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PrEP Up Pharmacies: Evidence of a pharmacy-based same-day pre-exposure prophylaxis (PrEP) screening and dispensing model in the United States Southeast

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Background: Only 30% of the 1.2 million people indicated for pre-exposure prophylaxis (PrEP) have a prescription. Evidence shows pharmacies can expand access, yet few models have been tested in this region.

Methods: We developed and tested the PrEP Up Pharmacies study, which trains pharmacists and pharmacy technicians to direct clients to an in-pharmacy health screening that includes an eligibility screener and for those eligible, a socio-behavioral survey, HIV self testing and counseling. Clients testing negative are offered a 30-day tele-PrEP prescription; those testing positive are linked to HIV care. We assessed uptake at each step, differences by client characteristics, and time from screening to self-testing or the corresponding point.

Results: Of 247 pharmacy clients informed about the screener survey, 26% (n=64) were screened and most (71.9%) were willing to complete the socio-behavioral survey. Men were more likely than women (p=0.021) to complete the socio-behavioral survey and there were no differences by race. Most clients were recommended for HIV testing (58.7%) based on self-reported sex and drug use risk behaviors. However, self-HIV testing uptake was low (17.4%); there were no differences in willingness to self-test by race, sex or age. Most clients tested HIV-negative and were offered PrEP (88%), however 71.4% declined PrEP due to low HIV risk perceptions. Two clients obtained tele-PrEP prescriptions within 24-hours, and one was referred to HIV care.

Conclusions: Preliminary results support same-day pharmacy-based PrEP delivery and highlight risk perceptions as a barrier. Future efforts will test how additional evidence-based practices impact PrEP uptake in more pharmacies.

Keywords: Pre-exposure prophylaxis (PrEP); HIV prevention; community pharmacies; self-testing; PrEP uptake

Abbreviations

PrEP	Pre-exposure prophylaxis
EHE	End the HIV epidemic
CFIR	Consolidated Framework for Implementation Research
SEIPS	Systems Engineering Initiative for Patient Safety
QR	Quick Response
IQR	Interquartile range
SD	Standard deviation

Background

HIV remains a significant public health problem, and despite promising interventions, pervasive racial and geographically distributed inequities persist. In 2022, 31,800 people were newly diagnosed with HIV. Over 70% of new HIV diagnosis were among Black people, despite Black people making up only 12% of the US population, and over 50% of all HIV cases are in the US Southeast [1]. Pre-exposure prophylaxis (PrEP) is one of the most effective, yet underutilized HIV prevention strategies. Daily oral PrEP can prevent up to 99% of HIV infections [2], but only 25% of those who need PrEP are currently prescribed [3]. Trends in PrEP use by race are dire: in 2019, 8% of Black people compared to 60% of White people who needed PrEP were prescribed [4]. Just three years later, in 2022, PrEP uptake only increased 5% for Black people compared to a 34% increase for White people totaling to 94% of White people who need PrEP being provided a prescription compared to just 13% of Black people [5]. Successful increases in PrEP uptake for White populations coinciding with dismal increases for Black populations indicates that current interventions to increase PrEP uptake are failing to reach Black populations who are at the highest risk. Thus, innovative strategies to reach Black populations is desperately needed to End the HIV epidemic (EHE) [3] .

Compelling evidence shows that access to PrEP clinics is a major barrier to increasing PrEP uptake among Black Americans. Harrington et al showed that in the US Southeast, many counties with high HIV risk had no PrEP clinics or an inadequate amount of PrEP clinics to serve the risk needs of the population. Yet, geospatial analyses show that pharmacies were evenly dispersed across all areas in the US Southeast and could increase access to PrEP by 80-fold if they were integrated into the HIV prevention strategy to EHE [6]. Overwhelmingly positive evidence has shown that pharmacies are a viable option for increasing PrEP access, particularly for Black populations. Most populations, regardless of race, live within five miles of a pharmacy and they

have long business hours outside of standard workdays [7]. Pharmacies are often located in the highest HIV risk neighborhoods which also are more likely to be Black and lower income neighborhoods [8] that are disproportionately affected by HIV. Pharmacists that work in these neighborhoods have a good reputation with community members who view them as a trusted source of health care [9,10]. Importantly, data consistently show that both pharmacists and pharmacy clients want HIV prevention, and PrEP specifically to be available in pharmacies [11]. A seminal study by Weidle et al showed that of 21 community pharmacies in Virginia who participated in a pharmacy-based HIV testing intervention, most (n=17) planned to continue offering HIV testing after the study period because of its' workflow integration and cost effectiveness [12]. Another seminal study by Tung et al, found that pharmacy clients who were screened for PrEP and onboarded by pharmacists in Seattle had an over 90% PrEP adherence [13].

