

DATE

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RE: Expanding PrEP in Communities of Color (EPICC)

Howard Brown Health appreciates the opportunity to comment on CDC's EPICC study. Howard Brown is a federally qualified health center and the largest LGBTQ+ health center in the Midwest, serving over 40,000 patients across 11 clinic locations in Chicago, Illinois. We provide comprehensive, high quality and affordable care—including primary care, behavioral health, HIV/STI prevention, and sexual and reproductive healthcare—to all patients, regardless of their ability to pay or insurance coverage status. We are particularly grateful to provide comments on this study, as Howard Brown is rooted in HIV care and prevention with a mission to eliminate LGBTQ+ health disparities. We believe that expanding and improving PrEP access is vital to ending the HIV epidemic.

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

CDC pledges to treat all people with dignity and to base all public health decisions on the most up-to-date, scientific data. These commitments directly apply to efforts to end the HIV epidemic, including this research project on increasing PrEP access for disproportionately impacted communities. While PrEP use has increased on average 56% each year,¹ there are significant gaps in PrEP awareness and use among Black and Hispanic people. These populations already experience a disproportionate risk of HIV and often have difficulty accessing preventative and primary care due to social inequities and structural racism. An analysis by Emory University of state-level PrEP use data by race/ethnicity from 2020 and 2021 illustrates these disparities well. According to this study, Black people represented 42% of new HIV diagnoses in 2020, but just 14% of PrEP users in 2021, while Hispanic/Latinx people represented 27% of new HIV diagnoses in 2020 and 17% of PrEP users in 2021. In contrast, white people accounted for 26% of new HIV diagnoses in 2020

¹ LAAD Longitudinal Access and Adjudication Dataset HIV data, January 2012 – December 2021.
<https://aidsvu.org/prep-use-race-ethnicity-launch-22/>

and 65% of PrEP users in 2021.² This is a racial justice issue—finding ways to expand access to PrEP and support adherence are essential to addressing the reality that HIV disproportionately affects communities of color. We applaud the CDC for testing out innovative approaches to increase PrEP awareness, uptake, and adherence in at-risk populations. The emphasis on ensuring the study has a majority of Black and Hispanic/Latinx participants is especially important, as strategies that consider racial disparities are vital to ending the HIV epidemic. The EPICC study is necessary as it especially focuses on improving clinical experiences for minority MSM by testing evidence-based strategies to boost provider knowledge, comfort, and counseling skills. By giving opportunities for new, more accessible ways to stay engaged through a mobile app, gathering regular feedback from patients on trial effectiveness will be easier and more convenient.

We believe that one way this study could provide even more useful and timely data would be to include younger age ranges. While this CDC study includes younger age ranges beginning at 18, research shows that those as young as 13 have a great unmet need for PrEP. We urge the CDC to consider including younger age ranges to this study or developing a study that does. Minority teenagers and young adults aged 13-24 years represent 20% of new HIV diagnoses but only 13% of PrEP users.³ Additionally, younger minority populations especially have a higher HIV risk. Young Black MSM account for 52% of all new HIV diagnoses among MSM in that age range.⁴ Younger populations must be included in HIV prevention, and PrEP uptake and adherence studies.

2. Enhance the quality, utility, and clarity of the information to be collected.

We applaud CDC for acknowledging the importance of developing affirming data collection processes to gather useful and high-quality information from minority YMSM. Collecting data helps us to track health risks and develop tailored interventions to lower the HIV risks of YMSM and other LGBTQ+ subpopulations. It is important to prioritize how information is collected. We are encouraged that this study is providing LGBTQ+ competency training to providers, as affirming providers can reduce barriers to engagement and improve outcomes for minority populations, ultimately supporting PrEP uptake and adherence.⁵

² LAAD Longitudinal Access and Adjudication Dataset HIV data, January 2012 – December 2021.
<https://aidsvu.org/prep-use-race-ethnicity-launch-22/>

³ CDC. NCHHSTP Atlas Plus.

⁴ Centers for Disease Control and Prevention. HIV Surveillance Report, 2019; vol.32.
<http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021.

⁵ Bockting W, MacCrate C, Israel H, Mantell JE, Remien RH. Engagement and Retention in HIV Care for Transgender Women: Perspectives of Medical and Social Service Providers in New York City. *AIDS Patient*

When collecting data, particularly sensitive health information, protection of the participant's information must be a priority. The use of mobile health can be incredibly beneficial and secure way to collect data, however, information privacy requires technology literacy. To ensure information privacy for those involved in the study, training for mobile and web information security should be provided when a participant is being taught how to use the data collection tool.^{6 7} Additionally, participants should be informed of how their data will be stored and used to ensure confidence, and participants should be offered control in what information they share.⁸ It can be helpful to allow participants to create unique usernames⁹ to support the protection of participant identity and to share how their identity may be linked to information they provide. Being aware of potential information risks that could cause participants to feel unsafe or outed is crucial. Involving community members, particularly those most affected by the study, in discussions about privacy, safety, and security of information during the development of the tool is beneficial

