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

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

[Dawn Smith]: So welcome to the Webinar on the 2021 draft guideline PrEP. I'm [Dawn Smith] and also today on the call is Dr. Gemma Dimitri, who is our guidelines team person.: Gema, do you want to go ahead and start?

[**Gema Dumitru]:** Thank you. Yes. Thank you, Dawn, Hope you can hear me. I am Gema Dumitru on the guideline team in the Division of HIV AIDS prevention and I would like to welcome you all to our webinar to discuss the 2021 draft clinical practice PrEP guideline and clinical supplement and I hope you are energized after lunch. Ready for a good discussion. So, next slide please.

[Gema Dumitru]: This is 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 comments from the audience. Similarly, after the overview of the clinical supplement changes and additions. We will welcome your comments and. Next slide please.

[Gema Dumitru]: So the purpose of the webinars is to provide the public comment opportunity for stakeholders. HIV infection are our primary target audience for the PrEP clinical practice guidelines and supplement. During each webinar, the guideline and supplement changes and updates are going to be presented for comment. Each webinar will be audio taped to provide complete and accurate records of the comments and all comments provided during the webinars will be considered. Of note, there is a no return comment period outside the webinar. Next slide please.

[Gema Dumitru]: And have some instructions to provide verbal comments. And we will ask for comments in the group's alphabetical by last name or another option is to make comments in the chat and we invite commenters to identify themselves by name and organization if they feel comfortable doing that. Otherwise, they can provide an anonymous comment. Also, we'd like to ask you to please keep your comments short no more than three minutes to allow participation have a large number of people. And to please not repeat the comments and questions already raised by others. Have noted that today the CDC staff will not make any, not give any specific responses to comments during the webinars, but we will answer and provide responses and those will be posted as Dawn will indicate towards the end of the webinar. Next slide please. So a few clarifications about if you choose to chat. You can do that at any time, please select chat at the bottom of the screen and select to everyone near the bottom of the chat panel. And if you

do to do verbal comments you can do it during any comment periods. And all participants are muted at this time, and we will let you know which group is eligible to speak, we hope to do that alphabetically but yesterday, we didn't need to do, There were just by simply raising your hand, you'll find that button under reactions at the bottom of the screen. You can flag that you want to speak and we will unmute you. One at a time. Next slide please.

[Gema Dumitru]: These are our two disclaimers. So the recommendations about PrEP include the use of commercial products, Truvada, Descovy, or cabotegravir when approved by the FDA. And draft documents are distributed only for the purpose of pre-dissemination review. They have not formally been disseminated by CDC. And the documents shared for review, do not represent and do not be present any agency determination or policy and I will invite Dr. Dawn Smith, please take the floor. Thank you.

[Dawn Smith]: Next slide. So what we're going to do first is, I'm going to go through things that were added to the PrEP guideline for this update or things that were changed from the 2017 guideline. I'm not going to go through the many parts of the guideline, which hasvenot changed.

[Dawn Smith]: In respect to additions that we made to the to the new guideline. The first thing was that we added a graded recommendation that clinicians should inform all sexually active adults and adolescents about PrEP. We did this it because of awareness that many clients do not know that PrEP exists and therefore don't ask for it and that many providers are too selective in who they discuss prep with. And so we wanted to try to make it a standard part of preventive practice to ensure that that patients know about PrEP.

The second graded recommendation that we added was to specify that F/TAF is an FDA approved choice and the populations for which it has been approved.

We have added sections in the document about PrEP provision via telehealth, about same-day PrEP initiation, and about prescription of Truvada or TDF/ FTC.

In addition, because we were receiving lots of comments about other primary care.issues that are relevant to persons who may be getting PrEP. We added a brief section about the primary care considerations that that providers should attend to while they're taking care of people with indications for PrEP. And last we expanded our guidance for transgender persons in the guideline. Next slide.

[Dawn Smith]: Prior to doing this update we conducted a survey of clinicians and asked what things they would like to see changed to improve the usability of the guideline. What things about the format or the way in which we presented the guideline would improve its usefulness to them. And as a result of those interviews we revised and reordered the sections of the

guidelines, such that first we describe guidance that applies to all PrEP patients, for example, screening for HIV infection, asking sexual behavior questions or injection practice questions, things that apply to all PrEP patients and then that's followed by sections that apply only to selected patient groups, for example, pregnant patients. And then we created sections for oral PrEP separate from sections for injectable PrEP as we wanted to be able to modify the guidelines.in understandable sections as PrEP modalities come online.

[Dawn Smith]: The next thing that we changed was the HIV testing algorithm to more clearly establish what the preferred and less preferred options were for establishing HIV status. And we made a change in the viral load measure below which we would consider that this may be a false positive to harmonize with the acute infections section of the HIV treatment guidelines and lastly we revise the frequency of assessing estimated creatinine to reflect different recommendations, depending on the baseline age and estimated creatinine clearance when initiating PrEP. Next slide.

[Dawn Smith]: The summary table that we include at the front of the guidelines for daily oral PrEP is largely unchanged. You will see, however, that in the boxes below that we changed the renal function screening to say that, you know, patients who are over age 50 or who have an estimated threatening clearance less than 90 when they initiate PrEP.need to have their creatinine clearance checked every six months. Other patients, those who are less than 50 and who have creatinine clearance above 90 at initiation can be checked on an annual basis.So those are the major changes in the document that is summarizing daily oral PrEP. Next slide.

[Dawn Smith]: Then we created a second similar table for cabotegravir and you will see a couple of things. First of all, the doses, obviously, and the dosing schedule for cabotegravir is different and that for daily oral PrEP. And you can see also one of the changes that we made to be more gender inclusive in that instead of referring to pregnancy testing for women, we referred to pregnancy testing for persons with childbearing potential. Next slide.

[Dawn Smith]: This is an example of streamlining of the assessing indications for PrEP that was requested by the clinicians that we try, whenever possible, to use flow charts rather than the boxes that we previously had, or tables. The content of this hasn't changed, but it was put into the format of a flowchart.

The next thing is that in places where people clearly have indications for PrEP, we have indicated prescribe PrEP. On the other hand, when you get to the bottom and there's not a clear indication for PrEP, we have not said don't prescribe PrEP; we have left that open because we intend for clinicians to apply judgment. There may be individual reasons why a person does not have a risk indication, but still should be considered for PrEP. And to emphasize that point we

added text to the documents that clearly states that providers can prescribe whether or not they have identified indications for PrEP. Next slide.

[Dawn Smith]: This is the flow chart for injection drug users. Again, it hasn't changed in terms of what's in it. It's just converted into a flow diagram. Next slide.

[Dawn Smith]: This is the determination of HIV status flow chart that has been in all of our guidelines. You can see that we now say that either laboratory based antigen antibody tests or viral load tests are equally preferred options. This is especially important when we get to cabotegravir where viral load testing may be necessary more often than for oral Truvada

You can see also we changed the viral load cut off from the previous 3,000 to 10,000. This is under a great deal of discussion. Still, the reason that was done was to harmonize with the HHS treatment guidelines. That may well change following this public comment period. Next slide.

This is an example of the primary health primary care measures The table that we created with some screening tests that are compatible with both USPSTF guidelines recommendations and in the case of STDs with our STD guidelines. And so it's hoped that this is a way to remind clinicians that in addition to PrEP, there are other things that they need to do for the primary health care of patients who are receiving PrEP. Next slide.

[Dawn Smith]: So now we can open for comments about the guideline itself. I will say two things. Number one is for today's webinar, those who are from CDC, I would ask that you not give comments on the webinar so that our external partners can express all their comments you have other opportunities to weigh in on the guidelines. And similarly, for those of you who were on the webinar yesterday, I would ask you not to repeat the comments that you made yesterday. If you have additional comments that would be wonderful. But again, we would like to be sure that all the people who, for whom this is their only webinar have a chance to be heard.

[Dawn Smith]: I've noticed that there are many things going on in the chat box, obviously it's not possible to respond to them in real time because I'm listening to the comments that people are doing verbally. There are a couple things. Number one is I will put into the chat box, the link that works to the supplement because we realized that there was a problem with that. And all of the comments that are put in the chat box will be saved and will become part of the transcript of this webinar and we will develop written responses to all the comments, both in the chat box and those that are on the transcript of the verbal comments. So, the floor is open Gemma, do you want to manage the conversation?

[Gema Dumitru]: Thank you. That just quickly, if you don't mind, giving a brief rationale for not allowing written comments.outside the webinars. Because, because there were a few questions about that. And I know you've provided that yesterday

[Dawn Smith]: Basically, we have regulations that we follow to require public comment. There are several options that are provided to us. And in general, we are not allowed to mix and match them. So if we're going to do written comments, then we do written comments through the Federal Register. And that is a cumbersome process that takes a long time. And so we have opted instead to use the option of webinar comments supplemented by written comments that can be put into the chat. This is not uncommon. This is what we have done this previously for previous PrEP guidelines and in fact it was done for the STI guideline update this year.
I would encourage you to think of it as, you know, when we were very first back in the beginning, developing PrEP guidelines, we had a big public meeting and people went to the microphone and made their statements. And this is sort of the corollary of that . Once we commit to a method, then we have to make our responses to that method. So, we will record all of these comments, both from the chat and from the webinar itself We will collate them into a set of issues and then those will develop responses. The voice recording will be posted online for both webinars. The transcript of the webinars will be posted online and then the responses to all the issues raised will also be posted online.

[Gema Dumitru]: Thank you, Dawn. I see colleagues with their hands raised and I invite please go ahead and comment.

