or questions already raised that others have noted. The CDC staff today will not give any specific responses to comment during the webinars. The CDC will be posting the responses at a later time on our website. And a few additional clarifications on the next slide please.

Gema Dumitru: If you choose chat. You can do it at any time. Can we see the next slide please. So yeah, if you if you choose the chat. You can do it at any time. Select chat at the

bottom of the screen and select to everyone near the bottom of the chat panel. And type in your comment. If you provide verbal comments during the comment period. Please note that participants have been muted. We will let you know what group is eligible to speak alphabetically. Next, raise your hand and you can find that on the reactions at the bottom of the screen and we will unmute speakers, one at a time.

Gema Dumitru: And on the next slide. We have our two disclaimers. The recommendations about PrEP include the use of commercial products, Truvada, generic TDF, Descovy, and cabotegravir when approved by the FDA. And also the draft documents are distributed solely for the purpose of pre-dissemination review. They have not been formally disseminated by CDC and the documents for review. Do not be present and should not be construed to represent our agency determination or policy and now I'll invite Dr. Dawn Smith to take the floor.

Dawn Smith: Next slide. Okay, so I'm just going to highlight the changes and additions that we've made for this guideline update. I'm not going to go over things that really have stayed the same from the 2017 guideline and after a brief introduction to that, then we will open the floor for public comment. Next slide.

Dawn Smith: So we added to the guideline update a recommendation, a graded recommendation to inform all sexually active adults and adolescent patients about PrEP. This is intended to address the problem we're having with patients not even knowing that PrEP is an option for them.

We have added a recommendation for F/TAF or Descovy as an FDA approved choice for the populations for which FDA has approved it. And we have added a recommendation and guidance for using cabotegravir as PrEP and that guidance is conditional on the eventual FDA approval.

In addition, we have added a guidance about PrEP being delivered by telehealth which we've learned a lot about during the COVID response. We've added some guidance about same-day PrEP initiation, and we've added some guidance about the use of non-daily oral PrEP for the 2-1-1 regiments specifically.

We also added a brief section on primary care considerations for PrEP patients because increasingly we were being asked to add things to the guidelines that were not directly related to PrEP administration, but really are part of the primary care of patients. And so we wanted to include them in a slightly different way. And then we've expanded some of the guidance for transgender persons. Next slide.

Dawn Smith: Prior to doing this guideline update. We did a small survey with clinicians who were using the PrEP guidelines to find out ways that they felt that we could improve the format and the structure of the guidelines to make them more usable. And so, as part of that, we

revised and reordered the sections in the guideline to first describe guidance that's applicable to all PrEP patients and then specific sections about guidance that's applicable only to certain PrEP patients - pregnant patients, for example. And then we created sections for oral PrEP and injectable PrEP anticipating that as new PrEP agents come online, we will need to have clear delineation,

We replace some of the boxes that we had about indications for PrEP with flow charts; clinicians found them to be more useful. And we revise the HIV testing algorithm to clarify preferred and less preferred options at some steps in the testing algorithm and to harmonize with the acute infection section of the DHHS HIV treatment guidelines.

We also, based on new information, revise the frequency of assessing estimated creatinine clearance for persons on tenofovir-based PrEP by baseline age and an initial an estimated creatinine clearance. Next slide.

Dawn Smith: So, we created two tables at the front, two summary tables, one for daily oral PrEP and one for cabotegravir. The one for daily oral PrEP, the only changes are, you can see that we're now suggesting that you assess renal functions for patients who are over the age of 50 or who have a creatinine clearance less than 90 at PrEP initiation that those patients should be have their renal function checked every six months, but other patients can have their renal function tested once a year. Next slide.

Dawn Smith: We created an additional table for cabotegravir injection PrEP and you can see that this is one of the places where you can see that changes that we've made to be more inclusive in our language. So we talked about pregnancy testing for persons with childbearing potential as opposed to for women, and to recognize that transgender men may also be childbearing. We, you will know, I noticed as I was putting the slides together that we didn't make that change in the previous table and we will do that.

You can see that a lot of the things are similar to what's on the daily oral PrEP table. The major differences are that the dosing and the dosing intervals are different for cabotegravir than they are for daily oral PrEP. And because the dosing intervals at different we have changed the schedule of STI testing for people on cabotegravir to every four months instead of the every three months for daily oral PrEP. Next slide.

Dawn Smith: This is an example of the consolidated flow chart that we have down for assessing indications for PrEP in sexually active patients. And again, this was an attempt to make it easier for clinicians to follow what we would like them to assess. You'll notice as we get to the bottom, we haven't changed the actual questions that we wanted people to ask. You'll notice at the bottom that we have places where we say prescribe PrEP. For the other places. We don't say do not prescribe PrEP, because there are circumstances, regardless of the risk assessments, where providers may wish to provide PrEP anyway. But we want to be sure that

patients who do have risk indications are offered PrEP in the text. We also state that patients who request PrEP should be offered it regardless of the results of their risk assessment. And so again, this is an attempt to recognize that sometimes patients may not want to report certain behaviors and are requesting PrEP for good reason. And we should go ahead and prescribe PrEP to those patients. Next slide.

Dawn Smith: And this is the flow chart for persons who inject drugs. Again, the content hasn't changed. Next slide.

Dawn Smith: This is the flow chart for determination of HIV status. We now, we used to say that there was a difference in priority between laboratory-based antigen antibody essays and viral load essays, we've now made them both preferred options. Depending on the patient's regimen and the patient situation providers should choose one of those two and either of those is preferred over the less preferred option of repeating antibody tests and delaying PrEP initiation. The other thing that we changed was we used to have that viral load less than, than 3,000 copies per ml should be confirmed and could possibly be a false positive test. We changed it to less than 10,000 to agree with the HIV treatment guidelines section on acute HIV infection, but there is already a fair amount of discussion about whether that should stay that way. Next slide.

Dawn Smith: This is an example of the primary care measures that we were talking about where we wanted to be sure that patients who were receiving PrEP, we're also getting the other primary health care services that they need. Next slide.

Dawn Smith: Okay, so now we're going to open for public comment on the guidelines itself. Dr. Dumitru is going to call on people. You should raise your hand and then she will call on people to make comments, I will ask that the CDC staff who are attending the webinar not make public comments. We really want to leave the time open for our external partners to be heard in this session. So, Dr. Dumitru, take it away.

Gema Dumitru: Thank you, Dawn. There are a couple of messages in the chat box regarding people feeling they would prefer to remain anonymous without identifying themselves by name and organization. That's fine. We just thought to organize people by group. So I'll still invite people if they want if they feel comfortable belonging to the group A to D, for instance, we tried to find a way to organize because we know we have a large number of people who want to talk. So, but I'll invite the people who raise their hand. So first I have [Name], please go ahead unmute yourself, please.

Oral Comments During Webinar

[Name]: Hi, everyone. Thank you so much. And thank you for this presentation and this opportunity. I want to make this brief I'm [Name], I was running [Name]. And still write about

