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ORIGINAL PAPER

The Promise of Pre-Exposure Prophylaxis – Examining Awareness, Knowledge, and Willingness to use Different Modalities Among US-Based African Immigrants

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Abstract

This study aims to describe and understand the relationship between sociodemographic factors and PrEP awareness, and willingness to use a PrEP modality (oral or injectable).Despite the availability of effective prevention tools such as HIV preexposure prophylaxis (PrEP), African immigrants in the United States are disproportionately affected by HIV. Although PrEP can significantly reduce HIV infection in this population, research evidence on PrEP outcomes, such as awareness, knowledge, and willingness to use, is extremely limited. Between April and May 2022, 92 participants completed an online survey assessing their awareness, knowledge, and willingness to use oral or injectable PrEP. The association between sociodemographic characteristics and PrEP-related measures was examined using descriptive and Pearson's chi-squared or Fisher's exact tests. Participants (N = 92) were born between 1990 and 1999 (46.7%), female (70.76%) and highly educated (59.6%). About 52.2% were unaware of PrEP, and 65.6% were willing to use a PrEP modality. Findings indicate that individuals who reported being aware of PrEP demonstrated a high level of knowledge regarding the medication. Having a healthcare provider was associated with PrEP awareness and willingness to use, while educational status was associated with PrEP awareness. 51.1% of participants were willing to use an oral pill for prevention and 47.8% were willing to use injectable PrEP. Our findings highlight the need for PrEP-related research and interventions for African immigrants to increase awareness and provide options for HIV prevention, as African immigrants are currently not well-represented in PrEP delivery systems in the US.

Keywords HIV prevention · African immigrants · HIV preexposure prophylaxis · HIV/AIDS

Introduction

HIV disproportionately affects African immigrants in the United States (US). Sobering analyses suggest that African immigrants are six times more likely to be living with HIV than other minority groups and the general US population [1, 2]. Accurate data on the odds of infections for African immigrants are lacking, in part, because African immigrants are often overlooked or misclassified as "Black" or "African American" in National HIV surveillance data [3, 4]. Given the ever-growing size of African immigrants in the US (approximately 2 million as of 2019 [5]) and the persistently high rates of HIV infections [1, 6, 7], new approaches to HIV prevention are needed among this population. One such approach is preexposure prophylaxis (PrEP), where

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antiretroviral medications are used to prevent HIV among HIV-uninfected individuals [8].

Oral PrEP has been demonstrated to minimize the sexual transmission of HIV significantly. Models predict that oral PrEP reduces the incidence of HIV by 99.9% for men who have sex with men (MSM) and by 90% for women, assuming daily adherence [9, 10]. Currently, three Food and Drugs Administration (FDA) approved PrEP medicines exist. Two are daily oral single-tablet combinations F/TDF (Truvada® or generic) The third is a 2-monthly injection, Apretude® (cabotegravir 600 mg), which was recently approved in December 2021. [11]. Oral PrEP has mostly been well received, yet overall uptake continues to fall short of what was projected [12]. As an alternative to oral PrEP, long-acting injectable (LAI) PrEP may improve adherence because it needs to be administered less frequently and may increase uptake. Given PrEP's (both oral and injectable) proven efficacy, it could help reduce the incidence of HIV among African immigrants.

A growing but limited body of literature on African immigrants' awareness and knowledge of PrEP indicates a low awareness and knowledge of PrEP as an HIV prevention option [13–15]. These studies were mostly focused on oral PrEP; thus, the option of injectable PrEP remains unexplored. While not much is known about the willingness to use both existing and new PrEP modalities among African immigrants, long-acting injectable PrEP may help lessen difficulties reported in oral PrEP research (e.g., around privacy and pill fatigue [16]). In addition, the studies on PrEP among this population remain primarily qualitative with limited sample sizes, thus limiting generalizability [13, 14]. To date, no known quantitative study has investigated awareness and willingness to use oral and injectable PrEP among African immigrants in the US. In this article, we aim to describe the proportion of PrEP awareness and knowledge, the willingness to use oral and injectable PrEP among African immigrants, and identify the associated sociodemographic factors. This study represents an initial effort to characterize awareness, knowledge, and willingness to use oral or injectable PrEP among African immigrants in the US.

