

Form Approved

OMB No. 0920-1423

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Expanding PrEP in Communities of Color (EPICC+)

Attachment 4r

Aim 1&2 Clinic Assessment Baseline and Final

Public reporting burden of this collection of information is estimated to average 130 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-1423)

Clinic Assessment Baseline and Final

*Note this assessment does not need to be completed for satellite or affiliate clinics.

Instructions: Clinic staff should complete at the beginning (start of provider training) and end of data collection (end of patient cohort follow-up).

Clinic Information

1. Name of clinic
2. Address
3. Days and hours of operation
4. Does your clinic provide bilingual services?
5. What mode of healthcare delivery is your clinic currently using?
 - a. In-person-
 - b. Telemedicine
 - c. Both
 - i. Estimated percentage of healthcare delivery that is in-person
 - ii. Estimated percentage of healthcare delivery that is telemedicine (includes both telephone and teleconferencing)
6. Estimated percentage of patient care revenue

Payer type	%
Private insurance	
Medicaid/Medicare	
Patient payments	
Other	
7. Number of clinical providers¹
8. Number of clinical providers¹ who prescribed PrEP in the last 6 months
9. Does your clinic have an in-house pharmacy?
 - a. If yes, does it dispense PrEP medications?
10. Does your clinic provide transportation support (e.g., gas vouchers, medical transport) for PrEP appointments?

PrEP Prescriptions²

¹ Persons with capacity to prescribe medications

11. PrEP prescriptions current calendar year to date

PrEP Regimen	All Clients	Clients 18-39 years	Men who have sex with men (MSM) 18-39 years	Black MSM 18-39 years	Hispanic/Latino MSM 18-39 years
F/TDF: Emtricitabine co-formulated with tenofovir disoproxil fumarate (trade name Truvada®), prescribed daily					
F/TDF: Emtricitabine co-formulated with tenofovir disoproxil fumarate (generic), prescribed daily					
F/TAF: Emtricitabine co-formulated with tenofovir alafenamide (trade name Descovy®)					
F/TDF: Prescribed for intermittent use (2-1-1 or event-driven PrEP)					
CAB: Cabotegravir intramuscular injections					
LEN: Lenacapavir subcutaneous injections					

12. PrEP prescriptions prior calendar year

PrEP Regimen	All Clients	Clients 18-39	Men who have sex	Black MSM	Hispanic/Latino

² Count of all prescriptions provided, may exceed number of PrEP patients as a patient may receive >1 type of PrEP in the time period

		years	with men (MSM) 18-39 years	18-39 years	MSM 18-39 years
F/TDF: Emtricitabine co-formulated with tenofovir disoproxil fumarate (trade name Truvada®), prescribed daily					
F/TAF: Emtricitabine co-formulated with tenofovir alafenamide (trade name Descovy®)					
F/TDF: Prescribed for intermittent use (2-1-1 or event-driven PrEP)					
CAB: Cabotegravir intramuscular injections					
LEN: Lenacapavir subcutaneous injections					

Clinical Services

13. HIV tests³ current calendar year to date (excluding testing for persons with previously diagnosed HIV infection)

HIV Test	All Clients	Clients 18-39 years	Men who have sex with men (MSM) 18-39 years	Black MSM 18-39 years	Hispanic/Latino MSM 18-39 years
Laboratory-based antigen/antibody					

³ Count of all HIV tests provided, may exceed number of patients tested as a patient may receive >1 HIV test in the time period

tests					
Point-of-care antigen/antibody tests					
Laboratory-based viral load/nucleic acid tests					
Point-of-care viral load/nucleic acid tests					

14. HIV test prior calendar year

HIV Test	All Clients	Clients 18-39 years	Men who have sex with men (MSM) 18-39 years	Black MSM 18-39 years	Hispanic/Latino MSM 18-39 years
Laboratory-based antigen/antibody tests					
Point-of-care antigen/antibody tests					
Laboratory-based viral load/nucleic acid tests					
Point-of-care viral load/nucleic acid tests					

15. Does your clinic employ a PrEP navigator or anyone on staff whose responsibilities include helping clients obtain and continue with PrEP prescriptions?

a. If yes, how many?