PrEP and access to [Name]. What I think is really good about these updates appear to be as [Name] as mentioned that there is no longer this requirement that you listed risky activities to a doctor that there is a mention of U=U in the new guidelines. I appreciate the new guidelines encouraged cholesterol monitoring for those who take Descovy and I appreciate that there is a whole section on same day PrEP implementation. So, thank you for that. Here's my struggle with what I was reading and the guidelines around page 41 PrEP. There is a statement that there is no scientific consensus on the startup time to use PrEP, oral PrEP for rectal sex that is simply not true, there is scientific consensus outside the United States, the World Health Organization. It says very clearly in their 2019 guidelines that there is scientific consensus that is someone is using PrEP for anal sex prior to a sexual encounter and continued to take another dose 24 hours later in 24 hours later, also known as the 211 method. And they go through the science and the data that shares that so when the CDC says we don't have a scientific consensus on this, it's disingenuous. And it's going to continue to show a rupture between what the consumers understand, what the scientific community says, and what the CDC is putting out there. I think the CDC is in a wonderful position here to be advocates and to really be on board with what the international scientific community is communicating to consumers. And they don't want to see them lose this opportunity and continue to expand the distrust in CDC that's already out there, in the United States. And lastly, I just want to say, on page 42 that as a consumer of PrEP. And as someone who has been working in talking everyday with consumers of PrEP for most of the last nine years now that follow up. Every three months follow up to talk about risk reduction behaviors is insulting. It's insulting. It's infantilizing. I don't need to talk to a health care provider every three months about reducing my risk reduction behavior. My risk reduction is that I take PrEP every day. And that's it. With the rest of it is my business. What I do with my body is my business. What I do with other consensual adults is my business. I don't need a healthcare provider telling me how to reduce risk behaviors. And this has been a real problem. I know that in theory, there's nothing wrong with that. And you may not see the problem with that is people writing guidelines in practice in the real world. This is a problem when people who are using PrEP have to talk to a doctor every three months. About how they're having pleasurable bareback sex with multiple partners. A lot of people won't even disclose that and when they do, they get shamed and condemned for that. So, I think, it is worth considering removing that portion of the checkups, because all that seems to indicate is that you don't trust me, and you don't trust other adults to make our own sexual health decisions. Which again is contradictory, we are making our own sexual health decisions by initiating PrEP and going on PrEP and taking PrEP consistently. That is the risk reduction decision right there. No one has a right to say anything else about that to any adult who is agreeing to this in my opinion. So, I do hope the CDC will consider that and thank you. Thank you for listening.

[Name]: Thank you for sharing. I was just curious to get a little bit more rationale on your background around decision to move the STI follow up to four months in comparison to routine STI testing at three months.

Dawn Smith: And so just a point of clarification for cabotegravir visits are not every three months there every two months. And for that reason, we move the STI testing to every four months. But that's just a point of clarification.

[Name]: What appointments every two months.

Dawn Smith: Okay, so if when we start using cabotegravir the injections are every two months. People will be coming in for care every two months. And so, we didn't want them to have a visit every three months. Just for STI testing. So, it remains every three months for oral PrEP. It's every four months for cabotegravir.

[Name]: Hi everybody this is [Name] from the [Name]. I wrote a little thing just to tried to be more concise so [Name] appreciate the updates to the PrEP guidelines is specifically that broadening of options in the forms of intermittent use and long acting injectables as a critical component of a stronger HIV prevention effort. A few things that we wanted to comment on number one, the choice of TDF vs TAF is still unclear should providers give preference to the cost-effective choice TDF or the expensive choice TAF for a given patient that doesn't have any additional risks and just keeping in mind that financial barriers are recognized barrier for PrEP uptake. We also think that while the extensive number of options is great for creating choices and modalities for potential users, the lack of expansion in guidelines for what is called substantial risk. It remains poorly worded not giving medical providers and not enough options to initiate a conversation about PrEP. For example, history, often consistent condom use could have evolved to history or desire to have condom less sex or, for example, individuals dealing with the justice system, or maybe going to jail remain at high risk for HIV and are outside of clinical guidelines. And just to say what [Name] already said about having to repeat this screening every three months. Lastly, the committee failed in addressing PrEP persistence by facilitating and encouraging easier ways to conduct PrEP quarterly visits or at home services or telehealth, but we do appreciate the recommendation for less renal screening for certain populations.

[Name]: I just want to say thank you. It's been very heartening to see increasing visibility of trans people in this document over the years. So, I have two items of comment that I would like to make. Number one, because we don't want providers to be too nervous to prescribe PrEP to trans people or to emphatically recommend that they use it perhaps. It's important to include the most recent data from a couple of studies that demonstrate, there's really no reason to believe that TDF FTC PrEP is less effective for trans people, even when taking hormones, and that includes data from the I-BrEATHe study that was published in 2020 which showed that there were no significant differences in TDF concentrations via dry blood spot between trans women trans men. And cisgender men and all trans women and trans men were projected to achieve highly protective concentrations of drug. And it's also important to include a presentation from a second study which was presented on CROI this year on. Medication levels in PBMCS among trans adolescence there were some differences observed between trans men and trans

women that were thought to be mostly the differences in kidney function. And the authors reported as a mean drug level and PBMCS were within the ranges of previously reported studies. So, I will put a link to these two studies in the chat and I just really wanted to ask this a section on transgender people emphatically state that there is no reason to believe that TDF FTC PrEP is less effective for preventing HIV among trans people even with or without using hormones and then my second item of comment is a bit shorter. In the sexual history taking question, the question you have sex with men, women are both. I recognize what are the genders of your sex partners as an open-ended question to capture all possible genders, that the patient has sex with and this is incredibly important for many populations, but specifically in the example of this cisgender men who have sex with trans women. Many of them don't realize that they're vulnerable to HIV acquisition due to the high prevalence in their sexual network. Many of them identify a straight man, I've had very little consciousness raising about HIV and they may transmit may acquire HIV and then transmitted to their trans female partners who are not taking PrEP.

[Name]: I am [Name]. I work in [Name]. I work in environment where we're frequently prescribing PrEP to people who inject drugs in a primary care and mobile setting, including in our homeless population. As a team we had a few concerns that we were hoped to discuss, including concerns about use of old references to support the statement that most HIV transmission in people who inject drugs is sexual not from injection. Between 2016 and 2018 the CDC was actually out in Lawrence and for an outbreak, including 129 people were 86% actually reported the exposure mode being injection drug use, with a much, much smaller percentage of folks reporting sexual risk. We think that this is important. Also because of the recommendation and the guidelines for the use of cabotegravir in people who inject drugs without actual data to really support that. And really, the lack of acknowledgement for people who inject drugs for the TAF FTC, which also hasn't been studied and people who inject drugs. And we all also concerned about the language that is potentially exclusive of individuals from same day. Same day PrEP. Because of housing instability or homelessness. And I think specifically it had written. Same day PrEP initiation may not be appropriate for folks who are homeless or unstable and may not be housed and may not be easily contacted for return appointments. And I, I understand the concern for loss to follow up, but I just want to acknowledge that this might be biasing people towards not prescribing PrEP to high risk individuals or individuals in with risk behaviors or on high-risk settings.

[Name]: Yeah. Hi and thank you so much for this opportunity to comment and thanks for the changes that have been made that I agree with a lot of what's been said thus far. I just had a minor point that I wanted to make with respect to be identifying indications for PrEP, I would highly recommend that the CDC consider changing the language so that it's not recommending PrEP for all sexually active adolescents and adults, but rather like informing everyone regardless of sexual activity. So, in other words, informing all people adolescents and adults about that because we're doing it so that it's only people who are sexually active. I mean, one it excludes people who inject drugs and might be at risk, even though they're not sexually active

as a CDC recognizes not everybody is going to disclose private behavior. So, a provider may or may not know somebody is sexually active. And, somebody is currently sexually active. It doesn't mean that they are if they are currently not sexually active. It doesn't mean that they cannot be sexually active in the future. So, it just seems like an unnecessary specifying, it would be better, I think, to just say informing all adolescents and adults about PrEP.

[Name]: My name is [Name] which is a [Name]in Philadelphia serving adults, adolescence, and kids. I just want to echo that [Name] just brought up, just some further recommendations or thoughts on the figure to the flow chart for primary care providers. To consider eligibility for PrEP. I think that flow the idea of having a flow chart is actually really good as one of the most common questions we get from primary care providers is just a little bit of confusion around who's eligible. So, I think breaking it down into a flow chart is actually a really good idea that will facilitate hopefully more providers kind of utilizing that. My concern is similar to [Name] in that it's a little confusing. I had a look at that chart myself. Many times, and I don't think I really understood what you meant until you presented it orally here in terms of when there's the No arrows, meaning that it's not that you don't know to prescribe PrEP. But it's, you know, if there's a way to clarify that where your No's are. PrEP may still be an option for patients and these patients, and you know PrEP should still be discussed. To make that a little bit more clearer I think would be helpful, because many providers may read that as a hard 'No' even though in the text, it may explain a little bit more that that doesn't mean don't prescribe PrEP and one of the biggest examples is just your very first break point, branch point where you say, you know, patients, people who have been sexually active in the last six months. But as you know, we see many people who have actually not been previously sexually active but would like to be and would like to have PrEP on board prior to being sexually active. And so, you know, even modifying the language to be, you know, sexually active in the last six months are planning to be. You know, in the near future, would be another way to make sure that sort of primary care providers, especially those who don't do this so often don't kind of tend to exclude those folks, based on the flow chart.