Oral Comments During Webinar

[Name]: Hi I'm [Name] with [Name] in Washington, DC. I really just wanted to first commend CDC for updating these draft guidelines. I think you've really done a very good job on adding many new components. I'm not going to have many comments. I think it's great that you added in Descovy and cabotegravir as well assuming those will be FDA approved soon. I think those are great additions. The one comment I would have when you talk about the differences between Truvada and Descovy, is that there is a pill size difference. You know we're trying to increase uptake and adherence to PrEP. I think that should be pointed out to providers and clients as well that the pill size is a lot smaller with Descovy. My other two comments have to do with the financial case and management issues section. There's a discussion that the US Preventive Services Task Force Grade A comes with no patient cost sharing for the drugs and the way it was worded it says when fully implemented. Well, it's already implemented - plans had to start doing it last June and all of them that have to comply had to do it this past January. So, I would just remove those words. Also, there was no discussion about paying for ancillary services in that section as well. You know, the ancillary services was throughout the document, but that’s one been one of the barriers actually paying for those ancillary services. So hopefully,

you know, there'll be guidance coming out of CMS that says that for people with private insurance that there's no cost sharing for those ancillary services, and with Medicaid, they should be covered as well. And then there's other options too, you know, government programs, the CDC funded health departments and CBOs should be helping with the ancillary services. Also, we now have the community health centers that paid for PrEP and PrEP services as well. So I just thought those things would be great additions. Thank you.

[Name]: Thank you, [Name]. [Name] please go ahead,

[Name]: Hi, everyone. Thank you. Next I would like to echo many of [Name]'s comments. We would like to suggestion some additions to the financial case management issues for PrEP section starting on page 63 in the guidelines draft for public comment. And really, the suggestions are additions to provide detail and clarify common questions from providers, including whether clinical visits and labs are covered with that cost sharing, which [Name] just mentioned, the zero dollar coverage and how it applies to out of network providers and how providers can convey to a health plan whether a PrEP related office visit or lab is part of a PrEP service and considered preventive. So very much along the same lines in terms of coverage. I will put our suggested additions with the regulatory references in the chat, and thank you, thank you so much for putting together these guidelines and for all of the updates.

[Name]: Thank you, [Name]. Next, [Name]. Thank you.

[Name]: Thank you. Um, I was just, you know, interested in the decision of the guidelines committee to sort of not really talk about hepatitis C virus screening really outside of basically just making a recommendation that it be done in coordinates with the regular CDC HIV testing guidelines. Given there isn't obviously consensus on this issue, but we are seeing now more and more emerging evidence that HIV negative individuals enrolled in PrEP especially MSM are at a particularly high risk of HTC seroconversion and acquisition. I just think that it would be useful for the guidelines can be even if not an explicit guidelines recommendation that are more frequent HCV testing implemented that a discussion of this issue be actually brought up in the guidelines, just to make clinicians aware of this. Thank you.

[Name]: Thank you [Name], please comment.

[Name]: This is [Name] from [Name] just a few quick sort of overarching comments. One is, I think you already addressed this, but the very, very short time frame that was allowed between when the publication came out and this webinar. So, while we certainly understand that this is the route you took folks only had a week to sort of get together comments. Which meant that associations like ours was not able to put together a formal comment during this timeframe and although many of our members have put some comments in the chat yesterday and today, so I

do thank you for allowing us to put that information there. The second comment I have is just that at least in the past pre-COVID, the FDA, which is part of HHS as well, did have an opportunity to provide comments both written and oral at meetings and I think that welcome addition to this while I realized that this is a way to get your feedback sooner. It really limits the ability in the in the way we can read feedbacks. For example, the chat has a character restriction so it just makes it very difficult to contribute comments. And then, just my last comment that I'd like to make Is that the provider supplement actually wasn't available so that couldn't have even have been reviewed and given comments by today if folks had other things on your plate. So I think just being mindful that this review process has been pretty limited and I would be interested in ways to share additional feedback so thank you.

[Name]: [Name], please go ahead.

[Name]: Thank you. Hi, this is [Name], I'm the [Name] at [Name] in Rochester, New York. Thank you for putting this together. I had a similar concerned about the timing, but my major concern is the information regarding our transgender patients and some of the language that's used throughout the document and also some of what's deemed “No data available” in terms of evidence. And I think the glaring one is if you look at Table 4 in the document that looks at the co-administration of F/TAF and feminizing hormones. So first of all, I hope this is a typo, because they're listing Spironolactone as a feminizing hormone and saying there's no data available. But keep in mind, we wouldn't say that for someone who is using Spironolactone as a blood pressure medication or a cardiac medication. So I have some concerns that this does need to be cleaned up a little bit. And the other concern I have is, which I'm really excited about, this is not a concern but there's an entire section on people who use IV drugs, but there is limited evidence in terms of a large cohort and how PrEP is used in that population. But I do love the fact that this is before it is something that we need to be doing. However, at the same time we're turning around and this document is really saying there is not enough information regarding the transgender community to make recommendations on whether or not you know things are effective. So I think the CDC has to really kind of reassess its position on the effectiveness of PrEP and transgender women. So I am a little concerned because I think that some of the wording needs to be changed. And I really think that we're going to make recommendations that go beyond the evidence, like we have for people who use IV drugs, then we should be making recommendations with the evidence that we do have. And there is an evidence that we do have, and there are studies that have been done in transgender patients specifically transgender women that do give us really good evidence. So I'm asking that that be looked at.

[Name]: Thank you, I see [Name] with hands raised. Please go ahead.

[Name]: Hi, thank you [Name] from [Name] in New York. And again, I want to echo everybody and in congratulating you on these updated guidelines really glad to see same day

PrEP make it in, U=U and on-demand PrEP. I also agree with the comments that it would be really helpful to provide further comments, because there's just not enough time to do that today. I will make a few separate comments. One is that in table 1A and 1B where you talk about identifying individuals at risk. Please strongly consider adding a bullet that says “Also, anybody who asks for PrEP” because that table makes it look like it's really only people with identified risk as opposed to. I know it's in the text comments But it's not in the table. Also adding on the table that anybody who asks for it is a candidate for PrEP would be very, very helpful. Also, including in the condom use section “Those who have a history of no condom or anticipate not using condoms in the future” would also be helpful in increasing the inclusion. In terms of follow up care, one of my biggest comment is that every three-month follow up is a huge barrier to access to PrEP. We know persistence in PrEP is a problem you say in a couple of different places that you give a 90 day supply you don't renew that until there's another HIV test but we know PrEP is effective. The danger of stopping PrEP in that situation is much, much higher than the danger of continuing PrEP and I would strongly recommend including some flexibility. Some language about working with the person and bring them in and provide another month of PrEP. We have seen a number of patients that are a health center who got HIV because they couldn't access PrEP because they couldn't make it into an appointment and by the time they got a new appointment, they had a risky exposure. So please consider some bigger flexibility around that. Where discussing T/FAT, if instead of saying that it's not for women having vaginal sex, if you could just say ‘vaginal sex’ because it does not include transgender men, it does not include non-binary folks. So if we could just say vaginal sex, it's the more accurate thing. And in general, around trans stuff. I'm so glad you've included you've changed some of the language and that's great. But I think there's still some ways to go. I think there's places where you say, men and women where it could actually just say all genders, that this is an appropriate option for all genders. Instead of saying, men and women, we have enough data to be able to say that it works in different settings. Two more comments including persons of childbearing potential. Not everybody who's of childbearing potential is actually at risk of getting pregnant to asking about risk and also somebody with effective contraception does not need to be pregnancy tested every single time they come in. But lastly figure 4, under baseline testing you say that for somebody with an exposure in the prior four weeks, you would do a viral load or an antigen antibody test. Why not a viral load in all of those folks? We're really going to be missing some of those folks who are seroconverting where they're not in the window for the fourth-generation test, but they are in the window for the viral load. I think that's a situation where a viral load is truly, truly indicated, not an ‘or’ but a ‘plus’ to get an antigen antibody and a viral load test and I will stop my comments there. Thank you very much.

[Name]: Thank you, [Name]. Please go ahead.

[Name]: Oh yes, I just want to start off by saying thank you. Thank you for having us here and hearing us out. I really only have one topic of conversation. My name is Dr. [Name]. I'm from

[Name] to be abbreviated as [Name]. I am the [Name]. My laboratory is CAPP credited and CLIA certified in 49 states. The guidelines currently state that one of the factors that limits the utility of routine use of therapeutic drug monitoring during PrEP is the, "limited but growing availability of clinical laboratories that can perform quantification of antiviral medicine concentrations under ready rigorous quality assurance and quality control standards". This is the same language that was used in the 2017 CDC PrEP guidelines, but there has been a lot of important developments in the field of adherence testing since that time. One such development is my [Name] has completed validations to perform quantitation tenofovir-diphosphate levels and the test is available nationwide to providers and PrEP users for both Truvada and Descovy. The laboratory also has the capability to process a very large volume of samples, more than 5000 a month. So in light of this expanded availability and the capabilities that [Name] has developed, we feel the language in the update to the guidelines should reflect a change over the 2017 guidelines language. At which point, this type of testing was not available. Thank you. That was the end of my comment. Thank you.