There are also strategies to reduce LGBTQ+ stigma and translate SOGI terms in a way that is culturally appropriate. To be mindful of LGBTQ+ stigma, questions must be introduced and asked in culturally appropriate and inclusive ways. Perspectives and terminology around sexual orientation and gender identity varies by culture, community, and geography, and this must be considered when developing data collection tools. Since this study involves multiple minority communities, members of these populations should be involved in the development of research and data collection about their communities.¹⁰ Further, data collection materials should be translated into languages other than English for greater accessibility. It is also a best practice to ask community members to review the translated wording for clarity and cultural sensitivity.¹¹

To further enhance data collected and gain a more thorough assessment of the needs of all MSM, we recommend the inclusion of TNB people in this or other CDC studies. Transgender people are often excluded from PrEP studies, despite being one of the most disproportionately impacted populations by HIV and having low PrEP uptake. Further,

Care STDS. 2020 Jan;34(1):16-26. doi: 10.1089/apc.2019.0067. Epub 2019 Dec 17. PMID: 31846348; PMCID: PMC6983737.

⁶ Urban JM, Hoofnagle CJ, Li S. Mobile Phones and Privacy. Berkeley, CA: University of California at Berkeley; 2012. (BCLT Research Paper Series, UC Berkeley Public Law Research Paper No. 2103405)

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4432854/>

⁸ Shilton K. Participatory personal data: An emerging research challenge for the information sciences. *Journal of the American Society for Information Science and Technology*. 2012;63(10):1905–1915.

⁹ Luxton D, Kayl R, Mishkind MC. mHealth data security: The need for HIPAA-compliant standardization. *Telemedicine Journal and e-Health*. 2012;18(4):284–288.

¹⁰ Park, Andrew. "Reachable: Data Collection Methods for Sexual Orientation and Gender Identity.," March 2016. <https://williamsinstitute.law.ucla.edu/wp-content/uploads/SOGI-Data-Collection-Mar-2016.pdf>.

¹¹ Ready, Set, Go! Guidelines and Tips For Collecting Patient Data on Sexual Orientation and Gender Identity (SOGI). 2022. Fenway Institute, Boston MA.

among transgender men, minority populations had the highest percentage of new HIV diagnoses with Black/African American trans men making up 41% of diagnoses, followed by Hispanic/Latino trans men at 26% and white trans men at 24%.¹² Trans men would benefit from being included in studies to enhance PrEP adherence in MSM. To collect clear, useful, and high-quality data with trans communities, it is important that study data materials use inclusive, gender-neutral language. It is important to recognize that much of the framework for providing sexual healthcare is based on cis- and heteronormative assumptions that exclude LGBTQ+ people. Study materials should clearly describe the entire populations to which they apply using clear, clinically relevant language and minimize use of gender-specific terminology.

3. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Since the onset of the Covid-19 Pandemic, mobile and virtual health options have expanded and become more acceptable. When surveyed, most participants in a national sample of MSM chose home-based PrEP care options over clinic-based options when given the hypothetical option.¹³ It is important to address access disparities with new approaches, like mobile health technology that can support client-centered digital care coordination. The benefits of using technology are determined by a variety of factors, including the patient's current health status, the frequency of measurement and intervention, the effectiveness of intervention, and the cost of measuring. We support the CDC in embracing technology to provide convenient data collection options to make PrEP more accessible and improve PrEP efficacy with adherence support tools specific to marginalized populations. As minority YMSM face greater disparities in accessing healthcare and adhering to daily medications, more specialized strategies are needed to reach more people to end the HIV epidemic.

For patients, mobile technology can make study participation and regular feedback easier. Supportive technology can provide virtual care options and other potential advantages, such as less travel time and expense, decreased potential stigma in attaining care, and

¹² Centers for Disease Control and Prevention. HIV Surveillance Report, 2019; vol.32. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021.

¹³ John SA, Rendina HJ, Grov C, Parsons JT. Home-based pre-exposure prophylaxis (PrEP) services for gay and bisexual men: an opportunity to address barriers to PrEP uptake and persistence. *PLoS One*. 2017;12(12):e0189794.

reduced demands on congested clinical sites. Additionally, for at-risk populations, ongoing support strategies like mobile texting, web-based tools, and smartphone apps are promising options for increasing continued study participation. A growing body of research shows that supportive technology can combat barriers to study participation. Many trials have used evidence-based chronic care models (such as mHealth, as in this CDC study) and social cognitive theory to adapt web-based tools and apps to include game-oriented features and social media to engage youth populations.^{14 15} Other technology to support participation and data collection use personalized risk surveys, electronic diaries, and virtual visits to promote participation—it may be impactful to include these features.¹⁶ YMSM may especially require tailored support and supplemental engagement opportunities.¹⁷ Studies have shown that participants of technology in HIV healthcare studies that offered more interactive online tools and apps, such as conversational avatars,¹⁸ reported higher rates of use long-term.¹⁹ Novel strategies, such as the use of interactive avatars to continue to build rapport, will be especially helpful in engaging patients and encouraging participation for patients whose providers are busy.