Methods

Study Population

Participants were drawn from a cross-sectional study conducted among African immigrants in the United States. Eligibility criteria were: [1] being 18 years and above; [2] identifying as an African immigrant; [3] reading and writing in English, and [4] not currently using PrEP.

Recruitment and Procedures

Enrollment occurred in April and May 2022. Participants were recruited using WhatsApp, a social media and communication platform [17]. A recruitment message with a REDCap link was posted on WhatsApp status of the first and second author, including the research assistant, and groups (about 30 different groups) that were made up of other African immigrants and asked to share with their networks. African immigrant WhatsApp groups usually have at least 50 people, with some groups having close to 700 people. Such groups are organized across shared interests such as ethnicity, education, religious or social interests. WhatsApp has been demonstrated to be highly effective in recruitment among this population [18], and remains the preferred research recruitment method of choice beyond word of mouth or through community-based organizations [19]. Studies highlight WhatsApp as an innovative, flexible, low-cost strategy to recruit African immigrants [18, 19]. The recruitment messages sent out to groups and individuals on WhatsApp asked that the link not be shared outside of WhatsApp. This was to ensure the validity of the responses. Eligible participants completed a web-based survey assessing demographic characteristics, PrEP awareness and knowledge, and willingness to use oral or injectable PrEP using their phones or computers in English. We documented informed consent by having participants check the "agree" box after being provided with details of the study. The survey was programmed to prevent participants from retaking the survey more than once. Participants received a $10 gift card as compensation. The IRB approved all study procedures at the University At Buffalo.

Measures

We collected sociodemographic data to aid our understanding of the composition of our sample. These items assessed year of birth, gender, marital status, education, annual income, healthcare provider status, and country of origin.

PrEP Awareness

We provided a brief description of PrEP and assessed PrEP awareness using a single item "*Prior to reading the description above, were you familiar with PrEP*?" [Response options: Not at all familiar = 1, familiar = 2].

PrEP Knowledge

For those who indicated they were familiar with PrEP, we assessed their PrEP knowledge using an 18-item PrEP

knowledge questionnaire [Response options: True = 1, False = 2, I don't know = 3].

PrEP Modalities

We used two stand-alone items to assess willingness to use a different modality of PrEP. Participants were asked, "*If there was a pill you had to take once daily every day, would you be willing to use it to help prevent you from getting HIV*?" and "*If there was an injectable, where you will need a dose every 12 weeks, would you be willing to use it to help prevent you from getting HIV*?" [Response options: Very unwilling, Unwilling, Neutral, Willing, very willing]. This variable was collapsed as unwilling to use/neutral (Very unwilling, Unwilling, or Neutral) and willing to use (Willing or very willing) to achieve our study's objectives. While injectable cabotegravir is administered every two months (8 weeks), we chose to inquire about PrEP usage every 12 weeks (3 months) [20].

Data Analysis

The analysis was conducted in STATA Version 16.1 (StataCorp, 2019) among a sample of African immigrants. We described the prevalence of PrEP awareness and willingness to use PrEP modalities by the participants' sociodemographic characteristics (i.e., year of birth, gender, marital status, education, annual income, healthcare provider status, and country of origin), respectively. We used Pearson's chi-squared or Fisher's exact test to determine the statistically significant differences in the prevalence rates by sociodemographic characteristics. A statistically significant test was set at < 0.05 based on a 2-sided test. We also computed the prevalence of PrEP knowledge among the participants who reported being aware or familiar with PrEP to describe those who reported correctly, incorrectly, or didn't know the use of PrEP.

Results

Sociodemographic Characteristics

A full summary of selected demographic variables is presented in Table 1. There was a total of 92 participants in the study. Majority of participants were female (70.7%), from West Africa (44.6%), college-educated (69.6%), married or cohabiting (63.0%), born between 1990 and 1999 (46.7%) and earning between $30,000-$59,999 (31.5%).

PrEP Awareness

Associations between sociodemographic variables and PrEP awareness are also presented in Table 1. More than half of the participants (52.2%) were unaware of PrEP. PrEP awareness was associated with educational status ($p = 0.026$) and healthcare provider status ($p = 0.005$). Among those who were unaware of PrEP, majority had high school or less education (90.00%) and based on the healthcare provider status (i.e., the type of healthcare receive regularly), had not received healthcare services regularly (90.0%). Those aware of PrEP mostly had college or higher education (54.7%) and received healthcare service regularly from primary care providers (60.3%).