A number of studies across the US have added to the chorus of positive evidence for pharmacy-based HIV prevention services [14]. In the US Southeast, qualitative studies have shown that pharmacists and pharmacy technicians have high willingness to provide PrEP services [15]. Quantitative evidence has also shown high willingness to obtain PrEP services in pharmacies, especially among Black populations at an elevated risk for HIV [16]. However, the legislative landscape of pharmacies in many states in the US Southeast require innovative strategies for these pharmacies to be able to provide these services. For example, many states lack specific guidance on pharmacists ability to perform PrEP screening as a part of their scope of practice, trainings to guide pharmacy staff on how to perform PrEP screening are obsolete as is the infrastructure for pharmacies to link clients with HIV clinicians for additional HIV prevention and care services [17-20]. To fill this critical gap in pharmacy services and community HIV prevention need, we developed and tested the PrEP Up Pharmacies study, which is a same-day PrEP

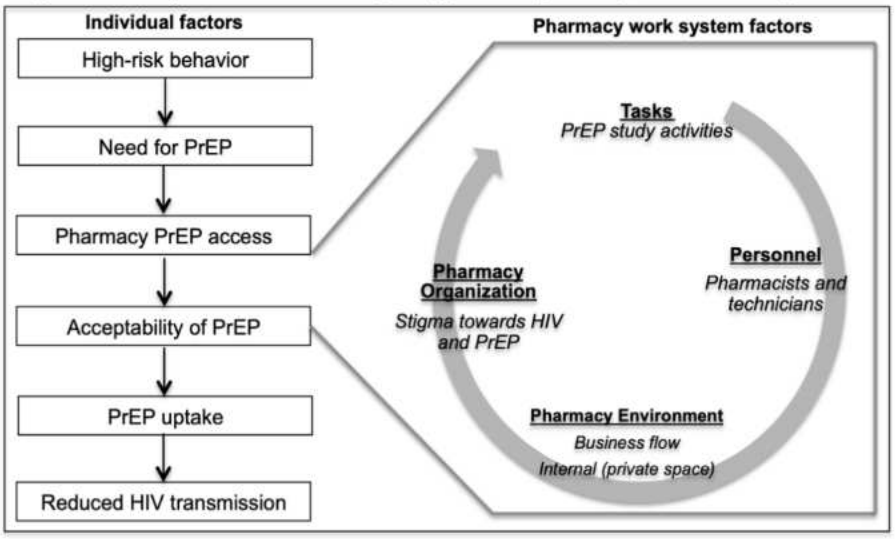
screening and dispensing model that fits within the legislative boundaries of most US Southeastern states [21]. The goal of this manuscript is to describe the implementation and feasibility outcomes among pharmacy staff and pharmacy clients enrolled in the PrEP Up Pharmacies study.

Methods

Study overview and conceptual model

PrEP Up Pharmacies was developed between May 2021 and February 2022 as a hybrid type 2 implementation trial [22] for pharmacy integration in Atlanta, Georgia. The pilot study began in June 2022. The PrEP Up pharmacies model was informed by two implementation frameworks: Consolidated Framework for Implementation Research (CFIR) [23] and Systems Engineering Initiative for Patient Safety (SEIPS) [24]. SEIPS was used to complement the well-used CFIR to ensure organizational feasibility and compatibility with pharmacy systems (Figure 1). As shown in **Figure 1**, the first line of entry to improving PrEP access in pharmacies relies on implementable activities. In turn, these activities are completed by the pharmacists and technicians who need training and self-efficacy to implement PrEP screening and dispensing. This work is then supported by the pharmacy environment which includes distal organizational structures that enable or prohibit tasks such as workflow, space, and time constraints [25]. Finally, pharmacy organizational factors may also underpin stigma towards PrEP services if these services or specific clients are singled out. Therefore, the process between work system and client factors including acceptability and satisfaction among the *pharmacy staff* and *clients* are explored in this study. All study activities were approved by the Emory University Institutional Review Board.

