



Original article

Models of HIV Pre-Exposure Prophylaxis Care Used in Title X Family Planning Clinics in the Southern U.S.

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A B S T R A C T

Purpose: HIV pre-exposure prophylaxis (PrEP) is underutilized by adolescent and young adult women, especially in the Southern U.S. Family planning (FP) clinics are potentially ideal PrEP delivery sites for adolescent and young adult women, but little is known about their PrEP services. We describe models of PrEP care in Title X FP clinics in the South and explore clinic resources that are needed to facilitate PrEP provision.

Methods: Providers and administrators from 38 clinics participated in qualitative interviews. We assessed five steps of PrEP care: (1) HIV risk assessment; (2) PrEP education; (3) laboratory testing; (4) PrEP prescription; and (5) PrEP monitoring.

Results: Among 38 clinics, 23 conducted at least one step and were classified into three models. Model 1 (n = 8) and Model 2 (n = 4) clinics provided up to Steps 1 and 2, respectively, but referred to an external PrEP provider. Model 3 clinics (n = 11) conducted all steps. Few barriers were identified for Step 1; using an HIV risk assessment tool was a key facilitator. PrEP educational materials facilitated Step 2; clinics not providing education believed they could easily do so with training and educational resources. Funding- and staff-related resource barriers were noted for Steps 3–5, including costs of laboratory tests and lack of time for longitudinal visits.

Conclusions: PrEP-providing publicly funded FP clinics in the Southern U.S. use referral services for many steps of PrEP care, which introduce patient burden. Increasing onsite PrEP services will require addressing concerns related to training, educational materials, cost, and staffing.

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IMPLICATIONS AND CONTRIBUTION

This study describes the different models of pre-exposure prophylaxis (PrEP) care currently used by Title X–funded family planning clinics and identifies key barriers and facilitators to PrEP provision at each point in the care cascade. The results can inform PrEP implementation planning and strategies to overcome barriers in this setting.

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Youth aged 13–24 years comprise approximately 20% of the nearly 40,000 people diagnosed with HIV annually in the U.S. [1]. One in eight new HIV diagnoses among this age group occurs in adolescent and young adult women (AYAW) [1], and the rates of new diagnoses among AYAW are highest in Southern states compared with all other regions of the U.S. [1]. HIV pre-exposure prophylaxis (PrEP) is a safe and effective HIV prevention intervention that the U.S. Food and Drug Administration approved in 2012 [2]. Open label studies and demonstration projects have

found that PrEP delivery is feasible in “real-world” settings, including for AYAW [3–5].

Consequently, dissemination and implementation efforts are now focused on bringing PrEP to scale in the U.S. [6]. Despite these efforts, PrEP awareness and use among AYAW in the U.S. remain low [7–10], whereas high levels of awareness and increased use among men have been recently documented [11]. In the last quarter of 2017, women were less than 5% of PrEP users, and women and adolescents had significantly lower levels of PrEP use relative to epidemic need [12].

Low access to PrEP-providing clinics [13] is a major potential barrier to PrEP use among AYAW in the South, particularly since the degree to which PrEP is provided in settings where most AYAW receive health care (i.e., women’s health and family planning [FP] clinics) is largely unknown. Models of PrEP care currently exist in sexually transmitted infection (STI) treatment clinics, community-based organizations, pharmacy-based programs, and community health centers [14]. However, FP clinics in high HIV incidence settings (such as much of the Southern U.S.) are potentially ideal for expanding PrEP care for AYAW because they are already used by sexually active AYAW for sexual health services, including HIV testing and prevention counseling. Furthermore, most AYAW use and trust women’s health clinics for sexual health services, especially AYAW aged 18–29 years [15,16]. Title X–funded FP clinics are an ideal setting for integrating PrEP into FP services, given that they are important safety net sources of care for AYAW, particularly in regions without Medicaid expansion, which closely overlap with regions that would most benefit from expansion of HIV prevention services [17]. Title X FP clinics serve nearly four million clients, including 1.5 million in the South [18]. Eighty-seven percent of the clients are women, 17% are under 20 years of age, and 46% are 20–29 years of age [18]. Although clinical guidelines for women’s health providers have recently incorporated recommendations for PrEP [19]; to date, there has not been widespread integration of PrEP services into Title X FP clinics, especially in the South [20,21].