PrEP Knowledge

Participants who indicated they were aware of PrEP were asked questions to test their PrEP knowledge. Table 2 shows the prevalence of PrEP knowledge among the participants. Overall, the participants reported a high prevalence of correct knowledge about PrEP use. More than 50% of the participants correctly reported that (i) PrEP/Truvada protects against HIV, (ii) PrEP/Truvada should be used with a condom during sex, (iii) PrEP/Truvada is effective when taken correctly, (iv) must be HIV negative to use PrEP/Truvada, (v) people on PrEP/Truvada still need HIV testing, (vi) there are side effects associated with PrEP/Truvada, but most people don't experience them after the 1st month, (vii) PrEP should be taken every day for it to be effective at preventing HIV, (viii) people on PrEP must be tested for HIV every three months. More than 50% of them also correctly reported that (x) PrEP is not a vaccine against HIV, (xi) PrEP also does not protect against other sexually transmitted diseases (STDs), like gonorrhea and syphilis, and (xii) PrEP is not a cure for HIV.

Willingness to Use a PrEP Modality

We examined the prevalence of willingness to use a PrEP modality (whether pill or injectable) and the association between willingness to use a PrEP modality and sociodemographic variables (Table 3). There was a high willingness to use a PrEP modality for HIV prevention among the participants (65.6%)0.70.4% of men were willing to use PrEP, compared to 63.5% of women who were willing to use PrEP. Additional analysis was run to examine willingness to use PrEP by the modality (whether Pill or Injectable), though the results are not presented in Table 3. 51.1% of participants were willing to use an oral pill for prevention and 47.8% were willing to use injectable PrEP. These findings indicate a high unwillingness to use injectable PrEP

Table 1 Descriptive and bivariate analyses of PrEP awareness based on sociodemographic characteristics of African immigrants (N = 92)

	Total sample	Unaware/Unfamiliar	Aware/Familiar	
	N (%)	n (%)	n (%)	P-value
Overall		48 (52.2)	44 (47.8)	
Age (Birth year)				0.402
1990–1999	43 (46.7)	20 (46.5)	23 (53.5)	
1980–1989	40 (43.5)	24 (60.0)	16 (40.0)	
1962–1979	9 (9.8)	4 (44.4)	5 (55.6)	
Gender				1.000
Female	65 (70.7)	34 (52.3)	31 (47.7)	
Male	27 (29.4)	14 (51.9)	13 (48.2)	
Marital status				0.080
Single	20 (21.7)	6 (30.0)	14 (70.0)	
Married/cohabitating	58 (63.0)	33 (56.9)	25 (43.1)	
Separated/Divorced/ Widowed	14 (15.2)	9 (64.3)	5 (35.71	
Educational status				0.026
High School or less	10 (10.9)	9 (90.0)	1 (10.0)	
Some College/trade school	18 (19.6)	10 (55.6)	8 (44.4)	
College graduate or higher	64 (69.6)	29 (45.3)	35 (54.7)	
Annual household income				0.155
$14,999 or less	11 (12.0)	6 (54.6)	5 (45.5)	
$15,000-$29,999	12 (13.0)	7 (58.3)	5 (41.7)	
$30,000-$59,999	29 (31.5)	14 (48.3)	15 (51.7)	
$60,000-$99,99	21 (22.8)	15 (71.4)	6 (28.6)	
More than $100,000	13 (14.1)	3 (23.1)	10 (76.9)	
Unreported	6 (6.5)	3 (50.0)	3 (50.0)	
Healthcare provider status				0.005
None	10 (11.0)	9 (90.0)	1 (10.0)	
Primary care	58 (63.7)	23 (39.7)	35 (60.3)	
OBGYN	13 (14.3)	10 (76.9)	3 (23.1)	
Dental and others	10 (11.0)	5 (50.0)	5 (50.0)	
Country of origin				0.208
North Africa	7 (7.6)	5 (71.4)	2 (28.6)	
Southern Africa	6 (6.5)	4 (66.7)	2 (33.3)	
East Africa	26 (28.3)	13 (50.0)	13 (50.0)	
West Africa	41 (44.6)	17 (41.5)	24 (58.5)	
Central Africa	12 (13.0)	9 (75.0)	3 (25.0)	

Group differences were based on Pearson's chi-squared or Fisher's exact test at <0.05 and a 2-sided test. Differences in the frequencies within categories are due to missing data. The "total" column displays column % while the "Unaware/Unfamiliar" and "Aware/Familiar" columns display row %

(52.2%). Also not presented in Table 33.3% of the 90 participants were willing to use both oral and injectable PrEP. In Table 3, willingness to use a PrEP modality was associated with healthcare provider status ($p = 0.03$). Those who received dental and other healthcare services regularly were the majority of the participants willing to use PrEP modality (80.0%). Most of those unwilling or were neutral to use PrEP modality were those who had not received healthcare services regularly (77.8%).