[Name]: I wanted to speak to the guidance for indications for PrEP for people who inject drugs. I think that something that would be really useful to add. The option for prescribing PrEP to individuals who may, in the future, share injection supplies or syringes. Because I think that there are a lot of instances where in someone may not plan to share needles, but that there is still an inherent risk of transmitting HIV in that. And so, including an option for people to access PrEP. That's something that they feel is important for them. The one other thing that I would suggest adding is, in addition to referrals for treatment for substance use disorder mental health services and other social services. Explicitly naming adding referrals to harm reduction programs. I think that that is something that is really important. And I think that, in the world of PrEP navigation and providing care to people who use drugs harm reduction programs are often overlooked just due to lack of education and I think naming that could be deeply beneficial for folks.

Gema Dumitru: Thank you, I do not see any other raised hands.

Dawn Smith: Then we can talk about the supplement. Can you put up the next slide?

Dawn Smith: So there were fewer changes to the supplement than to the guideline itself. We have a patient visit checklist for daily oral F/TDF and we updated that to include the options of F/TAF and 2-1-1 Truvada and cabotegravir. We then added information about F/TAF to the patient information sheet that already had information about F/TDF. And we added a separate patient information sheet about cabotegravir and then in several places we added text specific to cabotegravir where things would be somewhat different than they were for all tenofovir-based PrEP.

Dawn Smith: So, I guess the question is, what comments, people have about the changes and additions to the supplement. Next slide. Changes that we make to the guidelines based on comments we receive will get reflected in the changes in the supplement as well. Do people have any questions about or comments to make about the supplement?

[Name]: My name is [Name]. I'm a HIV specialty pharmacist at [Name].
And I just have a question with the oral or sorry, with the cabotegravir injections. I don't see any mention of the oral lead in. And my understanding is that is a 30-day oral lead in so like Table1B. In the guidelines don't mention that. And then they also don't see it on the supplemental checklist, either. So, something to consider there. And then I also it, it sounds like in one of the pages 51 it looks like for injectable cabotegravir. The recommendation is for a viral load test and it says it's under the at each bi-monthly visit. But then it also previously verbally. It sounded like the recommendation is every four months for the HIV testing. So, I just wanted to clarify one is the recommendation that with injectable cabotegravir is the HIV test is the viral load. And then secondly, is that every at each two months visit while on the injectable or is it every other visit, so it'd be every four months.

Dawn Smith: With regard to the oral lead in and I think there is a discussion of it in the text. But we will also respond to that in writing.

[Name]: I just want to highlight a couple things that put into chat, because I just think they're important and I want to underscore them. One is please include information about generic equivalence to TDF FTC or Truvada. There is a growing number. I think there's a lot of misunderstanding and misinformation that is out there about generics among population and among clinicians and so I think this is a really important to include that there are a number of options for generic Truvada that had been approved and/or therapeutically equivalent. The other thing I would say, and I dropped this or a couple things I just want to highlight again that I put in the chat. It would be really nice to start moving our language towards sexual health assessments as opposed to risk assessments. I really heard, but people were saying about a

regular check in on risk what how nice it would be to have a regular check in and about sexual health, or whether we're having the kind of sex and the pleasurable sex that we want. It's not just about disease prevention or disease management. Finally, with 211 the WHO has also endorsed 211 and noted in the guidance that you point out that IS-USA has endorsed it. That I think it's pretty relevant and pretty important that the World Health Organization also endorses it. So, I think that would be a nice addition to the guidance.

[Name]: Hi. Thank you. And now I see the supplemental and my worst fears were confirmed because you still have the provision. That counseling or referral for condom use. Will be involved in PrEP management and I just want to reiterate the point I made earlier. But I'm doing it again because we're looking at a different section that it's so insulting. If a provider tells me I should use condoms. I'm going to find another provider. There's absolutely no medical reason for that to be there. It is simply moralizing and infantilizing, and I really encourage the CDC to look at that and remove that provision. I know that for you on your side. These are tools, not rules, but a lot of doctors don't make that distinction and they think their rules and that they have to do this and that is a huge barrier than two people, maintaining access to PrEP.

[Name]: Yes, my name is [Name]of infectious disease diagnostics at [Name]. And through our work with clinical research partners and community engagement, we would like to recommend language around therapeutic drug monitoring be changed to objective adherence testing. So historically the term therapeutic drug monitoring or TDM has been used for difficult to manage medications and to assess optimal drug dosages based on the various patient. And medication characteristics, but this is not the case with PrEP. Objective adherence testing. On the other hand, more accurately reflects the use of biomarkers to assess recent and long-term adherence to PrEP to strengthen PrEP care. So, adherence testing empowers individuals on PrEP to have data showing them the drug is working for them. That gives providers objective data point help identify which patients need additional adherence or retention support.

[Name]: As most of many of the professionals and others on this call have today what I see in the document is attention to the disproportionate impact. Of the epidemic of HIV on black men, but I don't see solutions that continue to pay attention to some of the barriers that are still in translational research for me. That means ensuring that the language is looked at again to ensure as much neutrality in doing a risk assessment or doing a health assessment or doing a sexual activity assessment as is humanly possible. And to respect the fact that so many black men who start PrEP don't stay on PrEP and the many of the things that I'm looking at require a medical intervention on a regular basis versus encouraging folks to be able to go to a laboratory to get X set of review. And then if they need medical attention, be able to do that or be able to work with some of the pharmacist, the pharmacist has said. Work with their local pharmacy to be on a PrEP program there are financial barriers and logistics barriers that are not addressed in these recommendations yet.

Since we don't get to update recommendations regularly. I think all the barriers, particularly ones that will keep us sustaining the medical distance between people just because of race are removed, while we have this opportunity to do an update. And I think most of the people that I know who are on here are interested. In making sure there's increased access to PrEP versus additional barriers because we're only updating based on what's academically available in the literature.

[Name]: I am looking at the patient part and I think the thing you don't always realize is that it's not like always one or the other. You have a checklist there for daily, you have a checklist there for 211 and thank you. I'm really, really glad that 211 is included, but I think the real-life experiences. A lot of us go back and forth from time to time. It just doesn't seem to make any sense to get a client to be sitting there saying, well, I will contact my provider to only use daily or only use 211 and I'm going to talk about this which assumes I even have a provider who I trust to talk to. I don't really understand the purpose of this checklist thing and I just see like this is another barrier or ways to create further rupture of trust and barriers to service when you're making consumers fill out some sort of agreement or contract about how they're going to use PrEP it doesn't make sense to me as a consumer, why you would do that.

[Name]: I am [Name]. I am a physician here [Name] and we do a lot of PrEP at our clinic. We have been able to expand a lot of PrEP in our local area because of in order to fit it into an STD clinic model. And I wanted to echo some of the one of the concerns that came up in the chat about. The idea of lipid monitoring being a part of this. And then, you know, if that becomes a part of what kind of required for this, then that turned into is not really part of the current. The kind of boat is of STD clinic models to offer. So, when we're adding on things. And even if it's kind of screening for, this health-related thing or that health related thing. It may not be wrong to ask about certain things or the screens are things if you have the ability to follow up about it or you know is meaningful to the folks who are using your service. But making sure that as we conceptualize kind of where people are getting PrEP that we make sure that we're allowing for low barrier models to continue to exist. And, you know, STD clinic, being a good one that we've been able to leverage and allow for better access. So, as we have these general guidelines about health other pieces just making sure that we're not any of building something that can't be sustained in low barrier models.