PrEP care based on clinical guidelines is a multistep process [22]. The steps in PrEP care include (1) assessing a patient’s HIV risk; (2) providing PrEP education and counseling to determine interest in PrEP; (3) assessing a patient’s medical eligibility for PrEP through laboratory testing; (4) prescribing PrEP; and (5) follow-up and monitoring. Because of organization-level differences in structure, services provided, partnerships, capacity, and resources, clinics may implement different models of PrEP care, which may include the provision of a varying number of these steps onsite versus through referral [23]. Thus, FP clinics may vary considerably in their overall PrEP care models. The purpose of this study is to understand current models of PrEP care used in safety net FP clinics in the South and to explore clinic resources that facilitate PrEP provision, which will ultimately inform strategies to scale up PrEP in these important women’s health care settings.

Methods

Study design

The overall study used an explanatory, sequential mixed-methods research design [24] to explore models of PrEP care and barriers/facilitators to PrEP provision in FP clinics across the South. Quantitative surveys were administered online in Spring

2018 [25], followed by qualitative interviews to gain an in-depth understanding of the quantitative data captured. This study focuses on the results of the qualitative interviews. The results of the quantitative surveys are described elsewhere [20]. Qualitative interviews were conducted between March and July 2018. This study was based at Emory University, and the Emory Institutional Review Board approved the study protocol.

Study participants and recruitment

We invited FP providers and clinic administrators from Title X–funded clinics in the 18 states that comprise the Southern U.S. (DHHS regions III [Mid-Atlantic], IV [Southeast], and VI [Southwest]) to participate. FP providers were considered individuals who have the potential ability to prescribe, counsel, or screen for PrEP. Clinic administrators were individuals who served in an administrative oversight capacity over the Title X activities in their clinic.

As a part of the survey for this study [25], participants were asked to indicate willingness to participate in a follow-up qualitative phone interview. Individuals were uniquely selected based on various factors (i.e., purposive sampling), including whether their clinic prescribes PrEP, state, DHHS region, clinic classification (i.e., health department, community clinic, etc.), and urbanicity. Interviews took approximately 45 minutes to 1 hour, and participants received a \$50 gift card on completion.

Of the 519 individuals that completed the survey, 45 participants (34 providers and 11 administrators) from 38 unique clinics completed a qualitative interview. There were seven clinics that had two interviewees participate. For the purposes of this clinic-level study, interview data from participants in the same clinic were combined to gain a more robust picture of clinic operations and PrEP procedures.

Measures

Semistructured interviews sought to assess potential barriers and facilitators to integrating PrEP into clinic services using implementation-focused constructs from the Consolidated Framework for Implementation Research [26]. The guide consisted of eight primary domains: HIV Priority, PrEP Priority, Capacity & Implementation, Resources, Adoption & Decision Making around New Practices, Champions, Trainings, and External Factors. Interviews were conducted by trained research staff; interviews were recorded and transcribed verbatim.

Classifying models of PrEP care

Five steps of PrEP care were assessed through the interviews (Figure 1): (1) HIV risk assessment; (2) PrEP education; (3) laboratory assessment for PrEP eligibility; (4) PrEP prescription; and (5) PrEP monitoring. During Step 1, patients are screened for HIV risk factors and tested for HIV. During Step 2, patients are educated about PrEP as well as assessed on their interest and ability to adhere to PrEP. During Step 3, patients are assessed for any signs and symptoms of HIV infection and receive laboratory testing for kidney function, Hepatitis B and C, pregnancy, and other STIs. Step 4 involves prescribing PrEP to patients who are eligible (based on HIV risk factors, medical eligibility, and interest in PrEP). This step also may involve enrolling the patient in insurance or medication assistance programs to ensure they can pay for PrEP. Step 5 involves follow-up visits every 3 months for