Discussion

Given the absence of research on US-based African immigrants' awareness and knowledge about PrEP, the primary purpose of this study was to assess and describe their awareness and knowledge of PrEP and the willingness to use oral or injectable PrEP modality for HIV prevention. Results from this study demonstrate that African immigrants have low awareness of PrEP and a high willingness to use a PrEP modality for HIV prevention. Notably, the finding that women and individuals with lower levels of education exhibit lower awareness of PrEP, despite not being statistically significant, holds clinical significance. The significance lies in the fact that these subgroups may face increased barriers to accessing an effective HIV prevention method. PrEP has demonstrated substantial efficacy in reducing HIV acquisition rates, and its effectiveness is directly linked to awareness and uptake. Consequently, low awareness of PrEP among these subgroups may translate into greater susceptibility to HIV infection. This finding may also reflect broader health disparities and inadequate access to healthcare resources and information. Given the potential implications for HIV prevention efforts, the study

Table 2 PrEP knowledge among PrEP-aware African immigrants (n = 44)

	Total sample	True	False	Don't know
	n	n (%)	n (%)	n (%)
The purpose of PrEP/Truvada is HIV protection	43	41 (95.6)	2 (4.7)	0 (0.0)
PrEP/Truvada is an ART (antiretroviral therapy) for HIV patients	43	20 (46.5)	20 (46.5)	3 (7.0)
If you are on PrEP/Truvada, you should still use a condom when you have sex	44	38 (86.4)	5 (11.4)	1 (2.3)
PrEP/Truvada is effective when taken correctly	43	41 (97.7)	1 (2.3)	0 (0.0)
You must be HIV negative to use PrEP/Truvada	43	29 (67.4)	11 (25.6)	3 (7.0)
People on PrEP/Truvada still need HIV testing	43	43 (100.0)	0 (0.0)	0 (0.0)
There are side effects associated with PrEP/Truvada, but most people don't experience them after the 1st month	43	25 (58.1)	2 (4.7)	16 (37.2)
You can start PrEP/Truvada without labs, except for HIV	43	20 (46.5)	10 (23.3)	13 (30.233)
If you forget to take 1 pill, you must stop taking PrEP/Truvada because protection is no longer effective	43	9 (20.9)	20 (46.5)	14 (32.6)
A person must take PrEP every day for it to be effective at preventing HIV	44	34 (77.3)	2 (4.6)	8 (18.2)
PrEP prevents an HIV-positive person from making enough virus to transmit to a partner	43	23 (53.5)	12 (27.9)	8 (18.6)
People on PrEP must be tested for HIV every three months	43	24 (55.8)	3 (7.0)	16 (37.2)
PrEP is a vaccine against HIV	43	14 (32.6)	26 (60.5)	3 (7.0)
PrEP also protects against other sexually transmitted diseases (STDs), like gonorrhea and syphilis	44	7 (15.9)	23 (52.3)	14 (31.8)
People who are HIV-positive and take PrEP run the risk of developing drug-resistant HIV	43	12 (27.9)	11 (25.6)	20 (46.5)
PrEP is a cure for HIV	43	5 (11.6)	37 (86.1)	1 (2.3)
If a woman is taking hormonal contraceptives (birth control), PrEP will be less effective at preventing HIV	43	12 (27.9)	8 (18.6)	23 (53.5)
HIV-negative women can use PrEP to prevent HIV transmission when trying to have a baby	43	20 (46.5)	7 (16.3)	16 (37.2)

Differences in the frequencies within categories are due to missing data

underscores the importance of targeted interventions and education efforts to promote PrEP awareness and uptake among all individuals at risk of HIV acquisition, irrespective of their demographic background. The findings on low awareness of PrEP among women are consistent with previous studies on PrEP awareness among women in the US [21] and African immigrant women [14, 22]. African immigrant women are disproportionately affected by HIV, with an estimated 12-fold risk compared to women in the US population [1]. PrEP is a promising, female-controlled HIV prevention strategy that has so far been underutilized in women. In order to optimize the usage of PrEP among African immigrant women, it is critical to increasing awareness about PrEP. Evidence suggests that PrEP is a valuable HIV prevention option for women [21].

