U.S. WOMEN & PrEP WORKING GROUP

Working Group Statement on PrEP 2017

This reports highlights the Pre-exposure prophylaxis (PrEP) priorities of the U.S. Women and PrEP Working Group

US Women and PrEP Working Group Statement

Introduction

In 2015, the CDC estimated[i] that, in the U.S., approximately 492,000 men who have sex with men (MSM) could likely to benefit from using oral PrEP. The number of women similarly positioned was estimated at 468,000. These estimates did not differentiate between cisgender and transgender individuals in either category.

Most people, if aware of PrEP at all, think of it as something used by MSM. The CDC, however, calculates that about as many women as men could benefit from using PrEP. Unfortunately, no parallel national estimates exist regarding people of other genders.

Gilead Sciences, the company manufacturing Truvada (currently the only FDA-approved PrEP medication), reports that about as many women as men were getting PrEP prescriptions in 2013, when it first became available. Since then, however, uptake has climbed among men and remained stagnant among women. Women's minimal PrEP uptake has also been disproportionate by race with four times more White women currently receiving PrEP than Black or Latina women.[ii]This is likely due in part to the fact that PrEP is a prescription drug, making it more available to affluent (mostly White) women and those whose employers have comprehensive prescription plans. Due to campaigns and messaging about PrEP that have not included educating cisgender women, it is not surprising that 89% of all new private PrEP prescriptions written on 2015 were for men,[iii] predominantly White men.

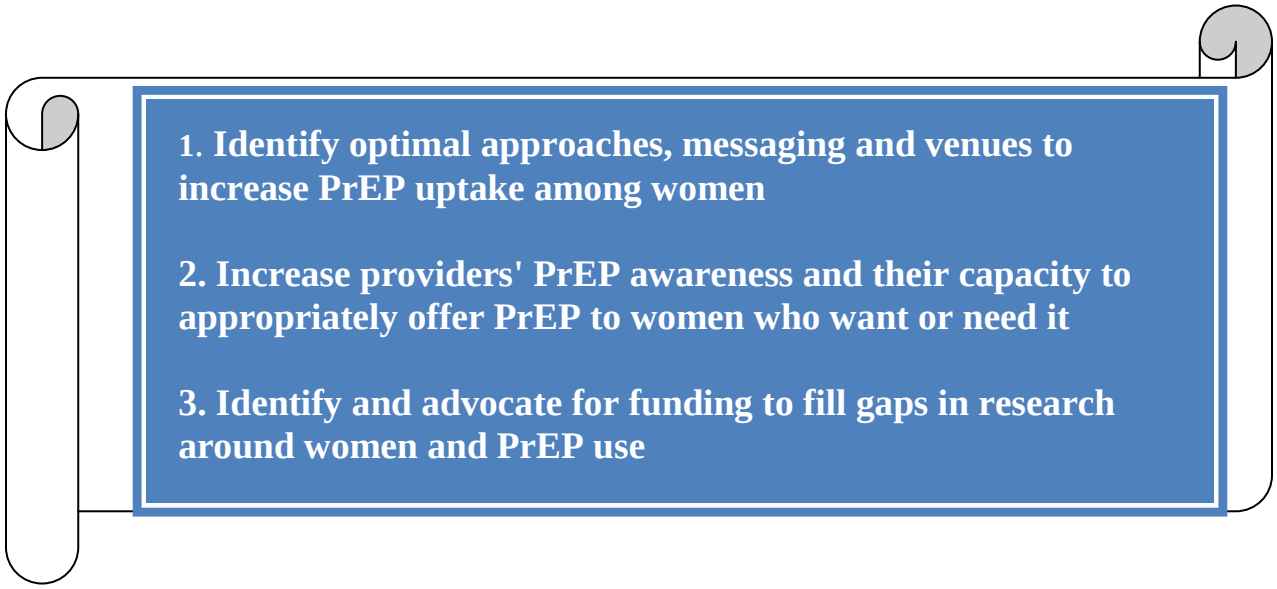
Regrettably, data on PrEP uptake by transgender and gender non-conforming people are unavailable because they are not counted in national data gathering systems. The U.S. Women and PrEP deplores this omission and has been, since its inception, calling for accurate, well-documented health data collection and responsiveness to the needs of people of all genders, especially for transgender women.