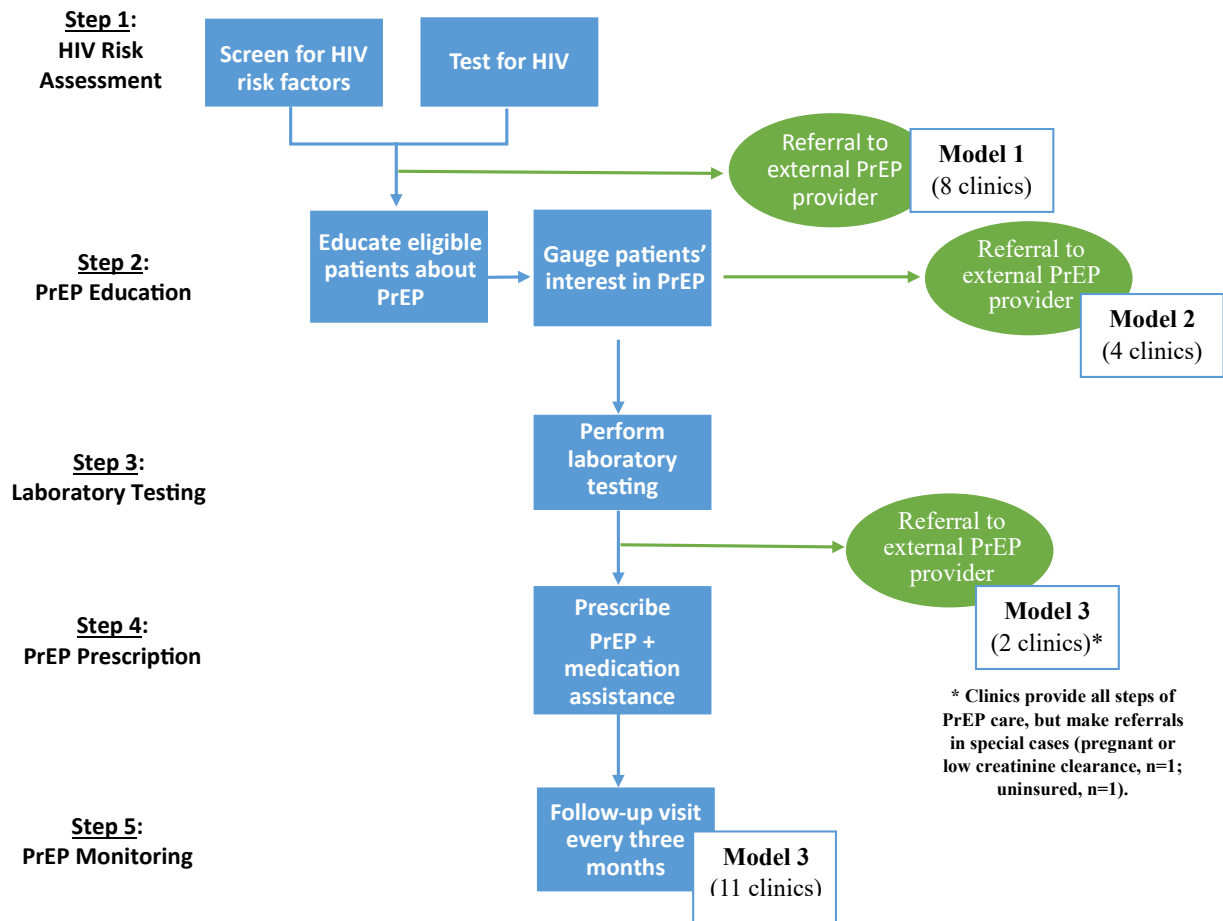


Figure 1. PrEP care models in Title X family planning clinics in the Southern U.S. (analysis of $n = 23$ clinics).

HIV testing, adherence counseling, risk reduction support, side effect assessment, pregnancy testing, STI testing, and kidney function testing. After reading the qualitative interviews from the 38 clinics, we classified each clinic based on which steps of PrEP care were implemented to identify PrEP models.

Data analysis

We ran descriptive statistics on the characteristics of the 38 clinics (stratified by the model of PrEP care), including location (large metropolitan, medium metropolitan, and small/nonmetropolitan), clinic type (health department, specialized FP, Federally Qualified Health Center, community, hospital, and other), region (III, IV, and VI), services (FP only or both FP and primary care), staff to enroll patients in insurance (yes or no), onsite pharmacy (yes or no), and onsite laboratory (yes or no). We also performed descriptive statistics on characteristics of the clinic's county, including percent of the population under 200% of the poverty level, percent of the population by race, percent of the population who are uninsured, and HIV prevalence [27].

Using NVivo 12 (QSR International), we used standard qualitative data analysis methods, including reading of transcripts, creation of a codebook, coding, and consensus meetings [28]. In the qualitative interviews, clinic resources emerged as the most salient factor for PrEP implementation and therefore is the focus

of this analysis. The codebook was created based on clinic resources (e.g., money, training, education, physical space, and time) that participants needed to conduct each step of PrEP care. We entered the resources into an Excel matrix by model and site and then assessed the direction (i.e., barrier or facilitator) and strength (i.e., likelihood of impacting PrEP delivery) of the resource across clinics and model type. To ensure that codes were being applied to the data accurately and consistently, two independent analysts separately coded and then compared codes and resolved all discrepancies through discussion. Resource-related barriers and facilitators that were salient across clinics were summarized for each step of the PrEP cascade by model type. Exemplar quotes that are presented in the results were selected because of their ability to represent the experiences of our sample of clinics.