For those who indicated that there were aware of PrEP, this awareness did not translate to correct responses on the knowledge items. Almost half of the participants incorrectly answered that PrEP is antiretroviral therapy for HIV patients. More than half also incorrectly answered that PrEP prevents HIV-positive persons from making enough virus to transmit to a partner. In addition, slightly more than half indicated that they did not know if a woman taking hormonal contraceptives (birth control) would make PrEP less effective at preventing HIV. These results suggest that health education and awareness-raising efforts are needed to increase PrEP awareness and improve knowledge, which can positively impact broad HIV prevention services and PrEP uptake among this population.

Consistent with studies on willingness to use PrEP among different African immigrant groups [14, 15], participants were willing to use PrEP for HIV prevention. Having a healthcare provider was significantly associated with the willingness to use PrEP, as people may have heard about PrEP from their provider or be willing to access it from their regular provider. This finding is consistent with existing literature highlighting healthcare providers' critical role in promoting and prescribing PrEP for African immigrants [13–15]. However, studies among healthcare providers in the US reveal low awareness and discomfort with prescribing PrEP [23, 24], as well as a lack of cultural competency to engage with African immigrants in a culturally responsive way [13]. Further research is among healthcare providers providing care for this population to understand their training needs to recommend and prescribe PrEP for African immigrant groups.

Limitations

There are important limitations to this study. First, this was a cross-sectional study, limiting our ability to make causal inferences from the finding. Second, the study materials

Table 3 Prevalence of willingness to use a PrEP modality based on sociodemographic characteristics of African immigrants (n = 90)

	Total sample	Unwilling to use/neutral	Willing to use	
	N (%)	n (%)	n (%)	P-value
Overall		31 (34.44)	59 (65.6)	
Age (Birth year)				0.281
1990–1999	42 (46.7)	11 (26.2)	31 (73.8)	
1980–1989	39 (43.3)	16 (41.0)	23 (59.0)	
1962–1979	9 (10.0)	4 (44.4)	5 (55.6)	
Gender				0.631
Female	63 (70.0)	23 (36.5)	40 (63.5)	
Male	27 (30.0)	8 (29.6)	19 (70.4)	
Marital status				0.809
Single	19 (21.1)	6 (31.6)	13 (68.4)	
Married/cohabitating	57 (63.3)	19 (33.3)	38 (66.7)	
Separated/Divorced/ Widowed	14 (15.6)	6 (42.9)	8 (57.1)	
Educational status				0.652
High School or less	10 (11.1)	2 (20.0)	8 (80.0)	
Some College/trade school	18 (20.0)	7 (38.9)	11 (61.1)	
College graduate or higher	62 (68.9)	22 (35.9)	40 (64.5)	
Annual household income				0.456
$14,999 or less	11 (12.2)	3 (27.3)	8 (72.7)	
$15,000-$29,999	11 (12.2)	1 (9.1)	10 (90.9)	
$30,000-$59,999	29 (32.2)	11 (37.9)	18 (62.1)	
$60,000-$99,99	21 (23.3)	8 (38.1)	13 (61.9)	
More than $100,000	13 (14.4)	6 (46.2)	7 (53.9)	
Unreported	5 (5.6)	2 (40.0)	3 (60.0)	
Healthcare provider status				0.034
None	9 (10.1)	7 (77.8)	2 (22.2)	
Primary care	58 (65.2)	17 (29.3)	41 (70.7)	
OBGYN	12 (13.5)	4 (33.3)	8 (66.7)	
Dental and others	10 (11.2)	2 (20.0)	8 (80.0)	
Country of origin				0.848
North Africa	7 (7.8)	2 (28.6)	5 (71.4)	
Southern Africa	6 (6.7)	3 (50.0)	3 (50.0)	
East Africa	26 (28.9)	10 (38.5)	16 (61.5)	
West Africa	39 (43.3)	13 (33.3)	26 (66.7)	
Central Africa	12 (13.3)	3 (25.0)	9 (75.0)	

