

An Evaluation of Maryland Providers' Knowledge, Comfort, Likelihood of Prescribing PrEP, and Perceived Barriers and Facilitators to Prescribing PrEP

Oluwatosin H. Olateju* and Sharon E. Barrett

¹Coppin State University, College of Health Professions, Baltimore, Maryland, US.

²Morgan State University, School of Community Health and Policy, Baltimore, Maryland, US.

*Correspondence:

Oluwatosin Olateju, Coppin State University, College of Health Professions 2500 West North Avenue, Health and Human Services Building (HHSB), Baltimore, Maryland, US.

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ABSTRACT

Purpose: To understand persisting knowledge gaps among providers in Maryland regarding HIV prevention for minors and evaluate the providers' comfort and likelihood of prescribing oral pre-exposure prophylaxis (PrEP), and their perceived barriers and facilitating factors to prescribing PrEP.

Methods: Between January 2021 and June 2021, we conducted semistructured, audio-recorded interviews of 18 community health clinicians who provide care to adolescents in Maryland. This qualitative study was well suited as a case study. The theories that served as the primary orienting lens for this research were the theory of planned behavior, and the diffusion of innovation.

Results: A total of 18 providers participated in the study. Nine main themes emerged. While reasonable knowledge was noted among most participants regarding the concepts of PrEP, only half (50%) were knowledgeable about the Maryland Minor Consent Law (MMCL) for HIV prevention treatment. In addition, the providers had dissimilar experiences in the prescription of PrEP.

Conclusion: Most of the participants were knowledgeable about PrEP, and many were also experienced in prescribing PrEP to eligible adults. Several provider-level barriers to prescribing PrEP were reported. Consequently, the implementation of PrEP in HIV clinics may be challenging without failing to address HIV providers' concerns.

Keywords

Adolescents, Minor consent laws, HIV prevention, PrEP.

Implications and Contribution

This study is the first to examine the awareness of HIV prevention law among providers. Though exploratory, these findings provide insight into current practices across the state of Maryland relating to the delivery of PrEP. This research also underscores existing barriers to prescribing PrEP in Maryland and highlights potential solutions to improving PrEP uptake among minors.

The Centers for Disease Control and Prevention (CDC) estimated that 1,189,700 individuals aged 13 years and older were infected with HIV in the United States at the end of 2019, including an estimated 158,500 individuals who were yet to be diagnosed [1]. Sadly, adolescents are disproportionately impacted by the HIV epidemic [2,3].

Oral Preexposure Prophylaxis (PrEP) is a daily single pill that is over 90% effective in preventing HIV infection in high-risk people when taken as prescribed [4]. Unfortunately, the uptake of oral PrEP remains low despite its effectiveness in preventing new HIV infections [5].

Culp and Caucci [6] emphasized that the impact of state laws on the clinical use of PrEP has not yet been measured. Moreover, the current barriers and facilitators to prescribing PrEP to minors among adolescent providers in Maryland are understudied. In 2018, over half (60.3%) of new HIV diagnoses in Maryland were among adults aged 20–39, and 56 of the 997 HIV diagnoses that same year were among people younger than age 20 [7]. Although oral PrEP has been proven to reduce the risk of new HIV infections, the implementation of PrEP programs has been restricted by the inability to methodically evaluate its uptake and use [8].

This study is important because it is the first to explore Maryland providers' knowledge of the Maryland Minor Consent Law (MMCL) regarding HIV prevention following the 2019 legal amendment to include provisions for minors to give consent for HIV prevention treatments at the same capacity as adults [9]. This study also sought to (a) describe the providers' barriers and facilitators to prescribing PrEP to adolescents, (b) highlight existing knowledge gaps, and (c) propose future recommendations and strategies for improving accessibility. Findings from this research will assist providers across the country who are interested in implementing new PrEP programs or improving existing ones.

Methods

This study employed qualitative research well suited as a case study. Pinto et al. [10] argued that there is a lag in PrEP implementation, largely due to the limitations in methodological approaches used in PrEP implementation studies; thus, more conceptually sound PrEP qualitative research is needed. In agreement with Creswell and Poth's [11] viewpoint about the relevance of a qualitative approach in studying a particular group or population, this qualitative inquiry provided a unique opportunity to better understand the facilitators and barriers encountered by providers when prescribing PrEP to minors in Maryland.

The conceptual model for this study is presented in Figure 1. This model is informed by the diffusion of innovation (DOI) theory and the theory of planned behavior (TPB).