[Name]: I just got to the part on supplemental section on condoms. Your whole take on condoms alienates consumers. This is why we don't trust the CDC, quote, you should not stop using condoms, because you were taking PrEP is taken daily. It offers a lot of protection against HIV infection, but not 100%. Okay so out of about 900,000 people that are currently using PrEP in the world or have been over 10 years we have about four documented cases of people who have acquired HIV with verified adherence. That's pretty high. I think condoms do not significantly add protection from HIV in that scenario where is your strength. In your condom argument exists in their ability to prevent other STI’s is that is very different. You kind of undermine your own message here by saying that condom should be used. And by the way,

anytime you tell someone what they should do. They often resist and do the opposite. So that's already problematic language, in my opinion. But the strength of your argument is not in how condoms prevent HIV. The strength of your argument is how condoms prevent other STI that people may be at risk for. And I think there's a way to say that that doesn't infer that PrEP does not offer the maximum protection if people are not using condoms.

[Name]: And I just wanted to mention I work for [Name]. I do wonder about the creatinine clearance monitoring and just monitoring certain folks once a year. And if we're really going to see changes in real time if we're monitoring that infrequently, and also some maybe more specific guidance about when to monitor more frequently could be helpful for clinicians who are monitoring PrEP.

[Name]: Um, hi. I just wanted to add to the conversation around condoms. Just I think that what [Name]is trying to say. And I'm going to try to say is just that the same certainty that we place on condoms protection, which has been revealed, not to be 100% right. We don't place it in PrEP, at least on those guidelines. So, for a physician that is not working with the LGBTQ population or a physician who is not necessarily comfortable prescribing PrEP. They are looking for the nuance on those guidelines, they are looking for-this should and shouldn't. So, when they hear that they should continue to use condoms. Literally the providers are scared of they're going to lose their license the patient comes back and say I had sex without a condom because I read it online that PrEP protected against HIV, and it does, you know. So, we have to be clear that on HIV prevention guideline, we are comfortable with the HIV prevention tools. And if we're doing the STI screening guidelines, maybe we can have a conversation about condoms. But those things are separate right because PrEP protects against HIV, more so than condoms, maybe that should be what the test. So, just a comment.

[Name]: Is it possible to take an antiretro viral medication in an injectable form that might bypass the first pass effect. By taking an injectable HIV antiretroviral medication that would probably allow the first pass effects damage to liver. To be avoided that that occurs with the oral medication is there is there is there a long-lasting depot injection. Intramuscular injection available for an anti-retroviral. Does anyone know if it's as if the if the pharmaceutical companies had developed that?

[Name]: There is a monthly injectable antiretroviral on the market. Yes. I think it might be a cabotegravir combination, but I would need to double check that.

[Name]: Is it ridiculously expensive. Because it's under patents.

[Name]: Yeah, it's the wholesale acquisition prices. So, several thousand dollars the cabotegravir injection has been studied for PrEP medication and I don't believe that one. Yet been approved by the FDA for use in PrEP, but it is approved in combination with another long

acting injection called raltegravir, and the two together. Are available as a one antiretroviral acting injectable medication.

[Name]: Now I think bodybuilders might have figured this out, even before the doctors that taking anabolic steroids orally fries the liver, because the liver enzymes, I guess, get overwhelmed. And the first pass of blood flow from the stomach to liver and that's dangerous and these intramuscular injections are way safer and do far less liver damage. How much does PrEP cost? How much does PrEP costs what insurance pays what for, for this for adult for a pill or what's, what is it what does insurance cover and not cover and how much is it?

[Name]: I am [Name] at [Name]. I want to first thank you to all my incredible colleagues for all of your very well-reasoned comments that I wholesomely agree with. On page 31, section seven I would appreciate if the lead in sentence could be corrected to reflect the minimal occurrence of these of folks who acquire HIV after initiating PrEP. I think that initial sentence is a little bit unclear. And see, it may seem a lot more common than it actually is.

[Name]: Sure, I'm in the provider supplement I oftentimes see Truvada referred, but now that we obviously have generic medication on the market to would it be helpful to identify. The medications more by its formulation, rather than its brand drugs as we can assume that more drugs will enter the markets or I just, I wouldn't want providers to not prescribe a generic because they think it has to be Truvada but Truvada may not be covered by insurance.

[Name]: Why aren't bodybuilding drugs prescribed for muscular atrophy in AIDS patients.

[Name]: These guidelines are not about AIDS; they are about uninfected people who are taking PrEP.

Text Comments in Chat during Webinar

[Name]: I was with you.

[Name]: Will slides by available after the presentations?

Dawn Smith: the entire webinar will be posted online.

[Name]: Comments in chat will be considered the same as verbal comments?

Dawn Smith yes, chat comments will be saved and considered.

[Name]: thank you **[Name]** 1: Given that HIV, sex, and injection drug use are highly stigmatized, must attendees identify themselves by name and employer in order to have their

feedback considered? People may want to speak from lived experience rather than strictly professional experience.

[Name]: I agree with “1” above. That need to declare employer and organization makes this process seem disingenuous. This was supposed to be a public forum, no?

[Name]: I appreciate the language in red - "patients who request PrEP should be offered it, even when no specific risk behaviors are elicited." that needs to be HIGHLIGHTED as much as possible.

[Name]: For F/TAF - I don't know I would recommend checking lipids every 6 months. I know that cholesterol can rise after starting F/TAF, but I feel like this should be age or risk based. An otherwise healthy 20yo on F/TAF probably won't benefit from q6mo lipid assessment.

[Name]: Will these slides be available for attendees?

[Name]: Wasn't the HPV vaccination age pushed beyond age 26?
[Name]: NASTAD suspects that many public and private payers will use the updated Guidelines in their coverage determinations, including in shaping clinical criteria for F/TAF coverage (particularly with $0 cost sharing requirements in alignment with the USPSTF Grade A recommendation). The recommendation for F/TAF based on renal markers is important and will be helpful here; having something similar for bone demineralization/frailty fracture risk would also be helpful. For example, a recommendation for adolescents that haven’t yet achieved maximum bone density and/or those with a dx of osteoporosis and osteopenia.

[Name]: for 2+1+1 section - please note that this strategy has also been endorsed by WHO - not just IAS-USA.

[Name]: Will there be opportunity to provide public comment outside of this and tomorrow's session?

[Name]: May we share public comments in the chat?

[Name]: NP from Denver Public Health. Will you be recommending for MSM taking Truvada 2 pills on first day to get maximum protection at rectum at 24 hours? rather than daily x 7 days.

[Name]: I may have missed it, but didn't see info specific to generic versions of TDF - if it exists, can someone please say where?

[Name]: NACHC: Great point **[Name]**!!!Fully agreed! Initiation for PrEP should be 2 pills, and it starts to work 2 hours after.

[Name]: THANK YOU **[Name]**!!!!!

[Name]: Yes, fully agree!

[Name]: "reducing risk behaviors" IS taking PrEP and it IS getting screened for HIV and STIs regularly.

[Name]: Fully support this!

[Name]: Very well put **[Name]**!

[Name]: I agree with **[Name]**

[Name]: These draft guidelines are highly anticipated. Many thanks to those who worked to bring these to reality. This document builds on essential PrEP information for prescribers, scientists, and the community prepared by CDC for now over a decade. Good to see 200+ people on this call and we all appreciate the opportunity to provide comments on the updated information. I'm going to put a few suggestions into the chat for CDC's consideration.

[Name]: I strongly agree with **[Name]** points. It is essential that the new guidelines state that cis men can start TDF/FTC with a 2-pill loading dose 2-24 hours before sex with daily dosing afterward and that they can discontinue through daily dosing two sex-free days, as the WHO and IAS-USA recommend. And I profoundly strongly agree with the importance of removing "risk reduction counseling" from the mandated activities in PrEP follow-up appointments. It is a huge barrier to care and fosters alienation and distrust. Someone who is using PrEP and has condomless sex with multiple partners should not be construed by providers as engaging in "risk behavior" that they need to be counseled out of engaging in. There is more to sexual health and wellness than avoidance of disease.