Results

PrEP models

Of the 38 clinics that participated in the qualitative interviews, 23 clinics conducted at least one step PrEP care (the 15 clinics that provided no PrEP-related services [39%] were excluded from further analyses). Among the 23 clinics that provided PrEP-related services, we identified three different models

of PrEP care (Figure 1). Model 1 clinics ($n = 8$) only conducted Step 1 of PrEP care and then referred potential candidates to an external PrEP provider. Model 2 clinics ($n = 4$) conducted Steps 1 and 2 of PrEP care: If they believed the patient was a good candidate for PrEP based on HIV risk assessments and PrEP education, Model 2 clinics would then refer patients to an external PrEP provider. Model 3 clinics ($n = 11$) conducted all steps of PrEP care. Two of the Model 3 clinics indicated that they may refer patients to an external PrEP provider in special circumstances, including if the patient is pregnant, ineligible based on creatinine clearance, or uninsured.

Table 1 provides description of clinic characteristics. Notably, Model 1 clinics had the highest representation of clinics from nonmetropolitan areas, the highest percent county-level poverty, and the highest county-level HIV prevalence. Model 2 clinics had the highest representation of clinics from large metropolitan areas and highest county-level percent nonwhite individuals and were more commonly from Region IV (Southeast). Model 3 clinics had a higher representation of clinics from medium metropolitan

locations, more commonly had a pharmacy onsite, and were more commonly from Region III-Mid-Atlantic.

Barriers and facilitators to PrEP care

The following sections highlight the most prominent resource-related considerations for implementing each step of PrEP care (Tables 2 and 3). Table 2 depicts the prevalence of each resource across clinics in the sample. Table 3 lists the resources required for each step of PrEP care, as well as an exemplar quote that extends the results presented below.

Step 1: assessing HIV risk. Model 1, 2, and 3 clinics all collected information about patients' sexual behaviors and conducted HIV tests. Many clinics used an HIV risk assessment tool, which asked patients about their sexual partners, condom use, sexually transmitted disease history, and injection drug use. These tools enabled providers to systematically identify which patients may be candidates for PrEP. In most cases, these tools were generated

Table 1
Clinical characteristics, by model of PrEP care

	Total (N = 23), n (%)	Model 1 ^a (N = 8), n (%)	Model 2 ^b (N = 4), n (%)	Model 3 ^c (N = 11), n (%)
Clinic location				
Large metro	11 (47.8)	3 (37.5)	3 (75.0)	5 (45.5)
Medium metro	7 (30.0)	2 (25.0)	1 (25.0)	4 (36.4)
Small/nonmetro	5 (21.7)	3 (37.5)	0 (.0)	2 (18.2)
Clinic type				
Health department	12 (52.2)	5 (62.5)	3 (75.0)	4 (36.4)
Family planning	4 (17.4)	1 (12.5)	0 (.0)	3 (27.3)
FQHC	3 (13.0)	0 (.0)	0 (.0)	3 (27.3)
Community	2 (8.7)	1 (12.5)	1 (25.0)	0 (.0)
Hospital	1 (4.3)	1 (12.5)	0 (.0)	0 (.0)
Other	1 (4.3)	0 (.0)	0 (.0)	1 (9.0)
Region ^d				
III	10 (43.4)	3 (37.5)	1 (25.0)	6 (50.0)
IV	8 (34.7)	3 (37.5)	3 (75.0)	2 (16.7)
VI	5 (21.7)	2 (25.0)	0 (.0)	3 (25.0)
Services provided				
Family planning	16 (69.6)	5 (62.5)	3 (75.0)	8 (72.7)
Family planning + primary care	7 (30.4)	3 (37.5)	1 (25.0)	3 (27.3)
Payment assistance ^e				
Yes	16 (69.6)	7 (87.5)	4 (100)	5 (45.5)
No	7 (30.4)	1 (12.5)	0 (.0)	6 (54.5)
Onsite pharmacy				
Yes	14 (60.9)	5 (62.8)	1 (25.0)	8 (72.7)
No	9 (39.1)	3 (37.5)	3 (75.0)	3 (27.2)
Onsite laboratory				
Yes	10 (43.5)	3 (37.5)	2 (50.0)	5 (45.5)
No	10 (43.5)	5 (62.5)	1 (25.0)	4 (36.4)
Unknown	3 (13.0)	0 (.0)	1 (25.0)	2 (18.2)
Percent poverty, mean (min, max) ^f	16.8 (5.9, 22.7)	18.2 (14.4, 22.7)	14.7 (8.8, 18.0)	16.6 (5.9, 21.1)
Percent uninsured, mean (min, max) ^f	11.3 (4.3, 21.1)	11.1 (6.7, 14.0)	12.0 (6.9, 16.9)	11.2 (4.6, 21.1)
HIV prevalence rate, mean (min, max) ^f	724.6 (57, 2,590)	811.6 (67, 2,307)	635.0 (106, 1,167)	695.6 (57, 2,590)
Percent of population by race, mean (min, max) ^f				
White	64.5 (29.6, 97.9)	63.7 (29.6, 96.4)	56.9 (33.3, 86.3)	67.7 (38.5, 97.9)
Black	23.9 (.6, 63.7)	24.4 (1.1, 63.7)	33.0 (5.0, 54.3)	20.2 (.6, 50.7)
Asian	2.7 (.2, 5.6)	2.3 (.5, 5.6)	3.4 (1.4, 5.1)	2.8 (.2, 6.2)
American Indian/Alaska Native	.6 (.2, 4.8)	1 (.2, 4.8)	.4 (.2, .5)	.5 (.2, 1.2)
Other	5.8 (.2, 21.9)	6.0 (.2, 17.2)	4.2 (2.2, 6.2)	6.3 (.4, 21.9)
More than one race	2.4 (.7, 4.4)	2.5 (1.5, 4.4)	2.1 (1.1, 2.6)	2.5 (.7, 3.2)