Recruitment and Sampling

A snowball-sampling frame was used to identify clinicians who participated in the study.

This study had certain inclusion criteria. First, participants must have been practicing at an ambulatory care setting in any of the 13 areas (county or city of Maryland) where HIV reported diagnoses rates (per 100,000 population) were equal to or greater than 3.0, as seen in data from the 2019 Maryland Annual Epidemiological Profile [12]. Second, participants must have been working a minimum of 4 hours per week in an ambulatory setting as a doctor, nurse practitioner, or a physician assistant. Third, participants must have treated patients aged 13–18 years in their practice. Lastly, participants must report their practice as "Family Medicine, Internal Medicine (IM), IM/Pediatrics, Obstetrics/Gynecology, Infectious Diseases, or HIV Medicine" [5]. Additionally, the providers were either practicing in federally qualified health centers, local health

departments, or private clinics in select regions in Maryland.

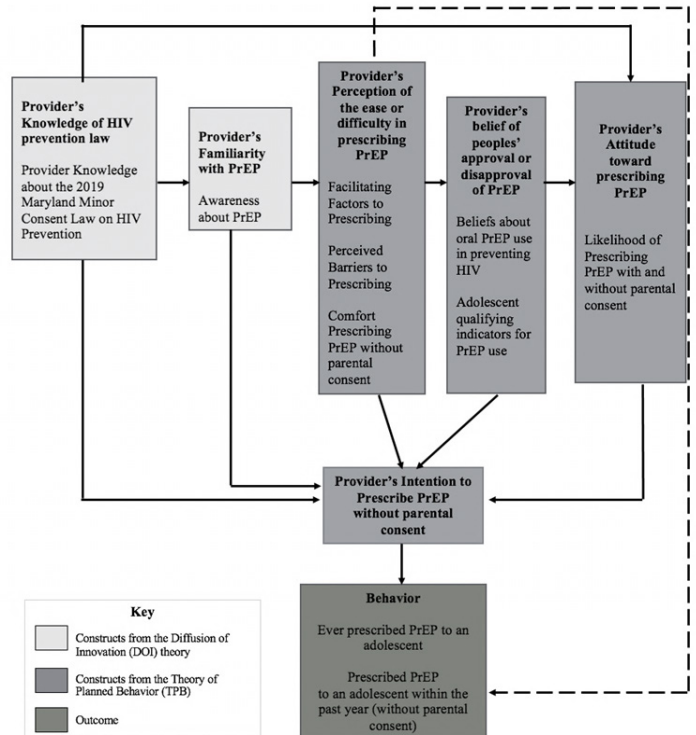


Figure 1: Conceptual Model for Prescribing HIV PrEP to Adolescents.

A list of contact information for all 24 local health departments (LHDs) in Maryland was obtained from the Maryland Department of Health's website [13]. The list was narrowed down to 13 LHDs meeting the inclusion criteria. The researchers also obtained a list of PrEP providers in qualifying locations across Maryland using an online database of PrEP prescribers [14]. The researchers then mailed these providers an invitation to participate in the qualitative study. Each provider who was interviewed was conveniently asked to recruit other colleagues who may be interested in participating in the interviews.

Data Collection

Through a detailed review of the relevant literature, consultation with subject-matter experts, and meetings with the proposed research team, the researchers developed a 16-item interview protocol to elicit responses from the providers. The interview protocol contained open-ended questions designed to explore knowledge, awareness of PrEP, perceived barriers, and facilitators to prescribing PrEP, and likelihood of prescribing PrEP among Maryland providers.

A descriptive/interpretative semistructured interview approach was employed to elucidate subjective answers to the questions asked [15]. Participants had the option to be interviewed in person or virtually; however, due to the lockdown restrictions in place to combat the COVID-19 pandemic, all interviews were conducted via direct telephone calls or zoom. Each provider participated in one open-ended, semistructured audio-recorded interview which

lasted for an average of 45 minutes and was offered a \$50 gift card in compensation for their time. Field notes were taken during each interview and all recordings were later transcribed and de-identified in preparation for analysis. Interviews were completed between January 2021 and June 2021.

Informed Consent and Ethical Considerations

Informed consent was obtained from all individual participants included in the study. This study received IRB approval from the office of Morgan State University IRB in March 2020 and approval from the Maryland Department of Health IRB in July 2020. In addition, the researchers protected the respondents from harm by masking their names and assigning participant numbers accordingly [11].