Black women make up 64% of all women newly diagnosed with HIV[iv] in the U.S. This rate is 16 times higher than that of White women and nearly five times that of Latinas.[v] There is a pressing need to prioritize efforts to reduce Black women's HIV risk. These disparities highlight the importance of HIV prevention strategies for women, including the use of PrEP. PrEP is the first highly effective HIV prevention method available to women that is entirely within their control. However, because so few women who may benefit from PrEP are aware of it, and so few women's health care providers offer PrEP to their patients, PrEP has not yet achieved its potential to reduce HIV infections in women. The U.S. Women and PrEP Working Group is deeply committed to rapidly expanding Black women's awareness of PrEP and access to it.

Framing Our Work

The Working Group is a national ad-hoc coalition of women's health advocates, health care providers and researchers committed to exploring the key issues arising for women in domestic PrEP research and implementation. We focus our advocacy on issues relevant to U.S. women and PrEP in the US.

In March 2017, the Working Group held a face-to-face membership meeting to prioritize critical steps for expanding PrEP access for cisgender and transgender women generally, and particularly for Black women. Based on the information we currently have, we agreed to focus on the following priorities:



Our goal, as a coalition, is to ensure that each priority above is addressed adequately during the December 4, 2017 meeting. We further intend to emerge from it with a clear, shared understanding of how we can work with ASHA, ACOG, the CDC and other entities to generate rapid progress in each of these areas.

1. *Stimulating demand by identifying optimal messaging, venues and targeting*

Messaging: To increase people's demand for a product, one must first get their attention and then show them that the product could benefit them.

Most women who are aware of PrEP tend to ignore it because it is most often framed as something for men (specifically MSM), not for women. Even the CDC brochures created to educate the public about PrEP feature diverse male images and only one female image -- that of a doctor in white coat and stethoscope, prescribing PrEP to a man.

For many Black women, skepticism about PrEP is also driven by distrust in the medical system due to historic abuses and/or personal experience of medical racism or other traumas.[vi] A major barrier to PrEP uptake by women is the lack of perception of risk for HIV acquisition[2]. black women for example, who may not perceive themselves at risk for HIV, have a higher probability of exposure to HIV despite practicing the same sexual behavior (condom use, number of partners) as other women[3]. Being in a sexual network with higher rates of HIV and STIs coupled with low awareness of partners' status or risk factors, increase the risk of HIV acquisition even with protective sexual behavior.

Other data note that women may be more receptive to promotional messages in which PrEP is associated with self-care, pleasure and relaxation, rather than fear and risk. It can be compared to oral contraceptive pills, for example. Both help you relax and enjoy sex — one by eliminating fear of pregnancy and the other, fear of HIV. Using contraception no longer has a negative connotation in most communities. Thus, associating the logic of using contraception with the possible logic of using PrEP may help put PrEP in a similarly acceptable context.

<u>Venues:</u> Community feedback recommends linking PrEP promotion to familiar venues where low-income women access their health care; including local family planning clinics, Federally Qualified Health Centers, pre-natal, pediatric and STI clinics, etc.

For four out of ten women in the U.S., family planning clinics provide the <u>only</u> health care they receive.[vii] Most Black women (83%) are using contraception.[viii] Taken together, these data suggest that such clinics can be important venues for PrEP education and access.

Black women comprise 18% of patients in publicly funded family planning services even though they are only 13%[ix] of the U.S. female population. They are also the hardest hit by the dearth of such services, especially in the South and in rural areas. In 2015, family planning providers were able to meet only 31% of the documented need for their services.[x] Attacking, withholding and defunding of public access to reproductive care inevitably defeats a city, state or region's ability to reduce its number of new HIV infections. HIV education and prevention happen for women in the context of their reproductive and sexual care. One simply cannot be accomplished without the other.

The Working Group identified the following as other trusted community venues appropriate for PrEP outreach and education: community-based providers of HIV/STI testing and behavioral interventions (like syringe exchange), substance use and mental health care providers and mobile health testing and education units.

The Sustainable Health center Implementation Pilot Project (SHIPP), initiated by the CDC in 2014, has enrolled 1200 women and men in four U.S. cities who are receiving PrEP at their local Federally Qualified Health Centers. The Context Matters Study, one component of SHIPP, is gathering survey information on (among other things) attitudes about PrEP among "lay people and key stakeholders in communities served by each clinic".[xi] These survey results, when available, should shed further light on this.