Figure 1. Conceptual framework integrating pharmacy work system influencing PrEP



Intervention procedures

Prior to implementation, a workflow assessment was conducted to examine staffing patterns, task flow, and space constraints within the pharmacy. Findings from this assessment guided the placement of PrEP related activities within existing operations [26].

Pharmacy staff who agreed to participate in the PrEP Up Pharmacies study were consented and trained on the fundamentals of HIV prevention, PrEP and the study activities via a one and half hour online, continuing-education certified training. Prior to the implementation of study activities, research staff created a private space using partitions, and noise machines to muffle sounds for all study-related activities. They also strategically hung posters and placed flyers throughout the pharmacy about a research study being conducted in the pharmacy that included a quick-response (QR) code so that clients could access a 10-question screener survey to determine study eligibility. The study advertisement materials were disease agnostic so that stigma related to HIV would not influence pharmacy client decisions about participating. Pharmacy staff informed pharmacy clients about the study and directed them to screen for the study using their smartphones. Pharmacy clients who did not have a smartphone but wanted to

screen were directed to the private space where they could screen using a tablet. Pharmacy clients who were eligible to participate in the study were prompted at the end of the screener survey to inform a pharmacy staff person. An alert that a client screened as eligible for the study was also sent to the pharmacy email and research study team emails. Eligible and willing pharmacy clients were set up to complete a 15-minute social-behavioral survey that assessed socio-demographic characteristics and HIV risk. Pharmacy clients who reported HIV risk behaviors were recommended to complete self-HIV testing. Clients who were willing to perform self-HIV testing, were provided the self-HIV test and visual infographic instructions on how to perform the test. Completed self-HIV tests were given to the pharmacy staff for interpretation and for post-test counseling. While HIV test results were processing pharmacy clients provided their follow-up information. Pharmacy staff informed pharmacy clients of their test results. Those who tested HIV negative were told that they could obtain PrEP via a tele-prescription. Those who tested HIV positive were immediately linked to HIV care.

Pharmacy, pharmacy staff and pharmacy client recruitment and eligibility

During prior formative work that informed the model tested here, a sampling frame of 43 independently-owned, non-chain pharmacies located in highest HIV neighborhoods in Atlanta, Georgia was determined. Through formative interviews, a pharmacy accessible via public transportation with a high volume of walk-in pharmacy clients was identified. The owner pharmacist was approached for participation in the study and after agreement the other pharmacists and pharmacy technicians were asked to participate. Other than employment at the pharmacy, there were no other eligibility requirements for pharmacy staff.

Pharmacy clients who screened for study participation were eligible if they 1) were at least 18 years old, and 2) had any type of sex in the past 6 months; or 3) engaged in unprotective sex in the past 6 months.

Pharmacy staff and client Surveys and Measures

Pharmacy staff completed a quantitative and open-ended assessment at baseline, three and six months. Quantitative measures assessed individual and pharmacy demographic characteristics, availability of various HIV and non-HIV services, counseling practices in the pharmacy, pharmacy neighborhood characteristics, and pharmacist collaboration index with physicians. Open ended questions assessed concerns about pharmacy-based HIV prevention services, engagement and difficulties with study activities.

Pharmacy client surveys assessed socio-demographic characteristics (age, race, gender), sex and substance use practices, pharmacy utilization of HIV and non-HIV related services, health outcomes, discrimination experiences, mental health and willingness, acceptability and safety perceptions of pharmacy-based HIV prevention services which included uptake of the socio-behavioral survey (yes, no), willingness to self-HIV test (yes, no), actual self-HIV testing uptake (yes, no), willingness to receive PrEP (yes, no) and PrEP uptake over three month period (yes, no).

Analysis

Open-ended questions from pharmacists and pharmacy technicians were analyzed using the Framework Method [25], to assess the feasibility and acceptability of implementing pharmacy

based-HIV prevention services. After transcribing and reviewing the data, two team members independently conducted open coding on a subset of transcripts to identify initial themes related to feasibility and task readiness. A shared codebook was developed through discussion and refined using unitization process to ensure consistency. Once finalized the codebook was applied to the remaining transcripts. Coded data were then organized into a summary table that compared responses across key domains.