^a Clinics refer to an external PrEP provider after Step 1.

^b Clinics refer to an external PrEP provider during Step 2.

^c Clinics conduct the all steps of PrEP delivery.

^d Department of Health and Human Services regions III (Washington D.C., Delaware, Maryland, Pennsylvania, Virginia, West Virginia), IV (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee), and VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas).

^e Onsite staff to help enroll patients in Medicaid/insurance programs/payment assistance programs.

^f Based on AIDSVu 2015 data from clinic's county.

Table 2Summary of available and needed resources for each step in PrEP care, by model of PrEP care^a

	Resource available			Resource needed		
	Model 1 (N = 8), n (%)	Model 2 (N = 4), n (%)	Model 3 (N = 11), n (%)	Model 1 (N = 8), n (%)	Model 2 (N = 4), n (%)	Model 3 (N = 11), n (%)
Step 1: HIV risk assessment						
HIV risk assessment tool	2 (25.0)	3 (75.0)	5 (45.5)	1 (12.5)	1 (25.0)	1 (9.0)
Assessment support staff	1 (12.5)	2 (50.0)	3 (27.2)	3 (37.5)	-	-
Risk assessment tool integrated into EMR	1 (12.5)	-	2 (18.2)	1 (12.5)	1 (25.0)	-
Step 2: PrEP education						
Patient educational materials	1 (12.5)	3 (75.0)	2 (18.2)	3 (37.5)	-	-
Educational support staff	4 (50.0)	-	2 (18.2)	1 (12.5)	-	2 (18.2)
Staff training and education	-	1 (25.0)	3 (27.2)	2 (25.0)	-	-
Step 3: Laboratory assessment for PrEP eligibility						
Laboratory (onsite or offsite)	5 (62.5)	-	4 (36.4)	-	-	-
Staff training and education	3 (37.5)	-	6 (54.5)	4 (50.0)	1 (25.0)	-
Funding for laboratory tests	-	-	-	5 (62.5)	-	2 (18.2)
Step 4: PrEP prescription						
Funding for prescription	-	-	3 (27.2)	3 (37.5)	-	-
Insurance navigators	-	1 (25.0)	5 (45.5)	5 (62.5)	-	2 (18.2)
Step 5: PrEP monitoring						
Staffing	1 (12.5)	-	1 (9.0)	1 (12.5)	-	2 (18.2)
Appointment reminder/follow-up system	-	-	3 (27.2)	1 (12.5)	-	-

EMR = electronic medical record; PrEP = pre-exposure prophylaxis.

