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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 120 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 D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

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?

¹ Persons with capacity to prescribe medications

PrEP Prescriptions²

11. PrEP prescriptions current calendar year to date

PrEP Regimen	All	Clients	Men who	Black	Hispanic/Latino
	Clients	18-39	have sex	MSM	MSM 18-39 years
		years	with men	18-39	
			(MSM) 18-	years	
			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					

12. PrEP prescriptions prior calendar year

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

PrEP Regimen	All	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/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					

Clinical Services

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

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

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

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			

14. HIV test prior calendar year

HIV Test	All	Clients	Men who	Black	Hispanic/Latino
	Clients	18-39	have sex with	MSM	MSM 18-39 years
		years	men (MSM)	18-39	
			18-39 years	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
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	PrEP Follow-
	(Considering or starting PrEP)	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 un-		
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?