[Name]: Thank you. My name is [Name], I am a [Name] for [Name] where our focus is on adolescents and making sure that they have all the tools that are needed to make the important decisions on their reproductive health. I just have a few brief comments to make. I echo the previous comments about some of the changes to language to be more inclusive of transgender young folks, also the comments that a written common period would allow us to make more thorough comments on the document. So I do appreciate that telehealth was included, and I appreciate that the guidelines do mention that laws and different jurisdictions affect the confidentiality and ability of young people to make decisions on their health without their parents. So I think that should be definitely be highlighted that, you know, clinicians considering providing PrEP to people under the age of legal adulthood to be aware of those local laws and regulations. One thing that I would like to encourage is that there be more added to that section about some of the barriers to care and adherence for young people. They are listed there and minors, you know, difficulty adhering to their gene appears in other places. But some of that language about clinicians weighing adherence against prescribing PrEP; it makes it seem as if young people cannot handle a PrEP regime. Especially the intermittent or the non-daily preparation. Young people, indeed, can handle these types of medication regimes, as long as they are receiving the proper guidance. So some sort of medical ongoing medical counseling, ongoing financial counseling and ideally PrEP would be in the future covered by title 10 and insurance to less than these barriers to young people accessing care. Additionally, as [Name] mentioned the other parts of being on PrEP like the, the consistent testing, you know, making sure to go into two labs for that testing can be a barrier for those living In rural areas or to young people that don't have reliable transportation. So I see some of those concerns are spread throughout the document, but I would like to see them consolidated in the part of adolescent health so that primary care clinicians have all of these things in mind when they are consulting their young patients. Thank you.

[Name]: Thank you [Name]. [Name] please go ahead

[Name]: Hi there. I'm also with [Name]. I'm [Name]. Thank you for this opportunity. Echoing [Name], we want to note that most adolescents are covered under their parent's insurance. This means that their parents are responsible for medical expenses related to PrEP, such as doctor visits, prescription costs and blood test. This may hold young people back from talking to the doctors about PrEP. There was a study that we think we came out with found that 22.6% of sexually active adolescence would not seek out sexual health care because they did not want their parents to find out. In addition to this, younger people under the age of 25 are most likely to be uninsured in the United States and this deters young people from booking necessary doctor's appointments for HIV screenings and blood tests. Today we're, you know, advocates for youth for strongly urge in the CDC to update minor confidentiality language. On page 61 right after this sentence, "clinicians considering providing PrEP to a person under the age of legal adulthood should be aware of local laws, regulations and policies that may apply". Our ask is adding two sentences: 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 explain, which are suggested by the PrEP education for youth serving primary care providers toolkit that was developed in partnership with SIECUS". Thank you.

[Name]: Thank you. I see [Name].

[Name]: Yeah, so just a comment. Young people may not be competent to actually assess their reproductive health needs and abilities until the age of 25. Apparently, according to the Scientific American magazine the brain hasn't fully developed until that age.

[Name]: Thank you, [Name].

[Dawn Smith]: Unless I hear, otherwise we can move on to the supplement. Can you give me the next slide? Okay, this the supplement is obviously briefer than the guideline and really intended to provide some aids to clinicians that are based on the guideline itself.

[Dawn Smith]: And so one of the things in there as a patient visit checklist and we updated that to include sections for patients who are on Descovy, patients who are on 2-1-1 PrEP and patients who are on cabotegravir. The intent of the patient visit checklist is to make sure that the provider has in front of him a list of things that he needs to discuss with the patient when he or she is prescribing any of these.

[Dawn Smith]: We also added information about F/TAF to the patient information sheet that previously just talked about F/TDF. And then we added a separate patient information sleep sheet that's about cabotegravir. And then throughout the supplement, we add a text specific to cabotegravir whenever it seemed like it needed to be additional to what was previously there.

[Dawn Smith]: I know that there was difficulty in accessing the supplement. But do people have any comments about the supplement, who those who have had a chance to look at it. So a number of people have their hands up, or they are the hands up from previous questions and you didn't take it down or do you still want to be called on?

[Name]: This is [Name]. I did want to make an additional comment. So one of the other things I meant to say is the importance of including transgender men in these guidelines. There's a missed opportunity to educate folks about transgender men and the risk that transgender men who are having sex with men [have]. Transgender men can have sex with all kinds of genders, but transgender men having sex with men are at high risk for HIV and they're oftentimes not included in guidelines and so I'd really like to see some [information]. The whole section on transgender individuals doesn't say anything about transgender men, so I think that is an omission that we should correct.

[Name]: Now, I see [Name].

[Name]: Just a quick question, what specific communication or strategies are addressed in terms of the African American gay community, very specifically, culturally relevant strategies in terms of getting them to use PrEP?

[Name]: Thank you, [Name]. Do you have specific suggestions that you think should be included in the guideline?

[Name]: Well, I mean, just, you know, in terms of communication venues that are available. For example, many African Americans use apps now, apps like men for men, I'm sorry, Adam for Adam, Jack, those kinds of things. Is there a concerted effort to reach this population where they are, in terms of advocating for them to use PrEP? Those are some of the things that could be used in order to be able to do that because that’s where a lot of sexual communication activities are happening now.

[Name]: Thank you, [Name]. I do not see any other raised hands at this point but anybody wants to comment please go ahead.

[Name]: Okay not hearing any comments. Next slide.

[Name]: We will condense them into a set of issues. So for example if three people make the same recommendation, then we will put that all in one section and we will make a response to each of the comments that were see

Text Comments in Chat during Webinar

[Name]: Hi everyone, just wanted to articulate at the beginning Treatment Action Group's position that we believe there should be an opportunity to submit written comments on the guidelines.

[Name]: I can hear you.

[Name]: Thank you **[Name]**. On behalf of AIDS Foundation Chicago - we agree with your position.

[Name]: Thank you for the suggestion **[Name]**. However, this year we are using the webinar format for public comment. Please enter written comments in the chat or by speaking them for the recording and transcript.

[Name]: Limiting the ability to comment to a grand total of 3 hours across 2 webinars on 2 days before a major holiday means many individuals/organizations won't be able to provide critical feedback.

[Name]: Especially given that the provider supplement link we were provided initially did not work and we were just provided the corrected link yesterday during the webinar.

[Name]: Yes, thank you **[Name]**.

[Name]: Thanks **[Name]**, but that's not at all ideal for sharing comments - if there is a rationale for not accepting written comments, it would be helpful to hear it.

[Name]: The draft guidelines state that for most PrEP users, there is no reason to switch from F/TDF to F/TAF. This ignores both an individualized approach to patient care as well as a provider's clinical judgement. The CDC should update the guidelines to acknowledge that there are reasons to switch from F/TDF to F/TAF including : to preserve renal function in patients with renal risk factors or declining renal function, if the patient consistently takes medications that interfere with renal functioning or monitoring, to preserve bone mass in patients with risk for bone loss, or in patients with conditions that require medication that may reduce bone mass, if the patient has an intolerance to F/TDF, or if the patient prefers smaller pill size. The draft guidelines state that for most PrEP users, there is no reason to switch from F/TDF to F/TAF.

This ignores both an individualized approach to patient care as well as a provider's clinical judgement. The CDC should update the guidelines to acknowledge that there are r [omission]

[Name]: Are you developing consumer messages about the changes, especially the change the in the frequency of laboratory monitoring?

[Name]: My colleague and TAG's HIV Project Director **[Name]** shared some comments which I can post in the chat, but I think it will highlight the inadequacy of this process.

[Name]: The guidelines currently exclude data necessary to understanding the full clinical profile of CAB, notably, seroconversion and resistance data that may be critical to helping providers make informed patient care decisions (Marzinke M, et al. vCROI 2021. Oral #153 [slide 16-28], Delany-Moretlwe S, et al. vHIV R4P 2021. Oral #LB1479 [slide 11]).
With the inclusion of the most recently presented HPTN 083 and 084 data, the CDC should discuss the possibility of HIV infection and delayed seroconversion despite on time CAB injections, the development of INSTI resistance, and the potential implications of INSTI resistance on HIV treatment options for CAB users who acquire HIV.
Table 16 should be updated with resistance data from HPTN 083 (Marzinke M, et al. vCROI 2021. Oral #153 [slide 18-28]).

[Name]: Appreciate CDC getting ahead of CAB as PrEP conversation. I'll be interested in hearing how they want to move forward with this following an FDA approval. Will they immediately make adjustments or will we have to wait a significant amount of time before it's officially incorporated? Glad to see that they are lessening the frequency/burden of labs. Interested to hear what other advocates think about maintaining the 3 month HIV testing requirement- also, it should be clearer upfront what providers should keep in mind for masked infections. Also- shouldn't viral hepatitis testing be featured in the summary somewhere? This seems shortsighted- though it is included further down in a chart on page 43. I think it should be bumped up. Also- not sure why viral hep disappears in table 7 on pg. 49.

[Name]: Table 13 currently does not include the latest HIV-incidence data for CAB from HPTN 083. The CDC should update Table 13 accordingly (Marzinke M, et al. vCROI 2021. Oral #153 [slide 16]). Table 15 needs to be updated as it does not include complete adverse event data from HPTN 083 and 084. (Landovitz, et al. AIDS 2020 #OAXLB01, [slide 23-29], Delany-Moretlwe S, et al. vHIV R4P 2021. Oral #LB1479 {slide 21-24]). The draft recommendations do not provide guidance on what to do if a CAB user misses or is late for a scheduled injection. Recently presented data may help with this recommendation (Han, et al vCROI 2021. #373). The CDC should summarize this population modeling data for CAB dosing interruptions and consider providing provisional recommendations for management of CAB users who have missed scheduled injections. This is important as missed visits may occur

in the real-world and providers should understand how this may impact CAB users differently than oral PrEP users.

[Name]: We still need to ensure that the words in the guidelines account for people underreporting stigmatized behaviors. Simply asking about PrEP indicates that a person likely needs it- even if they don't talk about anal sex, injection drug use, lack of condom use, etc. because of fear of being shamed. I'm not sure if the wording gets there yet. They actually have good wording on this at the bottom of page 23, however.

[Name]: Under dosage in the first summary chart, I think it should show that generic F/TDF is available (right now it makes it look like Truvada is the only option).
The CAB summary chart doesn't talk about what to do if doses need to be taken early, late- if they're missed- or anything about at what time you have to start with a loading dose again. I think these are going to be significant questions as providers get used to prescribing.