Data Analysis

Data was stored, managed, and analyzed using ATLAS.ti 9. The interviews were transcribed into word document using a transcription application called Transcribe. The transcripts were read and reread to ensure familiarity with the concepts of the interviews. The researchers used member checking, also known as respondent validation, to enhance the study's validity and trustworthiness [16]. Additionally, the researchers adopted the analytic strategy referenced by Creswell and Poth [11]. Data were indexed and charted into themes using ATLAS.ti 9. Lastly, the researchers reviewed the codes, identified emerging themes using an iterative process, and interpreted the results.

Data collection was concurrent with the analysis, and the process continued until saturation was reached or no new themes emerged. The data analysis was guided by framework analysis [17]. The framework analysis is used in research when asking specific questions.

Results

A total of 18 providers participated in the study. Of these, 61% (n = 11) self-identified as Black or African American, 33% (n = 6) identified as White, and 6% (n = 1) identified as other. Seventy-two percent (n = 13) of the participants were female and 28% (n = 5) were male. Overall, about 30% of the participants were between the ages of 46 and 50.

Regarding their medical profession, 61% (n = 11) were nurse practitioners, 33.3% (n = 6) were physicians, and one (n = 1; 5.7%) was a physician assistant. Some of the providers practiced in more than one location; 44% (n = 8) of respondents were practicing in Baltimore City, 22% (n = 4) were practicing in Howard County, 11% (n = 2) were practicing in Baltimore County, 11% (n = 2) were practicing in Anne Arundel County, 6% (n = 1) were practicing in Allegany County, and 6% (n = 1) were practicing in Prince George's County.

Clarke and Braun [18] recommended that qualitative studies utilize a minimum sample size of at least 12 to reach data saturation. These recommendations were further referenced by Fugard and Potts [19] in their article, noting that "for small projects, 6–10

participants are recommended for interviews, 2–4 for focus groups, 10–50 for participant-generated text and 10–100 for secondary sources" [19]. Consequently, a sample size of 18 was considered sufficient for this qualitative analysis and interview-based study.

Nine key themes and more than 100 subthemes were identified from the data analysis. The subthemes were grouped to form main themes based on similarities, relevance, and context. Key findings of the analysis revolved around nine main themes: (a) knowledge: the knowledge and awareness about PrEP, and knowledge of the MMCL for HIV prevention treatment; (b) experience of PrEP prescription; (c) provider beliefs about PrEP; (d) likelihood of prescribing without parental consent; (e) comfortability in prescribing; (f) qualifying indicators for PrEP use; (g) provider perceived barriers to prescribing PrEP; (h) provider-reported adolescent barriers; and (i) facilitators or recommendations for promoting PrEP prescription and uptake. A summary of the key provider characteristics is shown in the Table 1, and provider perceived barriers to prescribing PrEP are detailed Table 2.

Adolescent Provider Demographics and Practice Characteristics (n = 18)

	N	Percent
Gender		
Female	13	72%
Male	5	28%
Race		
Black or African American	11	61%
White	6	33%
Other or not indicated	1	6%
Age		
30–35	4	22%
36–40	3	16%
41–45	1	6%
46–50	5	27%
51–55	1	6%
56–60	1	6%
61–65	2	11%
66–70	1	6%
Medical profession		
Nurse practitioner	11	61%
Physician	6	33%
Physician assistant	1	6%
Medical specialty		
Family medicine	11	61%
HIV medicine & infectious diseases	3	17%
Pediatrics	2	11%
Internal medicine/pediatrics	2	11%
Geographical location (practice area)		
Baltimore City	8	44%
Howard County	4	22%
<hr/>		
	N	Percent
Baltimore County	2	11%
Anne Arundel County	2	11%
Allegany County	1	6%
Prince George's County	1	6%
Percentage of adolescents seen in practice		
1%–25%	12	67%
26%–50%	6	33%

Note. Percentages are rounded to the nearest integer.

Category	Subcategory
Barriers affecting PrEP delivery and effectiveness	Suboptimal adherence to PrEP due to concerns about frequency of use; pill size; lack of motivation-patients are lost to follow-up; limited adolescent's knowledge of PrEP Logistical concerns: high cost of PrEP and copay; uncertainty about insurance authorizations; EOB and confidentiality; parents might find out about child's sexual behaviors and orientation; challenges in accessing minors most likely to benefit from PrEP use
Potential unintended consequences of prescribing PrEP	Parental concerns about long-term side effects; adolescents worried about side effects
Knowledge and skills	Limited provider awareness, education and training on prescribing PrEP; limited provider knowledge of the MMCL for HIV prevention treatment; limited skills in assessing for and discussing HIV-risk behaviors
Comfort	Moral conflict: provider concerned that patients may become unsafe while taking PrEP
Organization-level barriers	Organization's policies not up to date to prescribe PrEP to minors; telemedicine referrals may affect care coordination; challenges with staffing

	N	Percent
Baltimore City	8	44%
Howard County	4	22%
Baltimore County	2	11%
Anne Arundel County	2	11%
Allegany County	1	6%
Prince George's County	1	6%
percentage of adolescents seen in practice		
%-25%	12	67%
6%-50%	6	33%

note. Percentages are rounded to the nearest integer.