Exploratory data analysis was conducted on the pharmacy client survey data using R and SAS programming. For continuous variables, we calculated the median and interquartile range and for categorical variables, we calculated the frequency. Differences in pharmacy client reports of willingness, acceptability and safety perceptions of pharmacy-based HIV prevention services were compared based on pharmacy client socio-demographics, sex and substance use practices, pharmacy utilization of HIV and non-HIV related services, health outcomes, discrimination experiences, and mental health using Chi-square tests or Fisher's exact tests.

Process time data were derived from timestamped entries associated with each study activity. For participants who completed the full intervention, total process time was calculated as the duration between the initiation of the eligibility screener and the completion of HIV-self testing. For those who completed only a subset of activities (e.g., survey without testing), time was calculated based on the relevant start and end points. Time data were summarized using descriptive statistics to characterize the distribution of total and component-specific durations across participants.

Role of the funding source

The National Institute of Mental Health supported this work under award R34MH119007 and had no role in the study design, data collection, data analysis, interpretation or writing of this report.

Results

Pharmacy staff interviews showed that acceptability was high among all pharmacy staff for the pharmacy training and the PrEP Up pharmacies model. Specific to the training, pharmacy staff felt that two CE credits were sufficient for their time spent completing the training. However, substantial time and effort was required to ensure that all pharmacy staff were able to complete the training prior to model implementation. Specific to the PrEP Up pharmacies model, all of the pharmacy staff were able to perform the required activities (e.g., informing pharmacy clients about the screening, evaluating HIV testing results, provision of post-HIV testing counseling, PrEP and HIV care linkage). However, pharmacy staff were less likely to implement the model when the pharmacy was busy. Importantly, pharmacy staff reported their inability to perform the model when the research infrastructure was no longer in place since this facilitated their time costs. (Table 1)

Table 1. Themes and subthemes from pharmacy staff interviews

Theme	Sub-Theme	Finding
Training Acceptability	CE credits	Staff reported that two CE credits were sufficient compensation for their time completing the training.
	Training completion effort	Substantial time and effort were required to ensure all staff completed training prior to model implementation.
Model Acceptability	Ability to perform required activities	Staff successfully informed clients about screening, evaluated HIV test results, provided post-test counseling, and supported PrEP/HIV care linkage.
	Workload and competing demands	Staff were less likely to implement the model when the pharmacy was busy
	Sustainability and infrastructure	Staff reported they could not continue the model without research infrastructure to offset time costs.

There were 247 pharmacy clients informed about the PrEP Up pharmacies study, of which 25.9% (n=64) were screened and most (71.9%; n=49) were willing to complete the socio-behavioral survey. The median age of individuals who completed the socio-behavioral survey was 38 (IQR:30-53). As shown in Table 2, most pharmacy clients were male (61%), Black (88%), non-married (83.3%), with some college education or more (53·7%), low-income defined as making $20,000 or less (69%) and had health insurance (55%). Most pharmacy clients were heterosexual (91%) and almost half (47%) reported having unprotected sex. About one-third (31%) reported awareness of PrEP and slightly more (38%) were willing to screen for PrEP in a pharmacy, 71% were comfortable speaking to a pharmacist about PrEP, half were willing to be referred to PrEP by a pharmacist and only 2.2% had ever used PrEP.

Table 2. Descriptive characteristics of surveyed pharmacy client sample (n=49)

	Overall sample
	N (%)
Age (Median, IQR)	38, (30, 53)
Gender	
Female	19, (38.8%)
Male	30, (61.2%)
Race	
Black	43 (87.8%)
White	1, (2.0%)
Other	5, (10.2%)
Marital status	
Married	8, (16.7%)
Non-married	40, (83.3%)
Education level	

High school education or less	20, (44.2%)
Some college or more	25 (53.7%)
Income	
$20,000 or less	27, (69.2%)
Greater than $20,000	12, (30.8%)
Health insurance	
Yes	26, (55.3%)
No	21, (44.7%)
Sexual orientation	
Heterosexual	41 (91.1%)
Homosexual	4 (8.9%)
Sexually active	
Yes	32 (96.9%)
No	1 (3.0%)
Unprotected sex	
Yes	20 (46.5%)
No	22 (51.2%)
Substance use	
Yes	34(73.9%)
No	12(26.1%)
PrEP awareness	
Yes	15, (31.3%)
No	31, (66.6%)
Lifetime PrEP use	
Yes	2, (4.4%)
No	43 (95.5%)
Willingness to screen for PrEP	
Yes	18, (36.7%)

