

Expanding PrEP in Communities of Color (EPICC)

OMB # 0920-1423

Approved December 8, 2023

Summary of Changes

We are requesting a non-substantive change request to the information collection request (ICR) Expanding pre-exposure prophylaxis (PrEP) in Communities of Color (EPICC, OMB #0920-1423). The requested changes do not result in an overall change in the scope of data collection. There is a reduction in the number of burden hours and cost given a reduction in the number of participating clinics (previously OMB-approved change from 9 to 7).

This PrEP Choice study aims to help us gain a deeper insight on PrEP use (i.e. PrEP medications used, adherence and persistence). In this request, we are proposing adding a new HIV prevention PrEP injectable medication, lenacapavir (also referred to as LEN and Yeztugo), to data collection instruments- elaborating on questions and response options to include lenacapavir. Including lenacapavir as a PrEP option in participant assessments and clinic assessments will help us more accurately capture PrEP uptake and usage.

The proposed changes affect the following attachments, and are included with this request:

- Att 4i_Aim2a Cohort Baseline Survey (English and Spanish; Tracked and Clean)
- Att 4k_Aim2a Cohort Follow Up Survey (English and Spanish; Tracked and Clean)
- Att 4r_Aim1&2 Clinic Assessment Baseline and Final (English only; Tracked and Clean)
- Att 4s_Aim1&2 Clinic Assessment Every 6 mos. (English only; Tracked and Clean)
- SSA (Tracked and Clean)
- SSB (Tracked and Clean)

Other Changes

In addition to the proposed changes detailed above, we are also revising the SSA and SSB to reflect changes in CDC project staff, and EPICC staff changes. These changes do not impact the overall scope of data collection.

Table 1. Summary of Changes to Data Collection Instruments	
Att 4i_ Aim2a Cohort Baseline Survey (English and Spanish)	
Summary of Changes	Reason for Change Proposed
Added Yeztugo or lenacapavir as examples of injectable PrEP in response options. Pages 12-14,21-23,26-27,31,35-36, 46-48	Including Yeztugo or lenacapavir as an example of injectable PrEP.
Added Question F5 (Pg. 13) Which type of injectable PrEP are you currently on? <input type="radio"/> Aprelude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to accurately capture type of injectable PrEP use.
Added the following question to Sections G, H and I (G6- Pg. 23; H24- Pg. 31; I24- Pg. 40) Which type of injectable PrEP are you planning to start? <input type="radio"/> Aprelude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to capture these data.
Added Question J6 (Pg. 48): Which type of injectable PrEP are you considering starting? <input type="radio"/> Aprelude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to capture these data.
In the following questions- H16- Pg. 30; I16- Pg. 38; K1, K3, K7, K9- Pgs. 53-56, we elaborated on the response option that includes injections- to include “two-six months” timeframe since lenacapavir injections are given every 6 mos. (Cabotegravir injections are every 2 mos.).	We are expanding the timeframe to read up to 6 mos. in a response option to be inclusive of lenacapavir injections, which are given every 6 mos.
Pg. 56- Question K13: We elaborated on the timeframe for injectable medications from “two mos.” to “two-six mos.” to include timeframe for lenacapavir.	Adjusted the timeframe to account for lenacapavir injections given every 6 mos.
Pg. 62: L14, L15- Elaborated on questions to include lenacapavir injection: L14. Have you ever gone more than 2 months between Cabotegravir injections or 6 months between Lenacapavir injections? L15. How many times have you gone more than 2 months between Cabotegravir injections or 6 months between Lenacapavir injections?	We added lenacapavir injections and related timeframes for injections to these questions to capture this PrEP option usage.
Att 4k_ Aim2a Cohort Follow Up Survey (English and Spanish)	
Summary of Changes	Reason for Change Proposed
Added Yeztugo or lenacapavir as examples of injectable PrEP in response options. (See Pages 13-15,19,27,30,33,41,44, and 49)	Including Yeztugo or lenacapavir as an example of injectable PrEP.