Knowledge

Generally, participants were reasonably knowledgeable of the concepts of PrEP and of the MMCL, legislation supporting the prescription of PrEP to minors without parental consent. About PrEP, three providers (65.7%) were very knowledgeable and aware of PrEP, 14 participants (77.7%) were knowledgeable, and one participant (5.6%) had very limited knowledge of PrEP but was aware of it: “Um, currently I don’t really have that much knowledge of it. I have not prescribed it. I mean I’ve heard about it, but I can’t say I’m very knowledgeable” (Participant 12). About providers’ knowledge of the MMCL, half (50%) of the participants were knowledgeable about the legislation that would allow them prescribe PrEP to adolescents without parental consent.

Several participants were found knowledgeable because of their professional experience in implementing or prescribing PrEP. Some participants shared that PrEP was not extensively taught in medical school and contended that knowledge and information about PrEP could be gained through various professional development and training opportunities.

Participants also shared that, in some cases, they faced barriers in prescribing PrEP for adolescents despite their knowledge of the MMCL. Clinicians typically have other clinic protocols to follow in addition to the MMCL. One provider stated that, despite the passage of the MMCL, organizational policies and procedures may not be updated to reflect the legislative changes. Although some practitioners were not fully aware of the law, they reported being

connected to programs that offered sexual and reproductive health services to minors. Awareness of the MMCL for HIV prevention treatment could be another step to the prevention and reduction of HIV infection rates among minors in Maryland.

Experience of PrEP Prescription

The providers had dissimilar experiences in the prescription of PrEP. Thirteen of the participants (72.2%) had prescribed oral PrEP to adults in the past; however, since the passage of the MMCL, some have yet to prescribe PrEP to adolescents. Few participants reported having less experience with PrEP prescription. Nonetheless, all five providers (27.8%) who currently do not prescribe PrEP to adults or adolescents expressed great interest in prescribing.

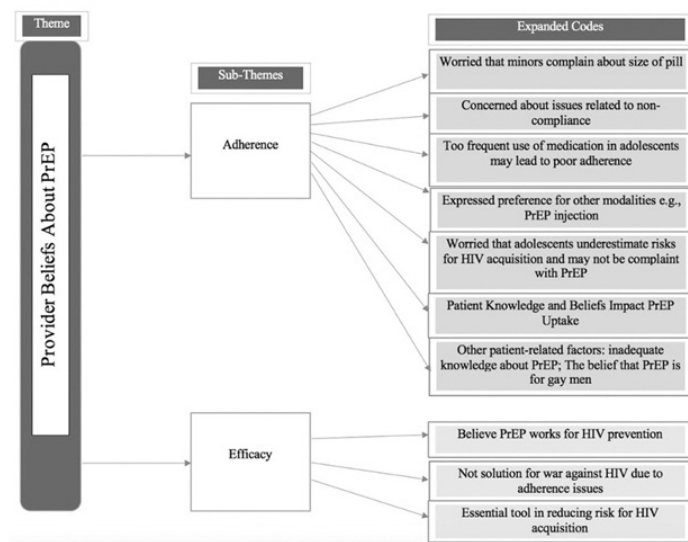
About exclusively prescribing PrEP to minors, eight participants (44%) reported prescribing PrEP to adolescents but did not indicate whether it was with or without parental consent. Of those, only three (16.7%) self-reported to have written PrEP prescriptions for minors in the past year: “I have prescribed to about two or three adolescents in the past year” (Participant 6). Many of the participants care for adults more frequently than they do for adolescents; therefore, they know about PrEP but do not have much experience suggesting this treatment for adolescents.

The need to expand adolescents’ access to PrEP services beyond traditional clinic settings was emphasized by many providers. Suggestions included offering PrEP-related education, testing, and treatment at school-based wellness centers, including to adolescents in middle and high schools.