[Name]: The American Pharmacists Association (APhA) appreciates the opportunity to provide feedback on the PrEP Clinical Practice Guideline and PrEP Clinical Providers' Supplement 2021. Pharmacists play an essential role in the management and provision of PrEP to patients and value providing care to those who seek it or are recommended for it. APhA gathered input from expert pharmacist members in this area who provided commentary and insight. Our feedback is as follows:
- APhA recommends ensuring inclusivity throughout both documents is comprehensive, especially in language (lack of consistency and inclusivity throughout) around the trans population.
- APhA encourages efforts to require coverage for HIV PrEP services, including for services provided by pharmacists and the medications associated with PEP/PrEP. Additionally, consider the population who may benefit most from new CAB therapy such as those affected by substance-use disorder, homeless, or others with issues around pill-burden and the lack of insurance.

[Name]: While the draft guidelines do acknowledge the PK "tail" of CAB, the CDC should include the recommendation that CAB users who discontinue should initiate oral F/TAF or F/TDF in relevant summary tables. Providers may overlook this recommendation if only included in the narrative portion of the guidelines. The CDC should also provide guidance for how long the PK tail should be covered with F/TAF or F/TDF after discontinuation of CAB.

[Name]: Because of the information provided to date that includes that African American's kidney function may be more of a clinical concern, the change in frequency truly needs clear justification to avoid medical mistrust.

[Name]: Hi there, I'm a clinical pharmacist at Equitas Health and wanted to provide comment on the listed drug interaction between TDF and feminizing hormones (spironolactone, estrogens) resulting in lower tenofovir-diphosphate rectal tissue levels in Table 4: Oral PrEP Medication Drug Interactions. It is my recommendation that Table 4 is amended to either omit this potential interaction whose mechanism and influence to efficacy of tenofovir has not been well-characterized or to update this table reflect the results of the studies being referenced and represent them in context with larger studies such as the DISCOVER trial. I have additional comments summarized in a document I will try to attach.

[Name]: I'm confused for figure one on page 24- why are "persons with virally-suppressed partners with HIV" at the center? If their partners are virally suppressed, I don't think they're the MOST at risk group.

[Name]: There should be very clear clinical indications for prescribing Descovy. There should be clear information about generic versions of Truvada that have been approved and are available.

[Name]: Figure 2 on page 25 seems odd- it doesn't say what the "no" responses lead to? And again, not sure we're leaving space for patients underreporting stigmatized behaviors. I think at the top it should say "patient requests PrEP? Then educate on what is and isn't a risk behavior and prescribe PrEP." Same for the flow chart on page 28.

[Name]: The draft guidelines recommend viral load testing for all CAB users but do not include rationale as to why. This information could better guide providers in making informed patient care decisions within the limitations of various point of care facilities. Some providers/settings may not have access to VL testing. There is a recommendation that HIV testing for CAB users be done "when" CAB injections are given, not "before." The CDC should clarify that HIV viral load results should be obtained prior to initial or subsequent CAB injections

[Name]: The American Pharmacists Association (APhA) commends the inclusion of tables and flow charts as they enhance ability to clearly follow steps and ensure completeness. However, discrepancies were identified with some of the clinical information (including missing information and incorrect references) and members provided recommendations on the organization and layout of document as well as identification of miscellaneous grammatical errors. Some of the detailed feedback and questions the received from expert pharmacist members includes:

[Name]: This language on page 26 worries me: "Clinicians should also briefly screen all patients for alcohol use disorder40 (especially before sexual activity), and the use of illicit non-injection drugs (e.g., amyl nitrite, stimulants). 41,42 The use of these substances may affect

sexual risk behavior, 43 hepatic or renal health, or medication adherence, any of which may affect decisions about the appropriateness of prescribing PrEP medication. In addition, if a substance use disorder is identified, the clinician should provide referral for appropriate treatment or harm-reduction services acceptable to the patient." CDC absolutely should NOT be making it sound like PrEP should be withheld for substance use.

[Name]: Please clarify and make consistent the recommended number of days prior to prescribing PrEP that an acute or chronic HIV infection must be excluded by symptom history and HIV testing. Although not required for initiation of daily oral PrEP therapy, is a HepB panel recommended at any point during the course therapy? Clarify in table 1a that men and transgender women at risk for sexual acquisition of HIV can also receive F/TDF for daily oral PrEP use. In regards to the dosing section in table 1b for Cabotegravir injection PrEP use - Is there any dosing lead way? Exactly 8 weeks? For Vocabria in HIV+ it is 7 days before or after their monthly date. If similar would define here and explain monthly date.

[Name]: The draft guidelines recommend viral load testing for all CAB users but do not include rationale as to why. This information could better guide providers in making informed patient care decisions within the limitations of various point of care facilities. Some providers/settings may not have access to VL testing.

There is a recommendation that HIV testing for CAB users be done "when" CAB injections are given, not "before." The CDC should clarify that HIV viral load results should be obtained prior to initial or subsequent CAB injections.

[Name]: Concerned on page 36: "Patients without insurance or a means to pay when picking up the prescribed medication that day." This likely needs to say that "medication coverage options are available, often with quick enrollment processes (see page 63)." Or something to avoid prescribers immediately assuming no insurance= no same day PrEP.

[Name]: Rather than leave the outcomes blank, recommend stating "discuss with patient."

[Name]: In regards to page 27, paragraph 2 - Does non-sterile injection occur uniquely among transgender people who inject medications? Does this risk exist purely within patients who use non-prescribed gender-affirming hormone therapy? I ask because a phrase later in this paragraph ("substantial risk") seems to imply these are significant causes for concern or that there are many transgender patients who acquire HIV-infection via these routes. It would be beneficial to include a caveat that the K65R mutation is not typically seen in clinical practice until several months have elapsed on PrEP monotherapy for HIV infection. Why should rapid point of care testing should be confirmed with laboratory testing? What is the incremental value

in doing so, and the number needed to test in order to detect a false-negative result yielded by point of care testing?

[Name]: Regarding this statement on page 31 “Chlamydia is very common, especially in young women and does not correlate strongly with risk of HIV acquisition so does not serve as an indication for initiating PrEP. However, because it is a frequent infection among sexually active women at high risk, screening for chlamydia is recommended at initiation and every 12 months for all sexually active women as a component of PrEP care.” Ask that “and as needed” be added to this recommendation. Payers may use this "initiation and every 12 months" as grounds to decline payment for chlamydia treatment. While the recs discuss how to address persons at substantial risk – they do not address how to respond to someone who requests PrEP and may not be at risk or is at inconsistent or changing risk based on his/her activities. This also does not address cases where a person requests PrEP but does not wish to disclose the reasons they are making that request. Should all persons who request PrEP be provided it?

[Name]: Unless I’m missing something in my quick scan- for the CAB section we need more on what to do for UNEXPECTED discontinuations/missing appointments. What should follow up be like? How do we reduce harm here?

[Name]: agree that leaving arrows and no direction is suboptimal.

[Name]: Table on page 25 is unclear … are the no responses “dead ends” should script follow the no response arrows? The guidelines do not specifically address risk from oral sex – should clinicians at this point consider risk from oral sex negligible for the purposes of assessing risk and prescribing PrEP? PrEP may actually result in delayed seroconversion and thus detection of infection by 4th gen assay and/or viral load? Finance section: does not address cost of CAB versus oral PrEP (generic) – and approval processes likely involved with use of CAB. Document does not address in any way increasing incidence of in-pharmacy prescribing and dispensing of PrEP – at least 2 states have advanced regulations in this regard (CA and CO). Will the approach to PrEP be tiered? How is a clinician to choose between a patient receiving cabotegravir, Truvada or Descovy? Will this be at the discretion of the provider as to which treatment is recommended or will there be guidance on the patient parameters that are required.

[Name]: I feel the financial management section on page 63 should also be included in a bullet in the summary- this is an important issue and should be featured at the top.

[Name]: There is an inconsistency regarding use of oral fluid screening on page 29 and listing oral swab based self testing in the telehealth section.

[Name]: The guidelines state individuals should start a new form of PrEP if they don't want CAB, within 8 weeks of stopping therapy. When is too soon? When is too late? Is there a difference between MSM and everyone else or whether they should do F/TDF or F/ TAF? Would CAB be a recommendation for serodiscordant partners/ can the negative partner receive CAB? If pregnant women are able to receive CAB, will there be a recommendation on which HIV treatment should be started in them initially? Whether it's 3TC/ efavirenz of F/TDF? Will the sexual behaviors that deem the recommendation of CAB be outlined in the recommendations? How often will an individual need to be tested after receiving the injection? Will testing be required prior to each moth injection? Since it is bimonthly the three-month testing rule applied to current PrEP therapy cannot be applied. Explore expanded use of pharmacies to conduct STI testing (Binx Health has CLIA Waived and home collection STI tests) and renal function (there are CLIA waived serum chemistry analyzers for this). This one stop shopping will help increase uptake and compliance.

[Name]: The injection drug flow chart does not include information on sexual partners. Recommend at least a statement to assess sexual behaviors as well as injection drug use.