No	30, (62.%)
Comfortable speaking to a pharmacist about PrEP	
Yes	34, (70.8%)
No	14, (29.2%)
Willingness to be referred to PrEP by pharmacist	
Yes	17 (50%)
No	17 (50%)

There were minimal differences in willingness to complete any part of the PrEP Up model by demographic and behavioral characteristics among pharmacy clients. As detailed in table 3, men were more likely than women (p=0.021) to complete the socio-behavioral survey and there were no differences by race. Most clients were recommended for HIV testing (58.7%) based on self-reported sex and drug use risk behaviors. However, self-HIV testing uptake was low (17.4%). Importantly, there were no differences in willingness to self-test by race, sex or age. Most clients tested HIV- negative and were offered PrEP (88%), however 71.4% declined PrEP due to low HIV risk perceptions. Two pharmacy clients obtained tele-PrEP prescriptions within 24-hours, and one was referred to HIV care.

Table 3. Acceptability of PrEP Up Pharmacy model

	Overall sample (n=64)	Socio-behavioral assessment (n=49)		Willingness to self-HIV test (n=14)		Actual self-HIV testing uptake (n=8)		Willingness to receive PrEP (n=9)		PrEP referral (n=7)	
Age (Median, IQR)	38, (30, 53)	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value
Gender			0.021		0.6		0.043		>0.9		0.01
Female	28(44%)	18, (37%)		5, (36%)		6, (75)		3(33%)		6, (86%)	
Male	35(55%)	31, (63%)		9, (64%)		2 (25%)		6(67%)		1, (14%)	

Race			0.4		0.4		>0.9		>0.9		>0.9
Black	61(95%)	48, (98%)		13, (93%)		8, (100%)		9(100%)		7 (100%)	
Asian	1(2%)	1, (2.0%)		0, (0%)		0 (0%)		0, (0%)		0 (0%)	
White	1(2%)	0, (0%)		0, (0%)		0 (0%)		0, (0%)		0 (0%)	
Other	0, (0%)	0(0^)		1(7.1%)		0 (0%)		0(0%)		0 (0%)	

Among pharmacy clients who completed all intervention components, the mean total process time was 47 minutes (SD:13), and the median was 43 minutes (IQR: 39,51). The sociobehavioral survey had a mean duration of 24 minutes (SD: 17) and a median of 19 minutes (IQR: 15,31). HIV self-testing and counseling required an average of 20 minutes to complete.

Discussion

The PrEP Up Pharmacies study developed and evaluated the implementation and feasibility of a same-day PrEP screening and dispensing model the US Southeast. The PrEP Up Pharmacies model shows strong feasibility for pharmacies ability to perform behavioral and clinical screening of pharmacy clients who are at risk for HIV and link to a PrEP prescription on the same day using telehealth. This model creates a pathway for pharmacies, particularly those in the US Southeast where HIV burden and transmission are high, to be able to provide critically needed HIV prevention services. However, while pharmacists and pharmacy technicians were supportive of the model, and could effectively complete the model activities and integrate them into their workflow, all of them expressed concerns about the sustainability of the model outside of the research infrastructure. This concern was driven by inadequate processes for obtaining reimbursement for their time performing the model activities which would not be covered beyond

the research study. Despite this, the PrEP Up pharmacies model is an important first step in establishing a model that could be integrated into pharmacies in the US Southeast.

The findings of this study that show that PrEP screening and dispensing can be safely and feasibly integrated into pharmacies are not unique to this study. Seminal work by Tung and colleagues have proven that pharmacist-led PrEP screening, even in collaboration with a clinician for prescribing can effectively reach populations at high risk for HIV and support high levels of adherence thereby reducing community transmission [13, 27-31] . These findings and others have encouraged several states, including Southeastern states to pass legislation allowing pharmacists to prescribe PrEP independent of a clinician. There are currently two states in the US Southeast, Louisiana and Tennessee, who have recently passed legislation authorizing pharmacists' ability to prescribe PrEP independent of a PrEP clinician [32,33]. This advancement would drastically simplify the PrEP Up pharmacies model, however, PrEP Up pharmacies could be implemented in most states without this legislative direction.