Provider Beliefs about PrEP

The study respondents reported several beliefs about oral PrEP. Those beliefs were further broken down into two subthemes: adherence and efficacy (Figure 2). The adherence subtheme was broken down into seven codes. The efficacy subtheme was broken down into three codes.

Provider Beliefs About PrEP



Likelihood of Prescribing without Parental Consent

Most clinicians (n = 12) reported being very likely to prescribe the PrEP treatment to minors without parental consent, whereas others (n = 6) reported being likely to prescribe. Many providers expressed that, just as with birth control pills, they were very likely to prescribe PrEP without parental consent. Patients who are on PrEP were seen and treated following the CDC guidelines, as shared by some of the providers.

Although many of the providers were likely to prescribe PrEP, a few shared reservations that might still impact their decision to prescribe. These reservations include the minor's risk for HIV acquisition, adolescents' willingness to participate in the PrEP program, having organizational protocols in place, and staff support (e.g., having PrEP case managers who will provide follow-up). Further, many providers attributed their likelihood of prescribing PrEP with the comfort of having legislation in place.

The sense of confidentiality and conducting all procedures with anonymity could make prescribing PrEP more seamless. The issue of the explanation of benefits (EOB) is a hurdle for some clinics without Title 10 designation, which results in some practitioners not prescribing PrEP to adolescents despite knowing about PrEP and the MMCL.

Comfortability in Prescribing

Among the respondents, four (22.2%) expressed being very comfortable with prescribing PrEP to minors without parental consent, 12 (66.7%) reported being either fairly comfortable or comfortable, and two (11.1%) reported feeling uncomfortable with prescribing. Two providers, both of whom are parents, expressed being uncomfortable with prescribing due to moral conflict. One of the clinicians stated: "I would do it, but I would be uncomfortable. In addition, it is mainly the moral conflict of being a parent.... I can't take out the fact that I'm a parent and I would feel that sense of conflict would still exist in my heart" (Participant 10).

Additionally, the providers who were least likely to prescribe PrEP linked their comfort in prescribing PrEP with their lack of knowledge and familiarity with PrEP. However, these providers stated that they would still prescribe PrEP to promote the health of clients regardless of their knowledge deficit.

Similarly, a few clinicians attributed the lack of PrEP-related training while in medical school as a barrier to feeling comfortable prescribing PrEP: "Providers are not taught PrEP in medical curriculum. And that may be why they're not comfortable prescribing PrEP" (Participant 2). Most providers who expressed either feeling very comfortable or comfortable in prescribing PrEP attributed their increased comfort to their increased knowledge.

Providers' comfort level with prescribing is also higher knowing that the MMCL is in place. Due to the MMCL, providers may not need to worry as much when parents find out their child

was prescribed PrEP without parental consent: "I believe the revised law gives me some level of comfort because the majority of these parents would freak out if they knew their kids were being prescribed PrEP. It would be an uncomfortable situation" (Participant 2).

Similarly, a few providers expressed less comfort in prescribing because of organizational policies. In other words, they are less comfortable prescribing due to the ambiguities in rules and policies of the specific setting or clinic.

Qualifying Indicators for PrEP Use

The providers shared a variety of indicators and criteria that they use when deciding whether to prescribe PrEP. The indicators were divided into four subthemes: adolescent knowledge, sexual orientation and behaviors, sexual health and history, and social factors. These findings are consistent with the clinical considerations for PrEP use made by the USPSTF [20]. The recommendations include the following: (a) sexually active MSMs with a serodiscordant sex partner, inconsistently using condoms during receptive or insertive anal sex, or with a sexually transmitted infection of syphilis, gonorrhea, or chlamydia within the last 6 months; (b) heterosexually active persons involved in a sexual relationship with a partner who is HIV positive, someone who is not using condom consistently with a partner with an unknown HIV status, or with history of syphilis and gonorrhea within the past 6 months [20]; and (c) persons who inject drugs and share drug injection equipment or at risk of HIV acquisition through sex [20].

Provider Perceived Barriers to Prescribing

Providers faced certain challenges when prescribing PrEP. These challenges are detailed through the following subthemes: barriers affecting the delivery and effectiveness of PrEP, potential unintended consequences of prescribing PrEP, knowledge and skills, comfort and moral conflict in prescribing, and organizational-level barriers to prescribing PrEP (see Table 2). The main concerns shared among the providers were related to adherence, cost of medication, hurdles with billing and insurance authorizations, and issues with navigating EOBs.