[Name]: The CDC should emphasize the importance of adherence and persistence support for all PrEP users (not just oral PrEP users) including support and guidance for STI/HIV testing during use of all forms of PrEP. Emphasis should be made on the additional needs associated with in-person visits for CAB injections, and support for in person visits with a provider. Assessment of patient's desire to continue injections should occur more frequently than annually based on the HPTN 083 and 084 studies. The CDC should recommend assessment of the PrEP user's desire to continue PrEP (either oral or injectable) at every PrEP visit.
If keeping Figure 1, update the inner most bubble to "persons with partners of unknown or detectable viremic status" as "persons with virally-suppressed partners with HIV (VL<200)copies/ml) " have virtually no risk of getting HIV from that partner (U=U clarified for providers with less experience)

[Name]: The guidelines state that one of the factors that limits the utility of routine use of Therapeutic Drug Monitoring during PrEP is the "limited but growing availability of clinical laboratories that can perform quantitation of antiretroviral medicine concentrations under rigorous quality assurance and quality control standards." This is the same language that was used in the 2017 CDC PrEP guidelines, but there have been some important developments in the field of Adherence Testing since then. One such development is [commercial lab] has completed validations to perform quantitation of Tenofovir Diphosphate levels, and this test is available nationwide to providers and PrEP users for both Truvada and Descovy. And it can be self-collected by the patient. [commercial lab] has developed the capability to process a large volume of samples for these assays. In light of this expanded availability and the capabilities [commercial lab] has developed we feel the language in this 2021 update to the guidelines sho

[Name]: The draft guidelines provide STI screening based on the PrEP medication chosen (e.g. q 4 months for CAB and q 3 months for oral PrEP). The CDC should consider STI testing frequency on the basis of STI risk instead of the frequency of PrEP visits as some PrEP users may require additional testing (Tang et al. AIDS 2020 [page 1183, paragraph 2-3, Figure 1, page 1184 Table 1, paragraph 1]). Consider an STI "take home/self-administered" testing recommendation for PrEP users who have "extreme" risk, ie >6 unique partners/month, regardless of type of PrEP, to Q 6-12 week intervals, not just a "one size fits all" based on convenience of refills/injections. Guidelines need to be consistent on what method of collection is recommended for STI screening (ie Urine instead of invasive, painful, and unnecessary uretheral specimens)

[Name]: Funny that COVID vaccination did not make the table. Seems it will go from pandemic to endemic, not elimination

[Name]: In light of this expanded availability and the capabilities [commercial lab] has developed we feel the language in this 2021 update to the guidelines should reflect a change over the 2017 language when this type of test was not available beyond the research setting.

[Name]: Attaching comments on hepatitis from [Name] at TAG.

[Name]: Thank you for the opportunity to provide comments. My comments are focused on the HIV testing section. Intro p.29: "Clinicians should document a negative antigen/antibody test result within the week before initiating…" It takes several weeks for antibodies to develop absence of antibodies within one week does not exclude HIV infection. "The required HIV testing can be accomplished by (1) drawing blood (serum or plasma) and…". Plasma should be added. Overall, it should be stressed that prior to initiating PrEP, exclusion of HIV infection should be determined using the recommended HIV Diagnostic Testing Algorithm starting with an HIV antigen/antibody (HIV Ag/Ab) immunoassay performed on serum or plasma. Screening with an antibody-only test or a point-of-care rapid test should only be used if the more sensitive lab-based Ag/Ab test is not available.

[Name]: For Table 8- consider retitling to be gender inclusive rather than "Women's Health"

[Name]: Recommend statement on CDC PrEP section of website that Insurance Companies are required to reimburse for PrEP since the website is a primary educational tool for consumers.

[Name]: Also, to avoid confusion, the guidelines should use consistent language throughout. For example, the following phrases are used "documented negative HIV test result", "document a negative antibody test", "documenting HIV-negative status", "HIV-negative test status" and

"establish HIV infection status."Acute HIV infection section p.29: If acute HIV infection is suspected for any reason (e.g. reported symptoms, exposure-prone behavior), an HIV-1 RNA test should be performed. That is general recommendation for suspected acute infection. Qualifying this by saying if the screening test is negative or indeterminate may be confusing, especially because Ag/Ab or Ab-only screening tests do not have an "indeterminate" result option. P. 30: The statement "… healthcare providers should be aware that available assays might yield false-positive low viral load results (e.g., <10,000 copies/ml) among persons without HIV infection." Please note that current HIV-1 RNA tests use highly automated, closed instrument systems, which make false-positive results due to contamination extremely rare. I suggest that rather than suggest that a low viral load may be a false positive, simply state that a positive HIV-1 RNA test result that occurs in the absence of any reactive Ag/Ab or Ab-only test result should be repeated to verify acute infection, as has generally be recommended. Note: If these guidelines are also intended for PrEP monitoring, a person who becomes infected and continues to take PrEP may have a very low, but truly positive, viral load result. Clinicians should be made aware of this. It should also be noted that if someone becomes infected while taking PrEP, seroconversion may be slower than usual because of partial virus suppression.
[Name]: Thank you for the opportunity to provide comments. I am a Clinical Pharmacy Specialist at Parkland Health & Hospital System with the Homeless Outreach Medical Services (HOMES) program. I am funded by a HRSA grant to focus on HIV prevention services for our homeless patient population. Same-day PrEP should be considered and available as an option for homeless patients, especially in cases where lab draws are readily available. With Truvada going generic, it will likely reduce the drug cost for institutions and eliminate the need for PAP program. Our homeless patients struggle with follow-up tasks due to multiple barriers (e.g. transportation to pick up prescriptions). If we were able to implement same-day PrEP, it could assist homeless patients with PrEP and remove barriers to PrEP initiation. Consider revising to not discourage providers from same-day PrEP for homeless patients.

[Name]: Is there value in addressing qualitative HIV-1 testing with the low LOD vs Viral load testing for suspected acute HIV infection considering there are 2 FDA approved assays for this purpose.

[Name]: As it relates to Descvoy vs Truvada, the document says that there is no need to switch from F/TFD to F/TAF- that is not what community members are hearing. Consider providing more information on long term side effects of F/TDF

[Name]: Please consider adding ACIP guidance for HPV vaccination for older age groups: For adults ages 27 through 45 years, clinicians can consider discussing HPV vaccination with people who are most likely to benefit. HPV vaccination does not need to be discussed with most adults over age 26 years. See ACIP's shared clinical decision-making FAQs.

[Name]:Agree with **[Name]**. Many docs not aware that HPV vaccine available for older than 26.

[Name]: I am concerned about the recommendation to use Cabotegravir PrEP for PWID in the absence of RCT data. (Rationale appears to be related to frequent concomitant sexual risk, however these studies are dated and do not reflect the current drug epidemics with very frequent daily injections. (Recent network analysis from recent HIV outbreaks among PWID (including recently in MA where I practice) show transmission via injection independent of sexual transmission). http://blog.mass.gov/publichealth/wp-content/uploads/sites/11/2019/04/Update-on-Lowell-Lawrence-HIV-Outbreak.PHC_.040319.pdf and https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305366.

[Name]: Thank you **[Name]** for talking about the critical wrap around services that are part of the PrEP program - it is not just a prescription
[Name]: Additional comment from **[Name]**: Happy to see that TAF is not being given preference over TDF- and it looks like the safety myth that Gilead has been pushing isn't being represented here. -Appreciate seeing this on pg. 37: "F/TAF and F/TDF have equivalent high efficacy and safety as PrEP for men at sexual risk."

[Name]: TAF advantages over TDF still need to be made clear and providers can make clinical decisions based on long and short term risks of TDF

[Name]: We need clear clinical guidance for prescribing TAF. Gilead would have us believe the advantages to this drug are many - when in fact that is not the case. We need guidance for individuals and for public health - not guidance that provides support for the profits of a company.

[Name]: **[Name]**, Acting Assistant Commissioner, New York City Department of Health and Mental Hygiene. Comments: **[**I would also like to underscore comments from **[Name]** to not exclude people experiencing homelessness (PEH) from being offered PrEP. There is new evidence to suggest that PEH who inject drugs can adhere to PrEP at similar rates as other priority populations when provided adequate supports such as PrEP navigation services. See: https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2021.306208.

[Name]: Thanks for the opportunity to comment on the CDC PrEP guidelines draft. The guidelines indicate that F/TAF is associated with weight gain based on data from the DISCOVER study, a head-to-head assessment of F/TAF vs F/TDF, with a recommendation for weight monitoring every 6 months. Similar magnitude of weight gain was observed in the F/TAF arm of the DISCOVER study, the CAB arm of HPTN 083, and the placebo arm of the

iPrEX study. Additionally, similar magnitudes of weight gain were observed in the F/TDF arms of the DISCOVER, HPTN 083 studies, and iPrEx. (Landovitz, et al. AIDS 2020 #OAXLB01, [slide 28], Delany-Moretlwe, R4P 2021 Oral #LB1479, Glidden D, et al. Clin Infect Dis 2018 [page 413, paragraph 1, page 414, figure 1], Mayer K, Lancet 2020 [page 248, paragraph 1]). Based on these data, the CDC should provide the same weight monitoring recommendation for both F/TAF and CAB or recommend weight monitoring as clinically appropriate for all PrEP options.

[Name]: Strongly agreed that it is harmful to withhold same-day PrEP from people experiencing homelessness, SUD, or severe mental health issues, as the guidelines encourage.