The PrEP Up pharmacies model lays an important foundation and provides evidence for integrating PrEP screening and dispensing in pharmacies. However, additional building blocks like legislative advancements are however critical to ultimately institutionalizing these services in pharmacies and decentralizing them from clinic based models, where populations at increased risk for HIV often have lower access. Importantly, pharmacy staff note that legislation must be accompanied by pathways that allow pharmacists and pharmacy technicians to be compensated as other health professionals are for providing these services. These compensation pathways should be viewed as a pathway to not only expand patient access and care but also as an innovative way to fold patients who are not currently accessing PrEP (and

other) care into the broader healthcare system as pharmacy-based PrEP screening will require follow-up and continuity of care that cannot be performed by the pharmacy alone.

This study is not without limitations. First, we tested this model in a pharmacy located in a community with high HIV burden and showed feasibility of the model from a clinical and business perspective. Ultimately, about 70% of the client population reported high risk sexual or drug use behavior, About 22% were willing to perform HIV self-testing in the pharmacy and 10% intiated on PrEP referrals. Each of these steps could create revenue opportunities for a pharmacy by offering HIV prevention products, HIV testing and PrEP dispensing. However, all pharmacies may not have the same HIV risk levels in their client population. Additionally, study resource limitations precluded us from being able to screen more pharmacy clients which may have impacted our results. We also experienced a number of important barriers to implementing the PrEP Up pharmacies model. The most significant barrier was training pharmacy staff. Pharmacy staff were required to participate in an online, CE-certified training for the model to be implemented. Time constraints were experienced by most of the pharmacy staff, but mainly the pharmacists due to their daily, competing work priorities. In small pharmacies especially where there are only 1-2 pharmacists and limited opportunity for work shift coverage, identifying time for training may present a significant barrier for model implementation.

Considering its limitations, PrEP Up pharmacies remains to be a strong model for integrating PrEP screening and dispensing in pharmacies in the US Southeast. The strengths of this model are the integration of pharmacy technicians into the workflow, self-HIV testing that limits the time spent on the model and the telehealth PrEP linkage that garners immediate PrEP access for patients who might otherwise have no way of obtaining these critical services. Future studies

should consider how integration of HIV prevention services varies depending on the services already provided in the pharmacy. Moreover, with more and more states creating legislation to allow pharmacists authority to prescribe PrEP, future studies should examine how this legislation is ultimately implemented in the pharmacy and its impact on pharmacy clients and PrEP uptake.

Conclusions

Together with prior research, our findings strongly support pharmacies as a scalable and practical avenue for expanding PrEP access in regions with persistent disparities and limited clinical infrastructure. Pharmacy-based PrEP screening and dispensing can reach populations who are under-engaged in traditional clinic-based care. However, sustained expansion will require legislative and policy changes. As more states move toward granting pharmacists prescriptive authority for PrEP, models like PrEP Up Pharmacies provide an evidence-based guide for implementation. Embedding PrEP services within everyday pharmacy workflow, combined with telehealth linkage, represents a promising strategy for reducing racial inequities in PrEP uptake and advancing progress toward end the HIV epidemic in the United States.

Declarations

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Authors' Contributions

NDC contributed to the supervision, data curation, formal analysis, investigation, project administration, methodology, visualization, and drafting of the manuscript. AH contributed to data collection, project administration, and drafting of the manuscript. CH assisted with analytic support and drafting of the manuscript. CC contributed to the study design, methodology and manuscript revision. KH supported the study design, methodology and manuscript revision. DA contributed to the methodology, data curation, and manuscript revision. SZ assisted with analytic support and manuscript review. DH contributed to the methodological guidance, interpretation of findings, and manuscript revision. Henry N. Young contributed to the methodological guidance, interpretation of results, and manuscript review.

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Availability of data and materials

De-identified participant data will be available upon reasonable request to the corresponding author. Access will depend on institutional review and completion of a formal data use agreement. Any shared data must be used solely for research purposes that align with the approved study protocol. To maintain confidentiality and comply with the restrictions from the data source, individual-level data cannot be publicly posted.

Ethics approval and consent to participate

Ethics approval was obtained from the Emory University Institutional Review Board (IRB00106370). Prior to participation in the study, all participants provided informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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