[Name]: The draft cites pharmacokinetic (PK) data for F/TDF but not F/TAF, stating "F/TAF PK study data are not yet available." That declaration is not accurate. There are PK data for F/TAF available, and those data illustrate that its PK profile is substantively different from F/TDF, including distribution of metabolites in plasma/tissue (Custodio J, IWCPHT 2015 [slide 16,17], Cottrell M, J Antimicrob Chemother 2017 [pg 1733, paragraph 3, 4, pg 1734 Figure 1, page 1735 Table 2], Schwartz JL, HIVR4P 2018 [slide 7, 9], Mayer K, Lancet 2020 [pg 248, paragraph 3]) While TDF and TAF are both tenofovir prodrugs, TDF has an extremely short half-life in plasma and is metabolized to tenofovir (TFV) there, while TAF has a longer half-life in plasma, resulting in higher concentrations of TFV-DP into peripheral blood mononuclear cells. With respect to timing, F/TAF delivers TFV-DP concentrations above the estimated EC90 for HIV prevention efficacy (40 fmol/106cells) within a median of 2 hours, whereas F/TDF requires 3 days of dosing to deliver enough TFV-DP intracellularly (Anderson P, Sci Transl Med, September 2012 [page 6 paragraph 2 – 5, page 15 Figure 3], Schwartz JL, HIVR4P

2018 [slide 9]). These distinct clinical pharmacologic properties account for the renal and bone biomarker differences between TDF and TAF and potentially indicate a faster time to protection with F/TAF compared with F/TDF. Further, the current time to protection estimate for F/TDF is based on available PK data, noting that time to protection is unknown, but acknowledging that time to steady state in tissues as the time to "maximum protection." Similar guidance could be given for F/TAF using the established time needed for intracellular steady state levels to be reached.

[Name]: The flow chart for cabo is a little confusing with the two timelines. I feel this need to be clear because the interpretation could be confusing.

[Name]: Thanks **[Name]**. Is there any update or change in STI testing recommendations or standards of care (including innovative testing modalities such as home-based testing) taking risk reduction and personal autonomy concerns into account but still ensuring opportunities for prompt STI detection and treatment?

[Name]: Fully agree with. Thank you!

[Name]: Would be nice for us to start framing "risk assessments" as "sexual health assessments" instead - sexual health is not just about disease.
[Name]: Agreed **[Name]**!

[Name]: I agreed with the "risk assessments".

[Name]: Agree **[Name**!!

[Name]: "Great point **[Name]** about the sexual health assessments"

[Name]: I agree with the change in vernacular.from risk assessment to sexual health assessment.

[Name]: I would like to see more clarity about offering of TDF - we know the vast majority of PrEP users (oral PrEP) do not clinically require TDF.

[Name]: Figure 4, Perhaps the use of <10,000 copies vs a lower quantitative level is less important than the decision to initiate PrEP is based on "VL<LoD w/o signs and symptoms" when the viral load was performed because of signs and symptoms or reported exposure event?

[Name]: Thank you for the opportunity to provide feedback on the draft updates to the CDC PrEP guidelines. I am offering comment on behalf of the HIV Medicine Association.
The updated guidelines make important updates to the recommendations to be more inclusive and to recognize importance advances in PrEP medication options and in new models for

delivering and expanding access to PrEP. Our comments largely focus on recommendations to further strengthen the guidelines.

- We were pleased with the recommendation for all sexually active adults and adolescents to receive information on PrEP and for the indications to be defined by be defined by behaviors rather than by population group. This is important to reach all population who can benefit from PrEP and to reduce stigma and discrimination.
- We urge for the document to specify up front that PrEP is not just a drug but is a package of services that includes screenings, lab monitoring and adherence counseling.

[Name]: We strongly urge the use of people first language throughout the document and avoid stigmatizing language, such as "HIV positive partner" "HIV-infected" and "HIV infection."

- We were pleased to see the addition of guidance for Telehealth for PrEP. For this to be a viable option, it will be important to make permanent the expanded coverage and reimbursement for telemedicine allowed during the pandemic. We also will need ensure that labs will accept self-administered swabs for STI screening (page 39).
- Lastly, with the increase in states that are authorizing pharmacists to provide PrEP, we urge CDC to provide guidance in this document or in future supplements on minimum standards and best practices for these models that offer the potential to expand access and connect individuals not in regular care with primary care and other preventive services.

[Name]: Suggest Table 1a: "estimated creatinine clearance >30ml/min", I suggest you write out in this point the full footnote #3 to make it really clear.

[Name]: Need to clarify my earlier comment - I would like to see more clarity about offering of TDF - we know the vast majority of PrEP users (oral PrEP) do not clinically require TAF. In an earlier comment, I mistyped.

[Name]: I am also wondering why it is not suggested that everyone, regardless of gender, on PrEP get STI testing q3mo (or q4 if on injectable PrEP).

[Name]: Yes **[Name]**!

[Name]: Absolutely!!!

[Name]: Yes! Helps eliminate the reinforcement of a gender binary. Great point!

[Name]: Agreed.

[Name]: Absolutely **[Name]**. Very important that assessment does not conform to binary sexual models.

[Name]: Thank you **[Name]** I write about that evidence /data in this article: https://www.thebody.com/article/ask-the-expert-restarting-hiv-prep . The data is out there. Consumers of PrEP have a right to see it.

[Name]: It's important that the CDC guidelines be revised to not mandate indefinite quarterly appointments. Patients can get their lab work done outside of an appointment context. Being required to attend appointments and potentially pay an office visit copay every three months while on oral PrEP is a barrier to care in overly medicalizing PrEP, especially when people may need to take off work to attend appointments.

[Name]: My name is **[Name]**, Biomedical HIV Prevention Coordinator at San Francisco City Clinic. I've been heartened to see increasing visibility of trans people in this document over the years, and want to see it go even that much further in that direction with this update. So I have two items of comment to make:

1. Because we don't want providers to be too nervous to Rx PrEP to trans people, or to emphatically recommend they use it, it's important to include the most recent data from iBreathe, which showed that there were no significant differences in TDF concentrations in DBS between TGM, TGW, and CGM, and that all TGW and TGM were projected to achieve highly protective concentrations of PrEP drugs https://pubmed.ncbi.nlm.nih.gov/32766890/. It is also important to include presentation from CROI 2021 on PrEP levels in PBMCs among trans adolescents. While there were some differences between TGM and TGW (thought to be due mostly to differences in kidney function), the authors reported that mean drug levels in PB.

[Name]: I agree with the comment by **[Name]** of the SF DOH regarding the inclusion of the data that we have to date regarding drug drug interactions with F/TDF and gender affirming hormones / androgen blockers. PBMCs were within in the ranges of previously reported studies: http://www.croiwebcasts.org/console/player/47391?mediaType=slideVideo&
So I ask that you emphatically state that there is no reason to believe that TDF/FTC PrEP is less effective at preventing HIV acquisition for trans people, with or without concurrent use of hormone therapy.

2. In the sexual history taking section, "Sex with men women or both" should be replaced with "what are the genders of your sex partners?" to capture all possible genders that the patient has sex with. This is important in the example of cisgender men who have sex with trans women, who are vulnerable to HIV acquisition given the high prevalence in their sexual network,and may transmit it to their trans female partners.

[Name]: Going to say something again, in a different way from earlier. I think it is important to be VERY VERY CLEAR in what cases TAF is clinically recommended. There are far too

many ppl on TAF who do not need to be on it for clinical need, These guidelines need to follow science - not the financial interests of pharma.

[Name]: Table 4 should be updated to reflect the GAHT ddi data

[Name]: I agree that the comment that same-day PrEP is still valuable even for people experiencing homelessness, substance use disorders, and/or severe mental illness.

[Name]: No attending quarterly visits should not equate to not receiving a PrEP rx…. if you think about it, it is counter intuitive.

[Name]: Agree with the comments about the change in quarterly monitoring *visits.* Lowering the barrier is huge, and for the folks I serve who are highest risk, there are a lot of barriers to meeting at X office at Y time. Agree with lab testing to assess for STIs, creatinine, and HIV.