[Name]: Also, the draft guidelines state that weight gain is a known adverse effect of F/TAF, however the USPI for F/TAF does not list weight gain as a drug-associated side effect observed in the DISCOVER study (Descovy US PI 2021 [Section 6.1, page 12 Table 2]). The CDC should consider updating or removing this statement.
[Name]: In the section on transgender populations, it would be helpful to include data from the iBreathe study indicating that there were no significant differences in TDF concentrations in dried blood spots (DBS) between transgender men, transgender women, and cisgender men, and that all transgender women and transgender men were projected to achieve highly protective concentrations of PrEP drugs https://pubmed.ncbi.nlm.nih.gov/32766890/. Other more recent data in transgender adolescents have also demonstrated that mean drug levels in PBMCs were within ranges or previously reported studies (Yager et al, vCROI 2021, Abstract 367). Please include a consideration of PrEP for people living with serious mental illness: https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30273-3/fulltext

[Name] : Throughout entire guidance:We recommend revising outdated and imprecise language around gender identity and sex assigned at birth, using:
- "all adults" instead of "men and women" to not exclude gender non-binary people
- "men" to collectively refer to cisgender and transgender men
- "women" to collectively refer to cisgender and transgender women
- "people assigned female sex at birth" and "people assigned male sex at birth"
- "cisgender women," "cisgender men," "transgender women," and "transgender men"

when referring specifically to those groups
Summary (p. 13): We recommend adding a key message emphasizing the importance of providing information about PrEP to all adult and adolescent patients who are sexually active or inject drugs.

[Name]: Specific to adherence… would suggest moving away from using the "monitoring" language and replace it with "testing" language in the adherence section. The word "monitoring" in this instance isn't necessarily well-received by the patient as opposed to using

the word testing to ensure the medicine is in your system and working properly. Would be nice to see more robust guidance around pairing HCV testing with PrEP labs.

[Name]: Identifying Indications for PrEP (p.23): We strongly support the ideas that "patients who request PrEP should be offered it, even when no specific risk behaviors are elicited." Since this key message is a bit hidden in the text, we suggest adding a message at the bottom of Figure 2: "Offer PrEP to patients who express interest in taking it, even if they do not report specific risk behaviors." We recommend noting in this section that people who have not had condomless anal or vaginal sex in the past six months may want to begin taking PrEP because they anticipate sexual debut or a return to sexual activity or because they are currently sexually active and want to stop using condoms.

[Name]: TAF's "advantages" over TDF have never been demonstrated to be clinically relevant in the PrEP population. In fact, given the inferior lipid and weight gain characteristics of TAF vs. TDF, saying that one FDC has a superior safety characteristic over the other is simply not appropriate. Indeed, the guidelines reflect this reality.

[Name]: "The extent to which PrEP use further decreases risk of HIV acquisition when the male partner has a documented recent undetectable viral load is unknown" - This wording in the guidelines denies U=U. You cannot reduce the risk of something that is zero risk. The CDC guidelines need to be consistent in articulating U=U.

[Name]:Thank you @**[Name].**

[Name]: **[**Acting Assistant Commissioner, Bureau of HIV, New York City Department of Health and Mental Hygiene. Comments from DOHMH. Identifying Indications for PrEP (p.23): We recommend emphasizing in this section that whether a patient should take PrEP should be a joint decision of the provider and patient (and not just the provider's decision to prescribe based solely on a flow chart). Assessing Risk for Sexual HIV Acquisition (p. 26): Given that exposure to intimate partner violence (IPV) can increase risk for HIV infection, we suggest recommending that clinicians ask questions to determine a patient's exposure to IPV as part of the risk assessment for sexual HIV acquisition.

[Name]: Recommend to add information under "Financial Case Management Issues for PrEP" highlighting various drug manufacturer's patient affordability programs, which are designed to help patients navigate insurance complexities to access medication.

[Name]: The quick guide does not recommend consideration of PrEP for individuals diagnosed with Syphilis or rectal STIs.

[Name]: Nonoccupational Post-Exposure Prophylaxis (p. 36): We recommend dropping "repeatedly" in the following sentence: "Patients who repeatedly seek nPEP or who are at risk for ongoing HIV exposure should be evaluated for possible PrEP use after confirming they have not acquired HIV infection." We also recommending the end of the sentence as follows: ". . . after it is confirmed they have not acquired HIV infection."

[Name]: "We recommend noting in this section that people who have not had condomless anal or vaginal sex in the past six months may want to begin taking PrEP because they anticipate sexual debut or a return to sexual activity or because they are currently sexually active and want to stop using condoms." Strongly strongly strongly agree with this statement. This is of the utmost importance. I myself would have never been allowed to start PrEP had my provider adhered to the guidance, because I sought to start PrEP prior to a return to sexual activity. People should not have to risk exposing themselves to HIV prior to being offered PrEP, any more so than people should have to risk pregnancy before being offered contraception.
Yes, every three month follow up is a tremendous barrier to PrEP access. Please allow PrEP users to do lab-only visits without an office visit copay to lower barriers and allow more flexibility. Every three month office visits is a tremendously strict monitoring schedule for a prevention regimen.

[Name]: Agree fully with **[Name]**'s comment regarding not stopping PrEP if no HIV screening at 90 days

[Name]: Table 1a states the CrCl requirements for oral prep medications as ">30 mL/min" and has a footnote that references differences between F/TAF and F/TDF. This footnote may be overlooked and lead providers to think F/TDF can be used down to 30 mL/min. Also, table 1a does not include that F/TAF can be used in persons with an eCrCl of <15 mL/min if they are on hemodialysis. The CDC should update Table 1a and other relevant sections to make clear the renal requirements for both F/TAF and F/TDF. (Descovy US PI 2021 [Section 2.5, page 5], Truvada US PI [Section 2.6, page 4]). The draft guidelines indicate renal risk factors to help guide use of F/TAF vs F/TDF but do not include data that highlights the unpredictability of renal AEs or PRT based on these factors. Consider including data from Daar et al IDWeek2020. Poster#986. The CDC should consider including all relevant data to help providers understand the potential for increased creatinine with integrase strand transfer inhibitor (Landovitz AIDS 2020 #OAXLB01).

[Name]:Table 5 suggest that baseline HCV screening should only be completed in PWID and MSM. We should be supporting the USPSTF guidance that all adults aged 18-79 should be screened for HCV. The follow-up testing may not be necessary, but the wording in the table suggest others do not require screening.

[Name]: I also agree with**[Name]** 's comments about not stopping PrEP if not HIV screening at 90 days in patients reporting regular adherence.

[Name]: The guidelines recommend routine screening for intimate partner violence for women and only women. MSM could also benefit from routine screening for IPV.

[Name]: true for all TGNCNB individuals, too, who have markedly increased lifetime exposure to IPV

[Name]: "CHECKLIST FOR INITIATING PREEXPOSURE PROPHYLAXIS (PrEP) [...] The following PrEP regimen (choose only one) [...] - Prescribed Truvada (300 mg tenofovir disoproxil fumarate, 200 mg emtricitabine) daily dosing [...] Prescribed Truvada (300 mg tenofovir disoproxil fumarate, 200 mg emtricitabine) 2-1-1 dosing (MSM)1" -- People deserve the freedom to switch back and forth between daily and 2-1-1 oral PrEP dosing regimens. It does not make any sense to require patients and providers to sign a document committing them to only using one of the two regimens.

[Name]: Apologies on comment regarding STI's in Quick Guide, I found the recommendation.

[Name]: "As the provider, I will: • Limit refill periods to recommended intervals for repeat HIV testing [...] 2-1-1 dosing (Truvada only, MSM only) ≤30 day supply)" -- It does not make sense to restrict patients planning to use 2-1-1 PrEP dosing to only being able to get one 30-day supply before they will be required to come back in for another HIV test. This will create barriers to PrEP use.

[Name]: "Conduct follow-up visits for: [...] Assessment of [...] HIV risk behavior and counseling support for risk reduction practices" -- This is a very stigmatizing practice that will alienate people from PrEP care and will not improve HIV prevention. Condomless and/or multi-partner sex while on PrEP is not an "HIV risk behavior." People engaging in those behaviors while taking PrEP properly are less likely to acquire HIV while doing so than people who always use condoms. People deserve the ability to pursue sexual wellness, which for some people includes condomless sex and/or sex with multiple partners, without their providers being instructed to counsel them out of doing so at mandatory quarterly appointments.

[Name]: **[Name]**. Section on transgender individuals only discussed transgender women. This is a missed opportunity to discuss and educate on transgender men. Transgender men who have sex with men are at high risk for HIV infection and are important to include in guideline.

[Name]: "This medicine does not completely eliminate my risk of getting HIV infection and does not reduce my risk of getting a sexually transmitted infection, so using condoms during

sex will provide additional protection." -- This messaging increases fear, fosters distrust in PrEP, increases HIV anxiety, and risk reducing patients' intimacy and pleasure.

[Name]: In the same day PrEP section of the draft guidelines, the CDC should consider including from FDA approved USPI for F/TAF where renal assessment is recommended when initiating F/TAF for PrEP, and also include F/TDF USPI where renal assessment is recommended prior to PrEP initiation (Descovy US PI 2021 [Section 5.4, page 8], Truvada US PI [Section 5.3, page 7]).

[Name]: In addition to my suggestion yesterday about informing all adolescents and adults about PrEP (not just "sexually active" adults and adolescents), I have a few recommendations specificities to the flow charts in Figures 2 and 3 that overlap with some of the comments made earlier re: Table 1:
(1) Make it clear that the flow charts are intended to be optional tools to help guide patient-provider conversations.
(2) Add a textbox at the bottom of each chart saying explicitly that PrEP should be provided to patients if they ask for it even if they don't disclose specific HIV risk. This is stated in the text, but I think it needs to be salient in the flow chart as well.
(3) Include partner/network/community-level considerations, not just individual-level behavior.
(4) Change language to include not just past behavior but also anticipated future behavior.

[Name]: My colleagues and I also had some specific suggestions in our critique of the last guidelines that may be useful: https://pubmed.ncbi.nlm.nih.gov/30689766/ Thank you for considering! And apologies if this overlaps with other chats/comments, I'm having trouble keeping up with them all!

[Name]: I think it would be helpful to also include reference to [commercial PrEP provider] on page 63 where Table 9 highlight State PrEP Assistance Programs, as [commercial PrEP provider] is a completely free service.