^a Model 1 clinics refer to an external PrEP provider after Step 1; Model 1 clinics refer to an external PrEP provider after Step 2; Model 3 clinics conduct all steps of PrEP delivery.

by the clinics to assess sexual health (because validated tools do not exist) and were embedded into general intake assessments that patients completed before their visit. Providers believed that assessments should be completed before seeing the clinician so that clinicians had more time to discuss the results during the patient's appointment. Some clinics collected information on risk behaviors using a paper and pencil questionnaire, which was completed by patients in the waiting area. In other clinics, nurses or medical assistants administered the tool during a one-on-one conversation with the patient and entered their answers into an electronic form. Having the assessment integrated into the electronic medical records (EMR) also facilitated providers' access to assessment results and reduced the need for data entry. Overall, clinics identified very few barriers to implementing this first step of PrEP care; however, having a risk assessment tool, having staff available to assess patients before seeing a clinician, and integrating the assessment into EMR were all facilitators.

Step 2: PrEP education. Model 2 and 3 clinics successfully integrated PrEP education into their routine procedures. For these clinics, PrEP educational materials and handouts helped facilitate the process by serving as a resource for patients and helping to guide the provider through the educational session. In some clinics, PrEP education was provided by medical assistants or health educators, which limited the burden on clinicians. Although they do not currently conduct Step 2, Model 1 clinics believed they had the capacity to adopt PrEP education if they had access to educational materials for patients. Model 1 clinics also wanted staff to be trained on HIV and PrEP before providing any patient education.

Step 3: laboratory assessment for PrEP eligibility. Model 3 clinics conducted this step of PrEP care. They either conducted the tests at an onsite or external laboratory. Before implementing this step, clinics conducted staff training on the procedures for drawing the tests and sending them to the laboratory, which

facilitated a smooth transition. Model 3 clinics noted that they were already familiar with many of the tests required for PrEP, so staff training was not a large burden. Also, because many of the Model 3 clinics received funding for PrEP (through grants or state-level PrEP assistance programs), they encountered few cost-related barriers to conducting the laboratory tests. However, Model 1 and 2 clinics were concerned they would not be able to offer laboratory testing without additional funding, and they believed that referring to an external PrEP provider for laboratory testing and continued care was the best option for them currently.

Step 4: prescribe PrEP. In our sample, Model 3 clinics conducted Step 4, whereas Model 1 and 2 clinics did not. For Model 3 clinics, a critical facilitator for Step 4 was acquiring grant funding for PrEP medications or being located in a state that offers PrEP assistance programs (i.e., states are billed for PrEP costs, so medications, visits, and laboratories are free to patients). Clinics without this funding, used staff, such as insurance navigators, to help enroll patients in Medicaid (which covers the cost of PrEP) or pharmaceutical medication assistance programs (which covers medication expenses for eligible patients). However, Model 1 and 2 clinics believed that their lack of funding and insurance navigators (coupled with the high cost of PrEP care) would limit patient access to PrEP at their clinic.

Step 5: PrEP monitoring. Only Model 3 clinics conducted PrEP monitoring. The primary challenge Model 3 clinics reported was retaining patients in care, including patient adherence to PrEP medication and attendance at quarterly follow-up appointments. For Model 3 clinics, having clerical staff available to schedule appointments facilitated patient visits every 3 months. Additionally having automated scheduling systems and automatic patient reminders enhanced the feasibility of PrEP monitoring and decreased the burden on staff. Model 1 and 2 clinics felt that it would be possible for them to conduct follow-ups, but they were concerned that patients would not be compliant with

Table 3
Resource-related barriers and facilitators to PrEP implementation, by step of PrEP care