[Name]: Strongly agreed with the verbal comment just made -- most people will have sex at some point, so waiting to educate people about PrEP until they're already sexually active and waiting to offer it while they're having sex makes no sense. Contraception offers do not hinge on already being sexually active.

[Name]: Comment for the Primary Care Considerations section: HPV vaccination should be considered for up to age 45 and not just recommended for age 26 for persons on HIV PrEP. While the general recommendation for age 27-45 is to have a discussion about HPV vaccination with their clinician, the benefits likely outweigh the risks for persons on HIV PrEP and should be at the very least mentioned to this age group as well. There are some comments in CDC guidelines about having less benefit in this age group because they may be exposed to HPV already, but the vast majority of people have not been exposed to all 9 strains in the HPV vaccine.

[Name], from DPH in San Francisco: will we see changes in eCrCL in real time if we are just monitoring yearly? Is there more specific guidance around monitoring decreasing eCrCl?

[Name]: The New York State Department of Health recommends PrEP be offered to people who *anticipate* having sex in the future: https://www.hivguidelines.org/prep-for-prevention/prep/#tab_2 " Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future." CDC should do the same in their guidelines.

[Name]: A few errors/typos for CDC's consideration: In Table 3, the list of most common side effects for F/TAF and F/TDF is incorrect. Please update to reflect that for F/TAF for PrEP, the most common side effects reported in the DISCOVER study were diarrhea, nausea, headache, fatigue, and abdominal pain (Descovy US PI 2021 [Section 6.1, page 12 Table 2] . For F/TDF

for PrEP, the most common side effects reported in iPrEx were headache, weight loss, and abdominal pain (Truvada US PI 2021 [page 11 Table 5]). The Table 4 drug interaction table currently excludes data on potential drug interactions with drugs that reduce renal function or compete with active tubular secretion. Please include examples of this interaction, which can be found in the USPI for F/TAF under section 7.2, "drugs affecting renal function." (page 14)

[Name]: In Table 13, "Evidence Summary of Randomized Clinical Trails – HIV Incidence Findings", please include HIV incidence data from the DISCOVER study, which is currently not included (Mayer 2020 [page 244 paragraph 2, page 243 figure b]).
In the second paragraph of the "Recommended Oral Medication" section, F/TAF's eCrCl lower limit should be "greater than or equal to 30ml/min", rather than "greater than 30 ml/min." (Descovy US PI, page 5, section 2.4). In the third sub-bullet of the draft guidelines summary under daily oral PrEP, the weight requirement for F/TAF should be "adults and adolescents weighing at least 77lbs", rather than "77kg" (35kg is the correct number in kg). (Descovy US PI, page 5, section 2.4).

[Name]: Agree with **[Name]**! Gender specific questions are not inclusive and pose a trust barrier between provider and potential PrEP user and we know historically that male partners of trans/transgender women most often do not disclose do to intense society stigma. Thank you.

[Name]!

[Name]: Thank you **[Name]**! <3

[Name]: Given that the CDC acknowledges that PrEP is substantially more protective than condoms, and given that PrEP use affords a person more autonomy and control than condom use possibly can (which is especially relevant for cis women, receptive partners, people experiencing intimate partner violence, etc.), it is important that PrEP be offered even to people who report consistent condom use. Some people may be experiencing substantial HIV anxiety while using condoms. Some people may be experiencing substantial reductions in sexual pleasure and intimacy related to condom use. We wouldn't withhold long-acting reversible contraception that reduces pregnancy likelihood to people who report using the withdrawal methods or condoms, because we recognize that those methods are not very effective long-term, while LARC is.

[Name]: There are a number of generic options for TDF. I recommend adding in information about these generic options. Too many folks - including clinicians - lack education and awareness about generic meds, and believe that generics are somehow automatically inferior. A chart with all approved generics would be helpful, with some context/text about generic meds

[Name]: Agree with **[Name]**. Including information about generic TDF/FTC being therapeutically equivalent to branded Truvada would be very helpful.

[Name]: Regarding language in the guidelines: based on the document & oral presentation it appears there's an intent to draft more inclusive language re: transgender persons (e.g "persons with childbearing potential"). I find it troubling that much of the language is still exclusive of transgender men and non-binary people. Specifying populations using language such as "men and transgender women" is nonspecific and confusing. While clinicians may understand that this "men" refers specifically to cisgender men, patients who are familiar with needing to educate their providers on PrEP and other healthcare issues may encounter this information and find it confusing.

[Name]: I wasn't able to access the supplement before this meeting

[Name]: The supplement was not actually accessible from the link.

[Name]: thanks **[Name]** - TDF/FTC (I dropped the FTC part - sorry for that).

[Name]: We weren't able to see the supplement.

[Name]: There was an error in the supplement link.

[Name]: I strongly agree with the verbal comment made that the guidelines for PWID need to include all PWID, even those who do not report having yet shared injection drug equipment. Information from National HIV Behavioral Surveillance indicates that nearly 60% of PWID in surveyed cities reported having shared injection drug equipment in just the last 12 months. It's very common, and PrEP should be proactively offered even prior to someone having engaged in it. Agree -- the supplement link had an error so we never were able to see it.

[Name]: yes, supplement link was not accessible to me either.
.
[Name]: me either.

[Name]: If you are considering wrapping up after a lull in questions - it would be great to keep this meeting open/running until the designated end time to allow people joining late to still add comments.

[Name]: yes **[Name]** - agree! Don't rush us off!!

[Name]: Neither link worked for me.

[Name]: ok, thank you; it may be helpful to also have at least in Table 1b so that it is not missed.

[Name]: Will there be a clarification on 211 TDF/FTC about guidance on missed doses? Are patients recommended to take nPEP if they forget a dose during 211? What is considered a missed dose (2 hours after? 4 hours after?).

[Name]: Will the recording of this meeting be available after the meeting?

[Name]: Can someone link the supplement draft in the chat? This is the link we were given that never worked - https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2021.pdf.

[Name]: Can you post link to supplemental?

[Name]: https://www.cdc.gov/hiv/clinicians/guidelines/index.html

[Name]: I have been able to access the Supplement from that link.

[Name]: @**[Name]** Then you are one of the very few.

[Name]: To include nonbinary people in the PrEP guidelines, it's important that the phrasing "sexually active men and women," "recommended for HIV prevention in men and women," "for both men and women" be revised in some way. An alternative could be "for sexually active people of all genders," "for all adolescents and adults," etc.

[Name]: Among sexually active adults, the indications for PrEP include "history of inconsistent or no condom use," but this excludes people who want PrEP because they would like to reduce or discontinue their condom use in the future. This is a critical group to include.

[Name]: Here is the working link https://www.cdc.gov/hiv/pdf/risk/prep/prep-cdc-hiv-prep-provider-supplement-2021.pdf

[Name]: @**[Name]**. Thank you. It's nice to offer clients the opportunity to talk about things that might affect their sexual health rather than have to disclose risk.

[Name]: *Strongly agreed* with **[Name**! It is essential that people who are interested in PrEP because they want to have more sexual partners, more condomless sex, nonmonogamous relationships, etc., be encouraged to use PrEP.

And strongly agreed with **[Name]** regarding the importance that people using PrEP not be told they must use condoms while on PrEP.

[Name]: I agree with what **[Name]** stated.

[Name]: great point on generics by last speaker. Perhaps include actual cost difference TDF/FTC vs TAF/FTC https://www.sfdph.org/dph/files/reports/StudiesData/STD/STD032021.pdf.

[Name]: Strongly agree with **[Name]**.

[Name]: Strongly agree with **[Name]** as well.

[Name]: Can we have a moment to review the supplemental guidelines now that we can see them?

[Name]: On the Supplemental document, pg 21 regarding Cabotegravir and missed appointments. I might suggest adding language regarding time frame by which that appointment should be made so as to not let too much time lapse between injections.

[Name]: American Pharmacists Association (APhA) has collated detailed (line-by-line) feedback from our members. What is the best way to submit this input to you for your ease of review?