[Name]: Q3 month visits should not be necessary. Individuals can do labs at an off site center close to home as often as indicated including q3m HIV testing (or home testing) and have visits 1-2 times per year, on site or virtual. Need flexible models. As I said in my written comments should not hold PrEP for a missed 3 month HIV test.

[Name]:Bone mineral density is addressed in the draft guidelines. Data from the DISCOVER BMD sub-analysis showed that at baseline, 24-30% of participants had either osteopenia or osteoporosis, these data are not included in the current draft. Inclusion of these data may help providers to contemplate and assess when appropriate low bone density among people who benefit from PrEP. (Wohl D, et al. IDWeek 2019. Washington, DC. Poster #1288).

[Name]: , Senior Program Manager of LGBTQ Health & Rights with Advocates for Youth. Most adolescents are covered under their parent's health insurance. This means that their parents are responsible for paying any medical expenses related to PrEP, such as doctor's visits, prescription costs, and blood tests. This holds many young people back from talking to their doctor about getting PrEP. According to a study from MMWR, 22.6% of sexually active adolescents would not seek out sexual health care because they did not want their parents to find out. This conversation can be quite intimidating for young people, especially if their parents are not aware that they are sexually active or using intravenous drugs, which puts them at risk of HIV transmission. Additionally, younger people under the age of 25 are most likely to be uninsured in the United States. This deters them from booking necessary doctor's appointments for HIV screenings and blood tests.
[Name]: It is important for my health to find out quickly if I get HIV infection while I'm taking this medication, so: I will contact my provider right away if I have symptoms of possible HIV infection (fever with sore throat, rash, headache, or swollen glands)." - It seems inappropriate to tell all PrEP patients that if they ever get a fever + sore throat, or something as common as a headache, that they need to worry it may be HIV and seek off-schedule HIV testing. Someone is extremely unlikely to acquire HIV when taking PrEP properly.

[Name]: We strongly urge the CDC to update minor confidentiality language on page 61, right after the sentence, Clinicians considering providing PrEP to a person under the age of legal adulthood (a minor) should be aware of local laws, regulations, and policies that may apply. Our ask is adding 2 sentences, Sentence 1 Clinicians should explicitly provide assurance of confidentiality and establish limits of confidentiality based on these local laws, regulations, and policies. And Sentence 2 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 developed in partnership by SIECUS, Advocates for Youth, and other adolescent sexual health organizations. PrEP Education for YSPs toolkit: https://siecus.org/resources/prep-education-for-youth-serving-primary-care-providers-toolkit/ .

[Name]: Move on.

[Name]: figure 2 please update the box "sex with men, women or both" to more inclusive anatomy based terminology to reduce stigma in persons who do not identify with traditional gender roles.

[Name]: In regards to language about switching from F/TDF to F/TAF, please consider a change of language to say that the CDC recommends the use of whichever approved HIV prevention medication is deemed medically necessary by the provider and patient.

[Name]: Change language to “what genders are your sex partners?”

[Name]: What specific communication/outreach strategies are there for AA gay men?

[Name]: The PrEP checklists in the supplements do not mention PrEP for injection drug use. They all refer to sexual behavior.

[Name]: Thank you for commenting on transgender men
[Name]: “Why take PrEP? Nearly 40,000 people get infected with HIV each year in the U.S. More of these infections are happening in some groups of people and some areas of the country than in others.” - This way of explaining why to take PrEP in patient-facing literature is very alienating and unconvincing. Why not explain it in a way that connects with people's self-interest more successfully, like suggesting that people take PrEP to take control over their sexual health and have bodily autonomy in relation to sexual partners, to be able to experience lowered HIV anxiety, to increase their sexual pleasure and intimacy, etc.? It would be very helpful to compare PrEP to contraception and destigmatize both sex and HIV in the response.

[Name]: Hi my name is **[Name]**, and I'm also a member of Advocates for Youth. To avoid repeating the same sentiments as other from my organization I wanted to share a link to an OP-ED I wrote about the struggles for youth to gain access to PrEP. https://www.tennessean.com/story/opinion/2020/03/11/prep-hiv-prevention-pill-difficult-youth-access/4979451002/.

[Name]: In the provider supplement the following statement is included: "When significant new data become available that may affect patient safety or graded recommendations for PrEP use, an announcement with suggested revisions to the existing guidelines will be posted on the CDC web site for a 2-week public comment period. " However, CDC only provided 1 week for review AND the provider supplement was not available until Monday May 24, 2021 which allowed at most a full 24 hours to review the document.

[Name]: Please do not end this webinar early. People still have additional comments to make even when there are brief lulls in people having their hands raised.

[Name]: For same-day prep initiation, unstable housing is a disqualification- how is stable housing being measured? Many black gay men are transient

[Name]: “You should consider PrEP if you are a man or woman who sometimes has sex without using a condom” - This way of talking about PrEP in patient-facing literature is very limited. What about people who get coerced or pressured about condom use, don't expect they

will be able to continue using condoms long-term, dislike using condoms, or want to have sex without condoms? Those are all valid reasons to consider PrEP and it is worthwhile for us as public health professionals to explain PrEP in ways that connect with people. If we say PrEP is only for people who already have sex without condoms, we contribute to stigmatizing PrEP, because condomless PrEP is highly stigmatized.

[Name]: Harvard Medical School -- CDC has recognized that communicating the personal benefits of Covid vaccination, beyond just Covid risk reduction, is critical to a successful vaccination program. Likewise, communicating the benefits of PrEP, beyond just HIV risk reduction, is critical for successful PrEP implementation. It would be helpful if the patient-facing FAQ highlighted such benefits, including reduced HIV anxiety, increased sexual satisfaction, and increased pleasure and intimacy.
[Name]: The draft state that higher rates of triglyceride elevation were observed in the F/TAF arm in the DISCOVER study and therefore lipids should be monitored every 6 months for those using F/TAF. In the DISCOVER study, participants in the F/TAF arm experienced median decreases from baseline for total cholesterol, LDL cholesterol, and HDL cholesterol through 96 weeks. The median increase in triglycerides observed through this time point among F/TAF participants was 3 mg/dL (Ogbuagu et al. CROI 2020 # 2940 [slide 15]). The median increases in HDL and LDL observed among participants in the F/TAF arm who were on F/TDF at baseline could be explained by the removal of the lipid-lowering effect of F/TDF. In the DISCOVER study, among participants with no F/TDF use at baseline, there was no difference in the proportion of F/TAF users who needed to start a lipid-lowering agent compared to F/TDF users (Campbell, et al. IDWeek, 2020. Poster #995). Data do not support the need for lipid assessment every 6 months for FTAF,

[Name]: 100% agree with **[Name]**'s comments. They are essential. If we truly want people to use PrEP, we must modify our communication in the way she is stating to best respect their choices and values.

[Name]: This is **[Name]** from Children's Hospital Oakland. We've had a lot of success in including PrEP/HIV posters in all of our exam rooms, including patients who learned about PrEP from the posters and initiated the conversation with MDs. It might be productive to have explicit guidelines for including this type of strategy for universalization/allowing patients to initiate the conversation.

[Name]: Yes, there are last comments -- people are continually commenting in the chat. Please keep the webinar open until 1:30 PM central.

[Name]: when do you expect the guidelines to be officially posted?

[Name]: Please keep the webinar open until the 1:30 pm if at all possible. I know there are other folks hoping to post comments who are in with patient's.

[Name]: If this process is used again (although not ideal), I'd recommend providing advance notice that written comments can be submitted via chat.

[Name]: Sorry yes 2:30 ET.

[Name]: Further regarding q 3 month follow up. Our stable HIV patients can some in every 6 months but individuals without HIV are coming in every 3, for a intervention we know is highly effective. This is a huge contributor to lack of persistence

[Name]: "If your partner has HIV infection, PrEP may be an option to help protect you from getting HIV infection while you try to get pregnant, during pregnancy, or while breastfeeding." - This patient-facing literature needs to explain U=U here. It denies U=U to fail to explain that just because someone's partner is living with HIV, that does not mean their HIV is transmissible. As well, it is highly stigmatizing to refer to someone as "having HIV infection." We don't want to encourage providers or lay people to speak that way about people living with HIV. Just say "living with HIV."

[Name]: Just to double-check: will uploaded documents be included for consideration?

[Name]: Agreed with **[Name]** that it makes no sense that PrEP patients are subjected to a more strict follow-up appointment schedule than patients in HIV care. If we want people to stay HIV-negative, we have to make it as easy and low-barrier as possible for them to remain in care.

[Name]: Thank you!

[[Dawn Smith]]: All comments received in the chat will be saved and considered

[Name]: On page 20: "Many of the studies that informed these guidelines included small numbers of transgender women and none included transgender men, as a result, data specifically relevant for transgender and non-binary people are often limited or not available. Most sections of these guidelines, therefore, use the terminology 'women' and 'men' unless specifically referring to transgender women or men." I would counter that there were sufficient numbers of transgender women included in the DISCOVER trial to garner FDA approval for both Cisgender Men and Transgender Women. I would encourage use of specific language throughout the guideline (using terms such as cisgender men, transgender men, or individuals assigned male at birth or assigned female at birth) to be specific to the populations being

referred to help prevent ambiguity in clinical application and not list transgender individuals only in terms of an "other" to the norm.

[Name]: “In these studies, when people took PrEP daily (or missed only occasional doses) or had regular PrEP injections, the risk of getting HIV infection during sex dropped by 90% or more.” - This seems inaccurate -- when only people who took PrEP daily or at least 4 times a week were assessed in studies of cis men, or who took PrEP at least 6 times a week in studies of cis women, there were no HIV transmissions.
[Name]: Dating apps such as , Grinder, Jack’s, Adam4Adam, Ect should be considered for outreach to AA gay men.