To ensure that focus groups and interviews in this study are least burdensome for providers especially, the study team could consider virtual focus groups. Studies show that virtual focus groups can be just as impactful as in-person participation, as virtual formats can allow participants to feel more relaxed in their home environment and more able to share deeper feedback.²⁰ Virtual interactions provide rich qualitative data while saving

¹⁴ Biello KB, Marrow E, Mimiaga MJ, Sullivan P, Hightow-Weidman L, Mayer KH. A mobile-based app (MyChoices) to increase uptake of HIV testing and pre-exposure prophylaxis by young men who have sex with men: protocol for a pilot randomized controlled trial. *JMIR Res Protocol*. 2019;8(1):–e10694.

¹⁵ LeGrand S, Knudtson K, Benkeser D, Muessig K, Mcgee A, Sullivan PS, et al. Testing the efficacy of a social networking gamification app to improve pre-exposure prophylaxis adherence (P3: prepared, protected, emPowered): protocol for a randomized controlled trial. *JMIR Res Protocol*. 2018;7(12):e10448.

¹⁶ Liu A, Coleman K, Bojan K, Serrano PA, Oyedele T, Garcia A, et al. Developing a mobile app (LYNX) to support linkage to HIV/sexually transmitted infection testing and pre-exposure prophylaxis for young men who have sex with men: protocol for a randomized controlled trial. *JMIR Res Protocol*. 2019;8(1):e10659.

¹⁷ Muessig KE, Pike EC, LeGrand S, Hightow-Weidman LB. Mobile Phone Applications for the Care and Prevention of HIV and Other Sexually Transmitted Diseases: A Review. *J Med Internet Res* 2013;15(1). doi: 10.2196/jmir.2301

¹⁸ Dworkin, M.S., Lee, S., Chakraborty, A., et al. (2019) Acceptability, Feasibility, and Preliminary Efficacy of a Theory-Based Relational Embodied Conversational Agent Mobile Phone Intervention to Promote HIV Medication Adherence in Young HIV Positive African American MSM. *AIDS Education and Prevention*, 31(1), 17–37. The Guilford Press, NYC.

¹⁹ Schnall, R., Bakken, S., Rojas, M. et al. mHealth Technology as a Persuasive Tool for Treatment, Care and Management of Persons Living with HIV. *AIDS Behav* 19, 81–89 (2015). <https://doi.org/10.1007/s10461-014-0984-8>

²⁰ Dos Santos Marques IC, Theiss LM, Johnson CY, McLin E, Ruf BA, Vickers SM, Fouad MN, Scarinci IC, Chu DI. Implementation of virtual focus groups for qualitative data collection in a global pandemic. *Am J Surg*. 2021

time and money, they also allow for the collection of verbal and nonverbal cues of expression, which contributes to a more in-depth analysis of the data.²¹ Through virtual platforms, participants can also express themselves through text chat options and emoticons, aside from strictly verbally. Other benefits of virtual engagement include gaining insight from a broader geographical area, providing accessibility options, such as real-time transcription, and offering more flexible scheduling options for busy providers. Previous CDC-funded research has shown online discussion groups to be an effective and efficient means of engaging youth-serving professionals, including providers, on topics of sexual health and HIV prevention.²²

We are encouraged to see studies like EPICC aimed at improving PrEP uptake and adherence in special, high-risk populations. We encourage the CDC to implement our recommendations so that the full MSM community is represented and included in study development and participation. If you have questions about our comment, please feel free to reach out to Tim Wang, Director of Policy and Advocacy, at timothyw@howardbrown.org.

Sincerely,

David Ernesto Munar, President and CEO
Howard Brown Health

May;221(5):918-922. doi: 10.1016/j.amjsurg.2020.10.009. Epub 2020 Oct 12. PMID: 33070983; PMCID: PMC7550163.

²¹ Glassmeyer, D. M., & Dibbs, R. (2012). Researching from a distance: Using live web conferencing to mediate data collection. *International Journal of Qualitative Methods*, 11, 292–302.

²² Cahill SR, Geffen SR, Fontenot HB, Wang TM, Viox MH, Fordyce E, Stern MJ, Harper CR, Johns MM, Avripas SA, Michaels S, Mayer KH, Dunville R. Youth-Serving Professionals' Perspectives on HIV Prevention Tools and Strategies Appropriate for Adolescent Gay and Bisexual Males and Transgender Youth. *J Pediatr Health Care*. 2020 Mar-Apr;34(2):e1-e11. doi: 10.1016/j.pedhc.2019.09.003. Epub 2019 Oct 23. PMID: 31653461; PMCID: PMC7122554.