Resource	Exemplar quote
Step 1: Assessing HIV risk	
Formal, standardized HIV risk assessment tool	"So on their risk assessment they usually have to fill out – how many partners they've had, if they've had any STDs in the past 6 months, what types of sex that they're having, are they currently having sex with someone who's HIV positive?—so that risk assessment normally is a good guide on letting me know if they will be a good candidate for PrEP from the jump before I even start discussing anything with them." [Clinic 15, Model 3]
Available staff to conduct HIV risk assessment before appointment	"The nurses do the assessment. We do not have any sheets that we pass out before they get there. So during the intake is when all [HIV risk] is assessed and put into the computer and then the nurses talk to them. And then when I go in the room after reviewing the chart, I look at the answers, and then I go in and reinforce or teach or educate depending on what's going on." [Clinic 9, Model 2]
Incorporation of HIV risk assessment in electronic medical records	"We have electronic medical records, so if they could...get to the point where they did [HIV risk assessment] actually in an electronic history, then it could just populate it in the chart." [Clinic 4, Model 1]
Step 2: PrEP education	
Patient educational materials	"We have some really good tools in terms of patient education sheets on PrEP that we can provide to patients that go over what the potential risks are, what the side effects are, what the benefits are. So our clinicians are not having to just come up with that out of thin air or remember it, memorize from our protocol. So we've got, basically, an education sheet that's right in front of them that they can be giving to the patient as they go through it." [Clinic 18, Model 3]
Availability of health educators/support staff	"The medical assistants are well informed. And our medical assistants do a lot of the education for our patients and counseling for our patients." [Clinic 14, Model 3]
Staff PrEP training and education	"I mean, I know a lot about HIV. I've been here a while, but some of the other staff would not, and I think that all the nurses in this clinic should be at least trained if we did implement this, to know what it's about." [Clinic 8, Model 1]
Step 3: Laboratory assessment for PrEP eligibility	
Access to laboratory	"In terms of testing for kidney function, hepatitis, those are sent out tests. So we can draw blood right there in the clinic. We do not have to send [patients] out to get their blood drawn. We'll draw it, and we'll send it off [to external lab]." [Clinic 22, Model 3]
Staff training and education on laboratory tests	"We talked to the lab and then we did a training amongst ourselves after we got that information. The rest of the tests—they're easy. We all have had to take classes for the HIV so we all know how to do that test and the other ones you just draw the blood in the proper tube and it goes to the state. The BMP [Basic Metabolic Profile] was the only thing different that we had not been doing. And since that goes to a private lab the state does not do it, we just had to learn to process." [Clinic 22, Model 3]
Funding for laboratory tests	"And then, if we're gonna do lab tests, we would have to know who's gonna pay for that. Like, in our Title X funding, I'm not sure the Title X grant is gonna pay for that. We do have the [CLINIC] system to back us up, but then they have to have a separate financial assessment to be eligible for what they're gonna pay for their labs. We have a lab here that they could just walk next door and get their blood drawn, but who's gonna pay for that?" [Clinic 4, Model 1]
Step 4: Prescribe PrEP	
Funding for PrEP prescription	"The thing that's made it easy for us is just the state paying for it [PrEP prescriptions] for one thing and it being free to the patients and having the PrEP coordinator too has definitely helped too. We do not have to deal with any insurance rejections or denials or anything of that sort and we do not have to deal with copays because everything is basically free. I do not think it will always be that way. I think that eventually, they're [the state] gonna run out of money or they're gonna decide that they should bill patients that have insurance or something like that. But right now and ever since we've started doing PrEP, it's been this way that everything is free, including all the lab tests too. So we have not really had any barriers, any significant barriers to implementing it." [Clinic 16, Model 3]
Insurance navigators	"We have an eligibility department that, once they call in, we screen them first before they come in to see, you know, what they're coming for and what, if they have insurance. And once we do the over the phone screening, then they—when we find out they do not have insurance, then we'll set them up an appointment with eligibility and then they will sit with them prior to the doctor and, you know, I guess bring in certain paperwork like proof of income, proof of residency, photo ID and whatever else they may need." [Clinic 15, Model 3]
Step 5: PrEP monitoring	
Clerical scheduling staff	"Mainly just appointment reminders, clerical staff to help with that, sending out appointment reminders and calling patients to remind them of appointments and that sort of thing." [Clinic 16, Model 3]
Automated scheduling/appointment reminder systems	"We have an appointment reminder system, like an automatic call...They made their appointment and then they missed it and so that will prompt the system to say, "Hey, you've missed your appointment. Please call and reschedule." [Clinic 20, Model 3]

PrEP = pre-exposure prophylaxis.

appointments. They were also concerned that more staff would be needed to schedule and follow-up with patients.

Discussion

Efforts to improve PrEP access for AYAW seeking sexual health care in Title X FP clinics in the Southern U.S. are needed. We identified three current models of PrEP care in these clinics: (1) HIV risk assessment followed by referral to an external PrEP provider (Model 1), HIV risk assessment and PrEP education followed by referral to an external PrEP

provider (Model 2), and completion of all PrEP care steps onsite (Model 3). Most clinics fell into one of the two models that used referral for PrEP care, despite intentional sampling of individuals from PrEP-providing clinics. Because referral models introduce additional patient burden for accessing PrEP, increasing onsite PrEP services in Title X clinics will require addressing identified barriers to PrEP care. Alternatively, PrEP access could be enhanced for AYAW seeking care at Title X clinics by strengthening linkages to nearby PrEP-providing clinics and developing referral strategies that are acceptable for AYAW.