[Name]: I'd like to see updates to the timeframe between follow up visits. Coming out of COVID, especially looking at the beginning of the shut down, many patients went 6 months without a follow up due to the shifts into telehealth. The success of those patients remaining on PrEP highlights the potential of reducing the amount of follow ups for patients. Also highlighting the cost reduction for office visits for patients with low income or uninsured would help reduce barriers.

[Name]: Throughout the patient information sheets it recommends to talk to your "Doctor or Pharmacist". This needs to be changed to "Provider" as there are other LIPs, such as Nurse Practitioners, who prescribe PrEP.

[Name]: “If you think you may be at high risk for HIV, talk to your doctor about PrEP.” - In the same vein as [Name]’s comments, this is a highly stigmatizing, alienating way to talk about PrEP and what it could do for someone. People do not self-identify as being "at high risk for HIV." It will limit who will choose to start PrEP if we convey that people who use PrEP are "at high risk," especially since the things that make someone especially likely to acquire HIV are stigmatized.
[Name]: I don’t understand the inclusion of viral load testing for CAB every 2 months. Yes there were instances where there was delayed diagnosis in the CAB study but we see the same with TDF/FTC and any use of antivirals as in PEP.

[Name]: “If you and your doctor agree that PrEP might reduce your risk of getting HIV infection,” - There’s no HIV-negative person for whom PrEP would not reduce the likelihood of HIV acquisition except people who are entirely unable or unwilling to take PrEP, so this framing does not make sense. There’s nothing for the patient or their doctor to “agree” on about that -- it’s just reality.

[Name]: In line with the spirit of some of the early slides, consider deletion of "who provide care to persons at risk of acquiring HIV infection" on page 21 under "The intended users of this

guideline include:" All primary care clinicians likely care for patients who are candidates for PrEP.

[Name]: consider including some information about legislation in some states permitting community pharmacists to dispense prep without provider rx for up to 60 days with hiv neg test within 7days of dispensing, especially helpful for prep uptake in marginalized populations not engaged in care. pharmacist shall also link the pt to care for further hiv testing, other labs and further prep rx. calif, colorado, texas, and other states with pending legislation
[Name]: “Since Descovy was not studied in persons assigned female sex at birth, it is unknown whether it is effective protection for vaginal sex. So, it should only be prescribed to MSM.” - Some men who have sex with men are assigned female at birth and are not included in Descovy's FDA indication due to lack of research. Please use trans-inclusive language. State "cis MSM" instead of just "MSM" when you are excluding trans men.

[Name]: Also on page 21: consider changing "primary care physicians" to "primary care clinicians" as listed in the first bullet point and to be inclusive of non-physician providers

[Name]: “If I take PrEP can I stop using condoms when I have sex? You should not stop using condoms because you are taking PrEP. If PrEP is taken daily, it offers a lot of protection against HIV infection, but not 100%. Condoms also offer a lot of protection against HIV infection if they are used correctly every time you have sex, but not 100%. PrEP medications don’t give you any protection from other infections you can get during sex, but condoms do. So, you will get the most protection from HIV and other sexual infections if you consistently take PrEP medication and consistently use condoms during sex.” - This messaging in the supplement is very fearmongering and does not honor patients' pursuit of sexual wellness. As well, it fosters distrust in PrEP's efficacy in not focusing entirely on STI and pregnancy prevention benefits of condoms while on PrEP but instead implying that PrEP offers insufficient protection against HIV to be used as a sole prevention method.

[Name]: In the NYS guidelines we included a follow up HIV test at one month for anyone who was in the possible window period where testing could be or would be negative. Three months is a long time to wait to get the next HIV test if someone started PrEP 6 days after their last exposure, when even a viral load test will be negative. I think some discussion of the window period is helpful. I also see providers not initiating PrEP because they are early in the window period where the test won’t show if they are possibly seroconverting. I would like to see this practice be addressed and stopped.

[Name]: “Truvada and Descovy are sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms)" - Almost nobody on earth truly always uses condoms. PrEP is *more effective* than always using condoms according to

the CDC's own website. People should be permitted to start PrEP because they desire to reduce their condom use, not just because they're already not using condoms and unwilling / unable to start. Condomless sex is highly stigmatized, so it's not helpful to say PrEP is for people who don't always use condoms without explaining that PrEP can also be for people who always use condoms but want more protection than condoms can provide or more autonomy or certainty in their HIV prevention method. Highlight the advantages PrEP has relative to condom use, like that it can be fully controlled by the receptive partner, used without a partner's knowledge or cooperation, used outside of moments of arousal and potential intoxication, that it does not in any way redu [omission]
"• Descovy is not prescribed for women (persons assigned female at birth)." - This statement misgenders both trans men and trans women in saying that the definition of women is one that includes trans men and excludes trans women. Why not instead say that Descovy is not prescribed for people assigned female at birth and then in parentheses say such as cis women? It is not trans inclusive in the slightest to define "women" as people assigned female at birth -- it is in fact the most trans exclusionary statement one could possibly make.

[Name]: On the 4th line of page 22, use of the word "blacks." When referring to racial identities in the medical literature, this should be used in adjective form and should be capitalized (i.e. Black persons). JAMA has guidance on this here: https://jamanetwork.com/journals/jama/fullarticle/2776936 .

[Name]: "In the last 6 months, how many of your male sex partners were HIV positive?" - This question in the provider supplement denies U=U and therefore fosters continued HIV stigma and anxiety among HIV-negative people in a way that is very harmful, since this is patient-facing. Someone's likelihood of acquiring HIV is not higher simply because they have partners living with HIV because those partners may have an undetectable viral load. My likelihood of exposure to HIV is not high because I've had several undetectable partners -- it's high because I've had several partners who believe they're negative but are not on PrEP and have condomless sex.

[Name]: On page 23, use of "both sexes, all genders" could instead be listed as only "all genders" or "all sexes, all genders." Intersex individuals are also at risk of HIV but this language is not necessarily inclusive of this group.

[Name]: Agreed with **[Name]**. More examples of inappropriate language related to gender -- "for sexually active men and women with indications for PrEP use"; "recommended for HIV prevention in men and women reporting sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition"; "For both men and women,"

[Name]: Also on page 23, "Transgender persons are those whose sex at birth differs from their self-identified gender." Typically this would be listed as "assigned sex at birth"

[Name]: Table 1- follow up care: rec change pregnancy test for women (with reproductive potential) to pregnancy test for individuals with reproductive potential. But also as I stated in my comments, I would only include those who are not on effective contraception.

[Name]: Z72.5 High risk sexual behaviorZ72.51 High risk heterosexual behaviorZ72.52 High risk homosexual behaviorZ72.53 High risk bisexual behavior ---- These diagnostic codes are highly stigmatizing and alienating. They are never necessary -- there are always less stigmatizing diagnostic codes. Please don't recommend to providers that they use these codes.

[Name]: As a community advocate and HIV professional, I'm requesting the CDC re-evaluate the language around client's need to switch from F/TDF (Truvada) to F/TAF (Descovy) to say that the CDC recommends the use of whichever HIV prevention medication is deemed medically necessary by the provider for their patient.

[Name]: For transgender women we do know that PrEP works if you take it, the same as in all other genders. I think it would be helpful to include this point and not solely state that we don't have evidence yet that it works.

[Name]: Please note this case the NYS PrEP guidelines made in fall 2019 for the importance of allowing flexibility with quarterly office visits: "Retention in care is a challenge for PrEP programs. A study that examined PrEP programs in 3 midsized cities found the rate of retention in PrEP care at 6 months to be 60% due to individual and structural barriers [Chan, et al. 2016]. "Over medicalization" of PrEP care may pose a barrier to retention by requiring healthy individuals to engage frequently with health care through quarterly clinic visits and laboratory tests. Although quarterly assessments remain the standard for PrEP monitoring, flexibility regarding in-person visits is encouraged when needed or appropriate. Quarterly laboratory testing is recommended even when a decision to adjust visit frequency has been made, but flexibility for individual patients regarding this time frame is appropriate, as quarterly screening is based on best practice rather than evidence. Barriers to retention in care should be exp [omission]

[Name]: On page 27: "Lastly, non-sterile injection sometimes occurs among transgender persons while administering non-prescribed gender-affirming hormones or among persons altering body shape with silicone or other "fillers." Though this may occur, the juxtaposition with the following sentence "can place them at substantial risk of acquiring HIV infection" implies that there are a significant number of transgender individuals who acquire HIV infection through these routes and could also increase stigma toward transgender individuals.

Any patient who reports non-sterile injection behaviors for any reason should be assessed for PrEP.

[Name]: Agreed. There is also a difference between non-sterile injection practices and injection practices that involve a chance of HIV transmission. If someone is injecting hormones in a non-sterile manner in that they're reusing their own needles, that has health risks, but HIV is not one of them.
It would make such a significant difference if the CDC guidelines were updated to 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 due to their interest in becoming sexually active or decreasing their condom use. This is not unprecedented. The NYS guidelines state: "Candidates who should be offered PrEP include individuals who: [...] Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future." (https://www.hivguidelines.org/prep-for-prevention/prep/#tab_2) Someone who thinks there is a possibility that they may have condomless anal / vaginal sex in the next 6 months, or actively wants to have condomless anal / vaginal sex in the next 6 months, should be offered PrEP, even if they're currently abstinent or using condoms perfectly.

[Name]: Something that is important to address around PrEP is acknowledging the disparity in PrEP utilization in Black women. It would be very powerful for the CDC to encourage providers to address barriers to PrEP access in this population, including the possibility of personal bias in screening. Thank you for the opportunity to provide feedback in this forum!