Table 1. Summary of Changes to Data Collection Instruments	
Added Question F2 (Pg. 13) Which type of injectable PrEP are you currently on? <input type="radio"/> Apretude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to accurately capture type of injectable PrEP use.
Added the following question to Sections G, H and I (G2- Pg. 27; H2- Pg. 30; I24- Pg. 44) Which type of injectable PrEP are you planning to start? <input type="radio"/> Apretude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to capture these data.
Added Question J2 (Pg. 50): Which type of injectable PrEP are you considering starting? <input type="radio"/> Apretude®, cabotegravir (injection every two months) <input type="radio"/> Yeztugo®, lenacapavir (injection every six months)	Including Yeztugo or lenacapavir as an option for injectable PrEP in order to capture these data.
Pg. 58- In Question K13, we elaborated on the timeframe for injectable medications from “two mos.” to “two-six mos.” to include timeframe for lenacapavir.	Adjusted the timeframe to account for lenacapavir injections given every 6 mos.
In the following question response options- K1, K3, K7, and K9- Pgs. 54-57, we elaborated on the response option that includes injections- to include “two-six months” timeframe since lenacapavir injections are given every 6 mos. (Cabotegravir injections are every 2 mos.).	We are expanding the timeframe to read up to 6 mos. in a response option to be inclusive of lenacapavir injections, which are given every 6 mos.
Att 4r_Aim1&2 Clinic Assessment Baseline and Final (English Only)	
Pages 3-4: For Q11 and Q12, “LEN: Lenacapavir subcutaneous injections” was added as a response option.	Recommend adding LEN response option to Q11 and Q12 to capture usage at clinics.
Pages 8-9: New questions- Q30-36 were added to gather information about lenacapavir availability, access, and cost.	Similar to other PrEP medication options included in this instrument, we recommend adding questions on lenacapavir (new medication available) to assess use at clinics. Note that clinic staff only complete applicable questions based on skip patterns.
Att 4s_Aim1&2 Clinic Assessment Every 6 mos. (English Only)	
Summary of Changes	Reason for Change Proposed
Pg. 3: For Question 9, LEN: Lenacapavir subcutaneous injections was added as a response option.	Recommend adding LEN response option to Q9 to capture usage at clinics.
Pages 7-8: New Questions 26-32 were added to gather information about Lenacapavir availability, access, and cost.	Similar to other PrEP medication options included in this instrument, we recommend adding questions on lenacapavir (new medication available) to assess use at clinics. Note that clinic staff only complete applicable questions based on skip patterns.

Table 2. Summary of Changes Other Study Documents (SSA, SSB)	
SSA	
Summary of Changes	Reason for Change Proposed
Page 1, 11: CDC Project Officer's contact information updated, as well as Point of Contact.	CDC staffing for this project has changed. Rupa Patel is replacing Katrina Byrd. Address was updated to reflect change to the CDC Chamblee Campus.
Pg. 5: Lenacapavir added as an example of a long-acting injectable example of PrEP.	Lenacapavir injection is being added as a PrEP injectable option.
Pg. 10: Removed Allysha Maragh-Bass as she's no longer part of the EPICC Team.	EPICC staffing changes.
Pg. 17: 10 more minutes of burden was added to each Clinic Assessment instrument (Every 6 mos. and Final) to account for new lenacapavir-focused questions. The number of participating clinics is being updated here from 9 to 7 based on a previous OMB approved change. These changes reduced the total burden hours from 759 to 753.	This change is being made to account for added lenacapavir-focused questions. Clinics will spend a total of 10 more minutes to document use of this added PrEP injectable option. Due to a previous reduction in the number of clinics, the overall burden hours is actually reduced.
Pg. 18: Cost for the completion of Clinic Assessments (Every 6 months and Final) are reduced given the reduced number of burden hours for these 2 assessments noted on Pg. 17. The Cost of the Baseline +Final Assessment changes from \$788.40 to \$657 and the Every 6 mos. Assessment changes from \$1,182.60 to \$1,051.20. Overall, this changes the cost for data collection from \$22,775.43 to \$22,512.63.	Updates to cost calculations are included given the new burden hours estimated. Given that there are 2 fewer clinics, there is a cost savings of \$262.80.
SSB	
Summary of Changes	Reason for Change Proposed
Page 1 (title page): Contact name, mailstop, zip code, phone number, and e-mail address were updated. Page 11: CDC Staffing change was made.	CDC staffing for this project has changed. Rupa Patel is replacing Katrina Byrd. Address was updated to reflect change to the CDC Chamblee Campus.
Pg. 11: Removed Allysha Maragh-Bass as she's no longer part of the EPICC Team.	EPICC staffing changes.