16. What financial assistance programs does your clinic provide (check all that apply, add additional to bottom of table)

Financial assistance program	Yes
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Income-based sliding scale for clinical services	
Assistance with enrollment in federal PrEP access programs (i.e., Ready Set PrEP)	
Assistance with enrollment in drug manufacturer PrEP access programs	
Other, please specify	

17. What components are included in typical PrEP initiation and follow-up visits? (check all that apply, add additional to bottom of table)

	PrEP Initiation Visit (Considering or starting PrEP)	PrEP Follow-up visit
Screening for potential to benefit from PrEP to reduce the risk of acquiring HIV		
Counseling about all available PrEP options		
Providing printed patient materials about selected PrEP regimen		
Counseling about effect of adherence on PrEP efficacy		
Adherence support		
Assessment of insurance status		
Assistance with insurance enrollment if uninsured or under-insured		
Assistance with enrollment in PrEP access programs (e.g. Ready Set PrEP) if needed		
HIV testing		
Other STI testing (please specify)		
Other clinical testing (please specify)		
Other (please specify)		

18. Does the clinic have a protocol for timing of PrEP follow up visits? If not, what is the range of time between the initial PrEP visit and the first follow up visit?

19. What is the process for scheduling follow-up visits? Is it clinic-initiated or patient-initiated?

20. Does your clinic have specific procedures for engaging (re-engaging) with patients who don't return for PrEP follow-up visits?

a. If yes, please describe

21. What PrEP adherence support does your clinic provide? (check all that apply, add additional to bottom of table)

PrEP adherence support	Yes
Printed patient materials	
Links/information about online materials	
Pill boxes	
Electronic medication monitors	
Automated medication reminders	
Peer-to-peer adherence support	
SMS/text reminders from clinic staff	
Motivational interviewing-based intervention	
App/smartphone based adherence support	
Other (describe)	

22. What types of educational materials does your clinic provide to clients? (check all that apply, add additional to bottom of table)

Educational materials	Print	Online	None	Other, please specify
Materials that address sexual health topics				
Materials that address sexually transmitted infections				
Materials that specifically address HIV				
Materials that specifically address PrEP				
Other (describe)				

23. Are cabotegravir intramuscular injections for PrEP available at your clinic?

b. If yes, then please complete cabotegravir provider section

c. If no, then please complete cabotegravir non-provider section

Cabotegravir provider:

24. Does your clinic keep doses of cabotegravir available (in stock onsite)?
 - a. If yes, how does your clinic order and maintain your supply? How many doses do you maintain in stock onsite?
 - i. Do stock outs occur? If yes, how frequently?
 - ii. Do shortages occur? If yes, how frequently?
25. Do any patients pick up the drug at a pharmacy?
 - b. If yes, how is it prescribed? Does the clinic call/transmit the prescription to the pharmacy? Does the patient take a written prescription to the pharmacy?
 - c. How do patients pay for the drug if they don't have prescription benefits?
 - d. If patients pick up the drug at the pharmacy, does the pharmacist administer the injection?
 - i. If yes, does the pharmacist charge an injection fee?
26. For the initial prescription, what is the average time between cabotegravir prescription to administration of the cabotegravir dose?
 - e. If applicable, how does it vary by stocked drug in the clinic compared to picking up the drug at a pharmacy?
27. How is the patient billed for the injection? Is there a charge for the drug? A separate charge for the injection?

Cabotegravir non-provider:

28. Why does your clinic not currently provide cabotegravir?
29. If you are planning to provide it, when do you expect to make it available?

30. Are lenacapavir subcutaneous injections for PrEP available at your clinic?
 - a. If yes, then please complete lenacapavir provider section
 - b. If no, then please complete lenacapavir non-provider section

Lenacapavir provider:

31. Does your clinic keep doses of lenacapavir available (in stock onsite)?

- f. If yes, how does your clinic order and maintain your supply? How many doses do you maintain in stock onsite?
 - i. Do stock outs occur? If yes, how frequently?
 - ii. Do shortages occur? If yes, how frequently?

32. Do any patients pick up the drug at a pharmacy?

- g. If yes, how is it prescribed? Does the clinic call/transmit the prescription to the pharmacy? Does the patient take a written prescription to the pharmacy?
- h. How do patients pay for the drug if they don't have prescription benefits?
- i. If patients pick up the drug at the pharmacy, does the pharmacist administer the injection?
 - i. If yes, does the pharmacist charge an injection fee?

33. For the initial prescription, what is the average time between lenacapavir prescription to administration of the lenacapavir dose?

- j. If applicable, how does it vary by stocked drug in the clinic compared to picking up the drug at a pharmacy?

34. How is the patient billed for the injection? Is there a charge for the drug? A separate charge for the injection?

Lenacapavir non-provider:

- 35. Why does your clinic not currently provide lenacapavir?
- 36. If you are planning to provide it, when do you expect to make it available?