Group differences were based on Pearson's chi-squared or Fisher's exact test at < 0.05 and a 2-sided test. Differences in the frequencies within categories are due to missing data. The "total" column displays column % while the "Unwilling to use/neutral" and "Willing to use" columns display row %. Unwilling to use/neutral = Very unwilling, Unwilling, or Neutral. Willing to use = Willing or very willing

were in English, which excluded non-English speaking participants from taking the survey. It must be noted the most sub-Saharan African countries have over 50 major languages, thus attempting to translate this survey into the many languages may not have been possible at this current time, however, the countries with the most survey responses (Nigeria and Ghana) have English as their official language thus making us more comfortable having an English survey. Additionally, this study did not ask questions about sexual orientation, sexual behaviors, HIV risk behaviors and testing. The cultural norms and values that undergird discussions related to sex, sexuality, and sexual health make it challenging to ask questions about these topics using surveys. Anecdotal evidence suggests that for African immigrants, sensitive topics such as HIV and sexual health topics are usually best asked using qualitative methods such as interviews with a culturally competent and sensitive interviewer. While sexual behaviors such as number of sexual partners within the last months, frequency of condom use, unprotected sexual intercourse, and HIV testing may have been critical and provided information to better situate the PrEP conversation among this population, the absence thereof does not negate the finding of low awareness generally among this population, and their willingness to use PrEP regardless of their sexual behavior. Furthermore, the small number of participants in the survey limits our ability to provide specific recommendations for PrEP and generalize the findings. Nonetheless, given the significance of the subject matter and the limited existing literature on PrEP uptake among African immigrants, these preliminary findings offer valuable data and insights. We initially aimed to recruit 150 participants; however, we fell short of our goal and could only enroll 90 participants. We acknowledge this recruitment shortfall as a study limitation. To address this

limitation and improve the robustness of future research, we plan to conduct expanded studies that include a larger and more inclusive sample of African immigrants. By increasing the sample size, these future studies seek to enhance statistical power and strengthen the generalizability of the findings, enabling more definitive recommendations regarding PrEP utilization within this populationIt is important to acknowledge that the available research on HIV in the African immigrant community in the US is limited, out of date, and largely consists of grey literature. This limitation is beyond our control, but it underscores the need for the current research we are conducting. Finally, African immigrants are a heterogeneous group; thus, a one-size fits all recommendation may not be effective. Despite this limitation, this study adds to the limited literature on PrEP awareness and uptake among African immigrants in the US.

New Contribution to Literature

This study makes several contributions to the literature. This study represents a first attempt to characterize awareness, knowledge, and willingness to use oral or injectable PrEP among African immigrants in the US. It provides baseline data on awareness, and willingness to use PrEP. Secondly, with the advent of injectable PrEP, it is critical to understand if this method would be an option for HIV prevention among this population. Thus, our study contributes to the literature on PrEP uptake and preferred modalities. Our study provides a foundation for understanding PrEP needs and how to effectively roll-out PrEP among this population. This may be instrumental in developing effective interventions and achieving positive outcomes such as the reduction of HIV infections.

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Author Contributions The authors confirm contribution to the paper as follows: study conception and design: Gloria Aidoo-Frimpong, Kafuli Agbemenu, LaRon E. Nelson; data collection: Gloria Aidoo-Frimpong, Kafuli Agbemenu; analysis and interpretation of results: David Adzrago, Sarpong Boateng, Samuel Akyirem; draft manuscript preparation: Gloria Aidoo-Frimpong, Kafuli Agbemenu, Sarpong Boateng, David Adzrago, Samuel Akyirem; draft manuscript revision and finalization: Gloria Aidoo-Frimpong, Kafuli Agbemenu, and Laron E. Nelson. All authors have read and approved the submitted version of the manuscript. All authors have read and approved the submitted version of the manuscript.

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Data Availability The datasets generated and/or analyzed during the current study are not publicly available due to it still being used for primary analyses but are available from the corresponding author on reasonable request.

Declarations

Ethics Approval This work is in accordance with the ethical standards of the University at Buffalo's institutional review board and with the 1964 Helsinki declaration and its later amendments.

Consent to Participate Informed Consent was obtained from all participants.

Competing interests The authors report there are no competing interests to declare.

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