Notably, few barriers were identified for the first step (HIV risk assessment), but having a formal risk assessment tool, having the tool integrated into the EMR, and having support staff to administer the tool before the clinician appointment were key facilitators. Assessment of HIV risk has been noted to be a key challenge in PrEP care, particularly for AYAW. For U.S. women, risk assessment tools that predict HIV acquisition risk do not exist, and Centers for Disease Control and Prevention clinical practice guidelines may not adequately identify women who are at risk and motivated to use PrEP [29,30]. Despite inadequacies with HIV risk assessment tools, they can serve as reminders to take a detailed sexual history [31,32] and can guide clinicians in conversations about PrEP [7,31,32].

In addition, clinics not providing PrEP education believed they could easily do step 2 with training and patient educational materials. These findings add to those from an earlier nationwide survey indicating that FP clinicians reported lack of training as a key barrier to PrEP implementation [21]. In a recent study among FP providers in Atlanta, we observed significant increases in providers' PrEP skills and knowledge after a single, 1-hour training [7]. Also, having health educators and educational materials to share with patients were key facilitators for providing PrEP education in the present study. Women-focused PrEP information tools have been developed, such as those shared online by HIVE at the University of California San Francisco (<https://hiveonline.org/prevention4women>) [33]. Thus, agencies that support the training and service delivery needs of Title X clinics should consider strengthening awareness and accessibility of PrEP educational materials.

However, substantial funding- and staff-related resource barriers were notable in the later steps of PrEP care (Steps 3–5). Given that the South has a higher proportion of individuals living without health insurance than other U.S. regions [34] and many states have not expanded Medicaid, resource barriers are likely exacerbated in this region. Although the cost of PrEP medication and medical visits are frequently cited patient barriers to PrEP use [35,36], clinics that service high proportions of uninsured AYAW, such as Title X clinics in the South, also have unique resource-related challenges to provide PrEP. Specifically, for clinics not conducting laboratory tests or prescribing PrEP, the cost of the laboratory tests, costs of PrEP prescriptions, and lack of dedicated insurance/cost navigation staff were frequently cited barriers. However, for clinics doing all steps, once they received training as well as funding to cover the costs of laboratory testing and PrEP prescriptions, they faced very few barriers to conducting the remaining steps of PrEP care. These findings indicate that scaling-up onsite PrEP in Southern states, which have high proportions of uninsured patients and high HIV prevalence, will require strengthening funding to offset costs of PrEP services.

In addition, emerging models of providing PrEP may also alleviate some of the identified barriers in the later steps of PrEP care. These include pharmacy-based PrEP [37], telemedicine for PrEP care [38], at-home PrEP services [39], and mobile PrEP delivery [40]. Nonetheless, to date, few of these emerging models of PrEP implementation have been investigated in the Southern U.S., and none have been adapted for or studied in AYAW. Therefore, optimizing access to PrEP for AYAW in the U.S. in the short-term must include expansion of PrEP services within publicly funded women's health clinics in high HIV burden areas in the South.

Our study has several limitations, including the use of a convenience sample, the use of self-reported information, and lack of generalizability to other women's health settings not located in the South. Nonetheless, a key strength of this study was the diversity in geographic location and clinic characteristics among our sample. The results of this study also provide critical insight into clinic-level resources that facilitate PrEP provision, which will inform strategies to scale up PrEP services in Title X FP clinics. In our ongoing work, we are using this qualitative research to inform the implementation and evaluation of PrEP adoption in Title X clinics in the South. This study focuses on one important determinant of PrEP implementation (i.e., clinic resources), but future work will explore additional determinants, such as provider attitudes, leadership engagement, and implementation climate [20].

In conclusion, our study noted three different models of PrEP care among publicly funded FP clinics in the Southern U.S., mostly requiring referral services for some of the steps of PrEP care. Resource concerns related to training, educational materials, cost, and staffing must be addressed to expand onsite PrEP availability in these otherwise ideal sites for AYAW to receive PrEP services. All Title X clinics should be provided with the support and resources (most of which are freely available) to provide universal PrEP education to their patients, particularly in the South, where the epidemic burden is high and PrEP awareness among AYAW remains low. In the absence of PrEP service offerings in the South, linkages between current women's health and PrEP programs must be strengthened in the region, and alternative PrEP care models that occur outside of the clinic setting must also be adapted for and studied in AYAW.

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