> ***The federal Office of Population Affairs is also conducting a project to develop an evidence-based decision making tool to assist Title X providers with determining the best approach for providing PrEP services based on the characteristics of their clinic setting and client population. This three-year project includes a literature review, development of decision making tool, and piloting the tool in up to nine clinic sites."[xii]***

"Targeting" is the challenge of conducting HIV risk assessment without raising the fear, shame and stigma issues discussed above. Here are two innovative approaches developed by Working Group members. Using a map, the Whitman Walker Clinic in Washington DC asks patients to show their provider where they live. All those living in areas in which HIV prevalence is over 2% are presumed to need PrEP information. The map enables the provider to focus on HIV risk as a situational factor, rather than a behavior one (which could raise guilt or shame). They present HIV risk as analogous to weather conditions and other inevitabilities that can be handled if one is well prepared.

Universal screening is another way to avoid drawing attention to an individual's level of HIV risk. The HIVE Clinic in San Francisco does this by asking its female patients, "Are any of your sex partners a man who has HIV, a man who injects drugs, or a man who has sex with men?" The responses are used to inform decisions about the level of PrEP education needed by each woman. Other relevant universal questions (such as having a partner who has been incarcerated, for example) can be added as needed in other geographic areas, depending on the dimensions of the local epidemic there.

2. *Increase providers' PrEP Awareness*

As of 2015, only one third of family planning providers could accurately describe PrEP and its effectiveness. Only 37% had seen the CDC's 2014 national guidance on PrEP.[xiii] Although the Working Group was previously advised that the CDC Professional's Kit on PrEP would be released by the end of 2016, it has not yet appeared.

Some non-governmental organizations working to fill this gap in professional knowledge have done so primarily with information about men's PrEP use. In 2016, NMAC (formerly the National Minority AIDS Council) unveiled *PrEPare for Life*[xiv], describing it as a manual to "train AIDS service providers, case managers and peer educators….to support their efforts to educate young men that have sex with men (MSM)".

An important exception to this trend has surfaced among providers focused on pregnancy and child-bearing. In 2014, the American Congress of Obstetrician and Gynecologists (ACOG) issued a "Committee Opinion" to educate its members about PrEP's potential value to women in sero-different relationships.[xv] ACOG's 36,000 members have access to additional PrEP education tools and CMEs if they take PrEP training. Contributions from SIECUS include a "PrEP Education for Youth-Serving Primary Care Providers Toolkit"[xvi] with sections on the specific needs of young women.

In August 2017, Planned Parenthood Federation of America (PPFA) announced that, with support from Gilead Sciences, they would be collaborating with the Black AIDS Institute to expand HIV prevention and education efforts in eleven PPFA affiliates in 2017-2018. This will include staff training on PrEP screening, prescribing and monitoring, thus enabling their staff to add PrEP to range of services PPFA offers.

Regrettably, such expansion will not be occurring in areas where Planned Parenthood affiliates have closed their doors due to drastic cuts or outright elimination of family planning funding. In Texas, for example, massive reductions and redistribution of public funding triggered the closure of 82 family planning clinics in 2013 alone.[xvii] Around that time, Texas ranked third among all states in the number of women living with HIV.[xviii]

HIVE, a project of the UCSF, has also developed indispensable provider resources including the "Family Planning Provider Tool Kit"[xix], a "PrEP Provider's Pocket Card"[xx] and "Integrating PrEP for HIV Prevention into Women's Health Care in the U.S."[xxi]

Despite these important NGO contributions, survey data in 2016 showed that "60% of women access their primary health care through family planning providers, yet only about 4% of family planning providers have ever prescribed PrEP."[xxii] Although this estimate addresses only one provider sector, it nevertheless suggests an extreme dearth of PrEP training among the providers best positioned to reach women, especially Black women, in the communities where they live.

This contrasts sharply with the US Public Health Service' 1994 response in terms of comprehensive provider education. That year, evidence was produced showing that zidovudine (and later combination therapy) could substantially reduce the risk of vertical transmission of HIV.[xxiii] All providers serving pregnant women were rapidly advised by UPHS to test their patients for HIV and administer prophylaxis to those testing positive. As a result of this prompt action and persistent follow-up to educate providers, perinatal HIV infections in the US dropped by 95% from their peak level of 945 cases in 1992 to 48 in 2004.[xxiv] This experience illustrates the effect that an urgent, broad-based, well-publicized action from the federal government can have to terms of getting health care

providers and institutions to add a preventive step to their medical practice. We question why such action to reduce HIV among women has not merited equally intensive action.