[Name]: **[Name]** makes a very good point.

[Name]: Thank you! Where will the recording be posted?

[Name]: I agree with **[Name]**. Not sure if this is in the document, but if you want to mention condoms I recommend it say something to the effect of "It is recommended that you have condoms available for free and on clear display at your clinic, if budget allows." Having condoms available enables people who want to prevent STDs using condoms, to easily access them at their visits. Without pushing condoms or making a values statement about the role they "should" be playing for any patient.

[Name]: Also want to go on record to say that limiting input around the guidelines into 2 webinars with no other way to give input is really problematic.

[Name]: To add to my previous comment, the supplement also neglects to include people who want PrEP so they can stop using condoms. For example, the FAQ "should I consider taking daily PrEP" responds "if you are a man or woman who sometimes has sex without condoms," but could read "if you sometimes have sex without condoms or would like to do so in the future."

[Name]: Agreed with **[Name]** regarding this being a very unideal format of feedback delivery.

[Name]: *Strongly* strongly agree with **[Name]**'s point above regarding people who are interested in stopping using condoms or no longer needing to rely on condoms for HIV prevention.

[Name]: Please include 2-3 page "summary" in the supplement on prescribing PrEP that can be accessed in point-of-care by primary care clinician; PrEP should be provided by primary care clinicians, but as a primary care clinician (and HIV specialist) I worry it is unreasonable to expect primary care clinicians to sort through 100 page document to provide necessary preventive care; this becomes a barrier in itself.

[Name]: Having concerns with lipid monitoring in STI clinics without access to primary care providers. Many of these clinics offer STI testing and treatment, but do not have capabilities to address hyperlipidemia with labs and with treatment. This could become a burden to these clinics without necessary resources.

[Name]: @**[Name]** - great point about keeping the access at STI clinics.

[Name]: Yes **[Name]**!

[Name]: A recording of each of the two webinars and accompanying transcripts and written responses will be posted at https://www.cdc.gov/hiv/programresources/planning.html.

[Name]: **[Name]**, She/Her/Hers, California Department of Public Health/Office of AIDS/Prevention Branch. Agree with **[Name]**. As we try to increase PrEP provider detailing outside of HIV experience, we know that providers already have a hard time taking sexual histories and adding a condom discussion only increases that difficulty, especially with communities they may not have experience with. Have the MA give them some safe sex lit on the way out.

[Name]: I agree with **[Name]**'s comment about barriers with asking patients to commit to whether they're doing 2-1-1 dosing or daily dosing. It is extremely problematic that the guidelines recommend that people using 2-1-1 PrEP only be given a 30-day PrEP prescription and must get a new HIV test before they can get another PrEP prescription. People should have the freedom to switch between the two dosing regimens, which requires that people reporting intending to use 2-1-1 still be prescribed the same quantity of PrEP pills as people using daily PrEP so that they can choose to switch to daily at will.

[Name]: An easy destigmatizing language revision -- replace "HIV infection" here with "HIV status": “HIV infection should be assessed at least every 3 months for patients taking daily oral PrEP.”

[Name]: Can CDC define PrEP as prescribed medication PLUS the wrap around services that are critical to this intervention - HIV, STI screening, medical monitoring, sexual health counseling.

[Name]: Again — Please give us a chance to review before ending this session.

[Name]: Table 1 b: Unclear why in the follow-up care "at least every 12 months (after the first injection). In the bullet it specifically states Chlamydia screening for women which is unclear as to why chlamydia only and not GC and why only targeting women.

[Name]: Why do the guidelines recommend that cis women only receive chlamydia screening annually but receive gonorrhea and syphilis screening every six months, when chlamydia is more common that gonorrhea or syphilis, especially among cis women?

Strongly agreed with **[Name]**'s comments about condom counseling for people using PrEP. It fosters distrust in PrEP to indicate that people should use condoms while on PrEP because PrEP doesn't provide 100% protection.

[Name]: I agree with **[Name]**'s point. We want to increase "PrEP confidence" like we have wanted to increase COVID-19 vaccine confidence - the intervention works and highly effective, way more so than masks/condoms. So rely on it! Don't hesitate to use it.

[Name]: I completely agree with **[Name]**'s comment about the FAQ on PrEP and condom use.
[Name]: CDC's own language around condom efficacy indicates they are LESS effective than PrEP – IJS.

[Name]: The language in the supplement “PrEP Information Sheet” states that Descovy is an option for men who have sex with men, and in the same paragraph goes on to say that it was “not studied in persons assigned female sex at birth. So, it should only be prescribed to MSM”. This is self-contradictory, as there are men who are assigned female sex at birth.

[Name]: I think this compliments **[Name]**'s points about alienating people from accessing PrEP: encouraging providers to discuss drug treatment programs with people who use drugs that are accessing PrEP is likely to discourage and alienate people who use drugs and are accessing PrEP. People are pushed toward treatment in so many settings, and it does a disservice to people who are seeking to care for their health while using drugs.

[Name]: It is very difficult to keep up with the written comments here while also reading the supplement that we didn't have access to until now.

[Name]: provide HIV PrEP to patients at City Clinic in San Francisco. I am wondering why updates to the PrEP Guidelines do not include routine q3 month screening for STIs for all MSM

(rather than suggesting q3-6 month screening frequency based on risk). Since the release of the last HIV PrEP guidelines, a study among MSM on HIV PrEP published in AIDS (https://pubmed.ncbi.nlm.nih.gov/32205724/) indicated that if screening had been conducted only semiannually or based on symptoms, identification of 34.3% of gonorrhea, 40.0% of chlamydia, and 20.4% of syphilis infections would have been delayed by up to 3 months. The vast majority of participants (89.2%) with asymptomatic STIs reported condomless anal sex and had a mean of 8.1 partners between quarterly visits. Quarterly screening provides the opportunity to treat these infections and decrease transmission of STIs in the community. While there may be some patients who may not require screening q3 months, it is much easier for physicians to routinely screen all patients for STIs every 3 months when ordering their HIV test. Increasing the frequency of STI screening can have a tremendous public health impact on reducing STIs in the community (https://pubmed.ncbi.nlm.nih.gov/20393383/; https://pubmed.ncbi.nlm.nih.gov/20393383/). HIV PrEP should be considered not only a method to reduce HIV infections but also a strategy to reduce STIs.
[Name]: I also agree with **[Name]**'s point re: condoms! The language about condoms seems to reflect values rather than science and is counterproductive to the extent it discourages PrEP uptake.

[Name]: Is the "annual chlamydia screening for [cis]women" just carrying over from USPSTF guidance? I don't think we should be considering the populations the same.

[Name]: yes **[Name]**!

[Name]: Providers in my area (southeast Tennessee) already have an opinion based on CDC guidelines that condoms MUST be used for daily PrEP. It's important for CDC to distinguish HIV prevention from Other STI prevention.

[Name]: I really like **[Name]**'s comments.

[Name]: Yes to **[Name]** and **[Name]**!

[Name]: I am suggesting that we need more consumer opportunities to manage screenings and that we should reduce barriers of cost. I am not suggesting we need less frequent testing.

[Name]: I worry about a statement around using "any ARV" for PrEP in PWID, without the data supporting this. Should clarify what "approved medication" means, and I would hesitate to recommend anything OTHER than F/TDF daily----Citing the statement in document "In addition, antiretrovirals are effective as post-exposure prophylaxis against needlestick exposures and as treatment for HIV infection in PWID. Therefore, PWID are likely to benefit from PrEP with any approved medication with or without an identified sexual behavior risk of HIV acquisition"

[Name]: Agree **[Name]** - this could be an opportunity to talk about self testing, testing at home (for HIV and STIs).

[Name]: Too much!

[Name]: Wholesaler prices range from $13.00 to $1,800.

[Name]: I am interested in the idea that TAF/FTC and cabotegravir are both recommended forms of PrEP for PWID given that studies of PrEP use by PWID have not been conducted with those regimens (or with the full TDF/FTC regimen).