Provider-Reported Adolescent Barriers

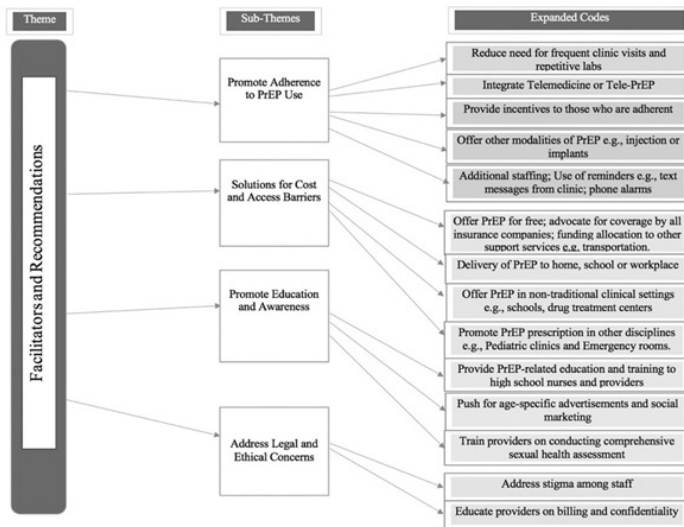
Adolescents also face challenges and barriers when navigating care for PrEP-related services. Those barriers can ultimately impact the uptake and ongoing adherence to PrEP. Key provider-reported adolescent barriers emerged from this theme and were broken down into subthemes, which include adherence, stigma, education, ethical issues, and other access-related concerns.

Facilitators and Recommendations

The proposed recommendations from this study were similar to those highlighted by Mullins et al. [21]. Clinicians that can be incorporated into the healthcare system to improve the implementation of PrEP and MMCL (Figure 3) suggested some solutions. Congruent to these findings, there is a need for "system-level improvements to increase coordination between patients,

providers, pharmacies, and payers to facilitate PrEP access and uptake” [22]. There should also be more focus in ensuring that the primary health workforce is ready to deliver competent and safe access to PrEP services across various settings and population groups [23].

Facilitators and Recommendations



Discussion

The DOI theory was instrumental in eliciting responses related to providers’ knowledge of PrEP and the MMCL. The TPB, on the other hand, was beneficial in yielding responses that could help in better understanding the facilitators and barriers to prescribing PrEP. Overall, the conceptual model worked very well for this study as intended.

Provider participation from Prince George’s County was remarkably low (n=1) despite equal recruitment efforts being made across all jurisdictions meeting the inclusion criteria. Unfortunately, data from the 2019 Maryland HIV Factsheet shows that the highest rates (per 100, 000) for new HIV diagnoses within the state were from Baltimore City and Prince George’s County [24]. In addition, in 2019, there were 289 new HIV diagnoses in Prince George’s County. Of those, 83.0% were Non-Hispanic Black, and 11.1% were Hispanic [25]. Although invitations were sent to clinics in all counties that met the study’s inclusion criteria, there was no provider participation from Calvert, Carroll, Charles, Kent, Montgomery, Washington, and Wicomico. Nine themes emerged from the data analysis.

In a qualitative study, Larazou et al. [23] reported that the few providers who shared negative concerns about PrEP had limited history working in HIV and PrEP programs. Larazou et al.’s findings are consistent with the results from this study because the few participants who reported having limited knowledge of PrEP also had limited experience prescribing to adults and/or adolescents. According to Patrick et al. [26], achieving an increase in PrEP coverage may be simply addressed by delivering PrEP-

specific education to providers.

Half of the participants were knowledgeable about the MMCL for HIV prevention treatment. However, not many providers had prescribed oral PrEP exclusively to minors in the past 1 year or were currently prescribing. It is important to note that over 60% of participants said they were very likely to prescribe PrEP to minors without parental consent. Findings from this research were consistent with results from previous studies regarding providers’ likelihood of prescribing PrEP. However, there continue to be few providers who prescribe to minors. The gap needs to be addressed to improve the delivery of PrEP within the adolescent age group.

The Food and Drug Administration (FDA) approved its first injectable treatment for HIV PrEP for use in at-risk adults and adolescents weighing at least 35 kilograms (77 pounds) Apretude (cabotegravir extended-release injectable suspension) in December 2021 [27]. One recommendation is to support research investigating adolescents’ adherence to nonoral PrEP treatments. To ensure that PrEP is more widely available to youths at increased risk for HIV acquisition, barriers specific to PrEP use in minors must be evaluated [21]. Future researchers should also assess incentive-based PrEP delivery models for adolescents and its impact on promoting adherence to PrEP.

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