3. *Identify and advocate for funding to fill gaps in research around women and PrEP use*

The Working Group has identified research priorities that merit immediate attention:

Social/behavior research on factors affecting PrEP uptake*:** Innovative woman-focused research in this area is lagging far behind such research on men. No comparable, domestic, federally funded PrEP projects involving women, for example, have been launched that parallel the federal PS15-1506[xxv] and 1509[xxvi] projects enrolling men of color. ***The Working Group is calling for proportionally appropriate federal investment in demonstration projects for women of color to fill this research gap.

University of Alabama's 1917 Clinic — one potential site for such research — is located in our country's ninth poorest state. Black women there are ten times more likely to acquire HIV than other women and most who do so are between 15-29 years old. In May 2017, the Clinic had 30 people on PrEP. Only six were women.[xxvii] The staff sees an urgent need for formative research based in the South to help them better understand how to effectively target women, which women to target, and what their preferences are in terms of delivery of PrEP services. Regional answers to these questions are essential to facilitating PrEP uptake among Southern women, especially those in rural settings.

We all agree that good implementation science is essential to gaining a better understanding of sexual health needs and values of women, their current impressions of PrEP, and how PrEP can be tailored to such needs and values. Despite the need for it, such research is sharply underfunded, especially at the federal level.

Private, philanthropic funding is supporting one major study (the first of its kind in side and scope) now underway in Washington DC, where Black women comprise 92% of all women living with HIV.[xxviii] With support from the MAC AIDS Fund, the DC-Partnership for AIDS Progress (PFAP) launched a collaborative effort in late 2016 that involves multiple entities including the Black Women's Health Imperative and the DC Center for AIDS Research (CFAR) at George Washington University. This campaign includes widespread use of social media tools (such as #PrEPforher), promotional posters on public transport, mobile van HIV testing, counselors, peer navigators and expanded PrEP access in community-based health clinics. Analysis of the CFAR data from this project is expected be instrumental in guiding strategies for expanding PrEP use among women in similar settings.[xxix]

***Time to protection*:** On the basis of clinical data, the CDC maintains that maximum PrEP protection during receptive anal sex can be achieved by taking a pill daily for seven days. Twenty days of daily use is required, however, for maximum protection during vaginal sex or injection drug use.[xxx] The World Health Organization (WHO), by contrast, asserts that PrEP is fully protective after seven days of continuous use, regardless of the site of HIV exposure.[xxxi]

The Working Group is committed to provide women with full and accurate information about PrEP. The message of "seven days for men and 20 days for women" however, causes confusion and can become another barrier to PrEP uptake. We urge expedited clarifying research in this area, in the hope that a simpler but fully accurate message emerges.

Mass incarceration as a factor raising Black women's HIV risk: Individually, Black women in the U.S. engage in less sexual risk than do Latino or White women. Despite this, they are three to four more times likely than women in other racial/ethnic categories to acquire HIV.[xxxii]

While comprising one third of the U.S. population, people of color make up 67% of the country's prison population. *The Lancet* reports that this mass incarceration, "together with ongoing racial segregation, contributes to the formation of insular sexual networks with overlapping concurrent partners."[xxxiii]

Some compelling studies[xxxiv,xxxv] have documented the impacts of these linked phenomena, which may well meet the definition of a syndemic that impacts both public health and human rights. More research and attention is needed to assess the impact that criminal judicial policies and practices are having on Black women, their communities, their partner relationship options and their increased risk of HIV acquisition.

More research into PrEP options for women: Phase 3 clinical trials are underway to assess two new (non-Truvada) drug combinations as new PrEP options. One is Gilead's non-inferiority DISCOVER trial studying TAF as oral PrEP, enrolling 5000 men and (very few) transgender women across 92 sites in North America and western Europe.[xxxvi] The other is an NIH study on the efficacy of Cabotegravir as injectable PrEP. That trial is enrolling 4,500 cisgender men and transgender women eight countries. Results from it are expected in 2021.[xxxvii]

A Cabotegravir injectable PrEP study enrolling cisgender women is also slated to start this year and finish in 2022. It will involve 3,200 cisgender women aged 18 to 45 who live in sub-Saharan Africa and are at risk of HIV.[xxxviii] This trial is important because previous PrEP trials conducted among cis-gender African women did not show high PrEP uptake. The reasons for this are still being debated. It will be helpful to know if injectable PrEP is acceptable to more women than the gel or pill formulations have been to date.