[Name]: It can now be as cheap as $1/pill but pricing is still leveling out since more generics have come out. For uninsured/Medicaid patients, it is usually $0.

[Name]: https://www.cdc.gov/hiv/basics/prep/paying-for-prep/index.html This might have some more information for you, **[Name]**

[Name]: Agree with **[Name]**, Thank you for connecting the dots between the increased need for quarterly STI screening!

[Name]: Thank you, CDC, for this meeting and for allowing us to comment on the new guidelines.

[Name]: @**[Name]**, first pass liver metabolism exists for currently drugs because it is a rate-limiting step that controls the amount of the 'drug' in the system.

[Name]: "Figure 4 Clinician Determination of HIV Status for PrEP Provision" This flow chart should include possible exposure to HIV within the past 72 hours and PEP provision.

[Name]: Strong agreement.

[Name]: Home testing is awesome, but it does have some limitations like no RPR for syphilis only IgG, HCV Ab without viral load, HIV AG/Ab without viral load, etc. Can be a little cost prohibitive, but definitely adds another dimension to reaching patients/clients.

[Name]: "Monitor patients to detect HIV infection, medication toxicities, and levels of risk behavior in order to make indicated changes in strategies to support patients' long-term health." This is an example of the language that Damon and others have been critiquing. Stating that PrEP providers must monitor PrEP patients' "levels of risk behavior" is highly stigmatizing of people's sexual practices and alienates people from HIV prevention services.

[Name]: I know there is a desire to harmonize the cutoff for "false positive" HIV RNA with the DHHS guidelines, however in our experience we have seen low (50-several hundred c/mL) HIV RNA in patients initiating PrEP that identified persons with hyperacute HIV infection at PrEP start. Rather than increasing\ the threshold to 10,000 c/mL. I would have suggested that, in a person with a high pretest probability of HIV infection at PrEP initiation, any detectable HIV RNA warrants consideration as a true positive, and further testing. Thanks.

[Name]: Thanks for these clarifications.

[Name]: “For HIV testing, provide patient access to an oral swab-based self-test that the patient can conduct and report the result to the clinician (e.g., photo of the test result).” - Why is this seemingly endorsed as an adequate form of telemedicine PrEP provision when elsewhere it is stated that oral swab HIV tests are insufficiently sensitive to use as part of PrEP provision? “When HIV-negative status is confirmed, provide a prescription for a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) to minimize trips to the pharmacy and to facilitate PrEP adherence.” - Why is this recommendation limited to patients acquiring PrEP through telemedicine? It would reduce burdens and facilitate adherence for all patients, including patients attending in-person appointments, to be able to get 90-day PrEP fills if their insurance companies will allow it.

[Name]: Good point about the "<10,000 c/ml" threshold - I have never thought of this being a false positive. I would probably be getting a genotype and sending in ART!

[Name]: I agree with **[Name]**'s comment. First, "risk behavior" language is imprecise (with respect to both behavior and the risk in question) and stigmatizing. Second, it's unclear why clinicians would need to monitor "risk behavior" among PrEP users. If the point is that clinicians should have ongoing discussions with their patients about whether PrEP is still desired and appropriate, then perhaps the guidelines could say that specifically.

[Name]: “This team-based approach may also provide a larger number of providers to counsel patients about self-management of behavioral risks.” People do not necessarily want to reduce their "behavioral risks" to HIV exposure while on PrEP because PrEP protects them from HIV without involving sacrifices in sexual freedom, pleasure, intimacy, or autonomy in the way that condoms, monogamy, and abstinence all do. The sexual activities that can transmit HIV absent PrEP's protection are not inherently a problem or worth counseling people to suppress, avoid, or abstain from.

[Name]: Agree with **[Name]**'s comment in the chat!

[Name]: Page 31 Section 7 - I would appreciate if the lead in sentence would more accurately reflect the rate of occurrence based on literature. The sentence makes it sound common.in the provide supplement.

[Name]: “and in cervicovaginal tissues at approximately 20 days.” - The WHO and IAS-USA are at this point both recommending 7 days of daily dosing as the time to protection for people having receptive vaginal sex. Why is the CDC continuing to state that 20 days of daily dosing are necessary for people having receptive vaginal sex?

[Name]: Cabenuva - cabotegravir and rilpivirine.

[Name]: I agree with Eric — but also glad there is some accountability when providers hear about suspected HIV acquisitions on PrEP.

[Name]: Cabenuva.

[Name]: Cabotegravir alone is being studied for PrEP has been studied - sory, it is awating FDA approval.

[Name]: “Assess and provide support for medication adherence and risk-reduction behaviors;” - Another example of stigmatizing, coercive practices that we're recommending be removed from the guidelines.

[Name]: Cab studies among adolescents are ongoing :)

[Name]: “Feminizing hormones (Spironolactone, estrogens) No data available. ”Why do the guidelines say there are no data available on administering CAB PrEP with feminizing HRT when 12% of HPTN 083 participants were trans women? What was the point of ensuring that high of a participation rate among trans women if we couldn’t conclude anything about this from it?

[Name]: Agree with **[Name]**— Please consider from the consumer point of view how the language promotes stigma and shaming.

[Name]: Agreed with **[Name**]- we should not be driving HIV Stigma in these guidelines.

[Name]: I think the CDC would do very well to work WITH consumers on how some of these provider guidelines may promote collaboration and conversation, and agency.

[Name]: “Clinicians who elect to provide the 2-1-1 regimen off-label should prescribe no more than 30 pills without follow-up and documentation of another negative HIV test. Patients having sex less than once weekly will have sufficient medication to cover up to 7 intermittent sexual events.” - This will create barriers to PrEP use. People should be given the freedom to switch back and forth between daily PrEP and 2-1-1 PrEP, which they can't do with this prescribing recommendation.

[Name]: Agree w **[Name]** 100%.

[Name]: I agree with **[Name]** about 211 PrEP. It doesn't make sense to limit # pills per prescription as people's risk changes all the time. What is the rationale for this?

[Name]: "the possibility of inadvertent disclosure of same-sex behavior to peers or family members since 2-1-1 dosing is only used by MSM;" - This guidance does not make sense. There is no reason why someone's peers or family would need to know why they were on the 2-1-1 PrEP dosing regimen specifically rather than daily PrEP. This isn't part of the counseling recommendations for PrEP generally even though almost exclusively MSM use PrEP. Including this here seems designed to turn people off from using 2-1-1 PrEP and discourage them."the possibility that this off-label use will not be covered by insurance." - This guidance that providers warn their patients that their insurance may not cover 2-1-1 PrEP seems designed to thwart the ability of people to use PrEP 2-1-1 or providers to prescribe it. The actual prescription does not need to be written that way for patients to use 2-1-1 PrEP.

[Name]: For our 2-1-1 patients, we prescribe enough drug at follow up visit so they have enough to get to their next quarterly visit as if they were taking daily PrEP, since many folks switch back and forth between 2-1-1 and daily.

[Name]: I'm confused about the figure 1 in the general guidelines - if we are advocating for U=U, why does it look like "persons with virally-suppressed partners with HIV" is the highest risk group?

[Name]: Could you please repost the website address, please?

[Name]: Thank you **[Name]** and everyone for opening this up..

[Name]: agreed - we need our clients to have access the best way it works for them. Clients moved from daily to 2-1-1 and back.

[Name]: Please allow the webinar to remain open until the time scheduled for ending.

[Name]: Thanks.

[Name]: my email address is **[Name]**@dhha.org. Because this meeting didn't require registration, I am not certain I am on your email list. The announcement was forwarded to me. I would appreciate getting follow up emails. THANK YOU!

[Name]: It's very challenging to listen while reading comments and while reading a 50 page document we were just given access to during this session.

[Name]: Thank you for allowing for this format of public comment! More guidelines should have this available**.**

[Name]: Just back up one slide, please.

[Name]: https://www.cdc.gov/hiv/programresources/planning.html.

[Name]: Thanks everyone!

[Name]: Thank you.

[Name]: Thank you all.

[Name]: Thank you. Will be here tomorrow.