Vaginal biome factors affecting HIV acquisition risk: Recent studies on the vaginal microbiome suggest that "behavioral, genetic and environmental factors are also likely to impact the effect of the vaginal microbiome on HIV risk.[xxxix] It is critical to learn more about the extent to which endogenous bacteria, viruses and other microbes in a woman's genital tract correlate with her level of HIV risk. Such data can potentially inform our understanding of how effectively PrEP (and its mode of delivery—gel, pill or injection) can best protect women in various populations from HIV acquisition.

Conclusion

As noted at the outset, the CDC estimates that about as many men as women would likely benefit from PrEP use. But PrEP promotion — and research on how to do that effectively —has disproportionally focused on men.

People frequently imagine that many more men are at risk of HIV than women -- and find these real numbers hard to visualize or believe. This may be because the men at risk mostly comprise a large section of a relatively small population (MSM). The women at risk, by contrast, comprise a small section of a larger population (all women). But the *real numbers* of people at risk is roughly equal. Women deserve as much access to PrEP education and services as men do, along with well-informed providers and research to define and address their specific needs. A life is a life, after all.

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[ii] http://hivinsite.ucsf.edu/insite?page=hmq-1609-06

[iii] http://www.abstractsonline.com/pp8/#!/4060/presentation/16214

[iv] https://www.nbcnews.com/news/nbcblk/let-s-talk-about-prep-targets-black-women-hiv-prevention-n504731

[v] http://www.kff.org/hivaids/fact-sheet/black-americans-and-hivaids-the-basics/

[vi] Seidman et al. R4P oral abstract 2016.

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[viii] https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/j.whi.2012.09.002.pdf

[ix] https://www.americanprogress.org/issues/race/reports/2013/11/07/79165/fact-sheet-the-state-of-african-american-women-in-the-united-states/

[x] https://www.americanprogress.org/issues/women/reports/2014/10/23/99612/ensuring-access-to-family-planning-services-for-all/

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[xii] Moskosky S. Office of Population Affairs. Personal Communication. 2 October 2017

[xiii] https://www.ncbi.nlm.nih.gov/pubmed/26772906

[xiv] http://www.nmac.org/wp-content/uploads/2014/06/PrEPManualEnglish-Final.pdf

[xv] https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus

[xvi] http://siecus.org/index.cfm;jsessionid=68C55C6A906E821C79E5CF6C6557A0D1.cfusion?fuseaction=document.viewDocument&documentid=595&documentFormatId=701&vDocLinkOrigin=1&CFID=196573212&CFTOKEN=5b7b19a4cc8796b9-04BDFE07-F3B5-3699-F1F79270E5201D22

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[xviii] http://www.kff.org/hivaids/fact-sheet/women-and-hivaids-in-the-united-states/

[xix] https://www.hiveonline.org/prep4familyplanning/

[xx] https://www.hiveonline.org/prep_implementation/prep_essentials_pocket_card.pdf

[xxi] https://www.hiveonline.org/prep_implementation/integrating_prep_womens_healthcare.pdf

[xxii] https://www.ncbi.nlm.nih.gov/pubmed/26772906

[xxiii] http://jamanetwork.com/journals/jama/fullarticle/191105

[xxiv] https://www.cdc.gov/MMWR/preview/MMWRhtml/mm5521a3.htm

[xxv]https://www.cdc.gov/hiv/funding/announcements/ps15-1506/index.html

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[xxx] https://www.cdc.gov/hiv/basics/prep.html

[xxxi] http://apps.who.int/iris/bitstream/10665/258509/1/WHO-HIV-2017.27-eng.pdf

[xxxii] https://www.cdc.gov/hiv/group/gender/women/index.html

[xxxiii] https://www.blackaids.org/news-2016/2805-mass

[xxxiv] https://gspp.berkeley.edu/assets/uploads/research/pdf/P48.pdf

[xxxv] http://pubmedcentralcanada.ca/pmcc/articles/PMC4456473/

[xxxvi] http://events.aidschicago.org/site/DocServer/Descovy_Trial_Factsheet.pdf

[xxxvii] https://www.hptn.org/research/studies/hptn083

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[xxxix] https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-017-0469-2