ARE WE PrEPARED?

STATE OF THE SCIENCE REPORT FOR PRE-EXOSURE PROPHYLAXIS (PrEP)

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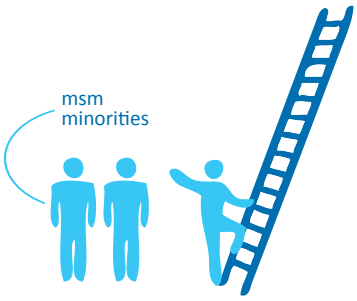
Background

In 2012, the Food and Drug Administration approved Truvada (Emtricitabine/Tenofovir) as pre-exposure prophylaxis (PrEP) for individuals at substantial risk for acquiring HIV.[1] In May of 2014, the US Public Health Service released a set of clinician guidelines for PrEP use.[2] In these guidelines, PrEP is regarded as one extra measure in the HIV prevention toolbox for those at substantial risk by nature of their sexual practices or drug use patterns. Between January 2011 and March 2013, there were less than 2,000 people on PrEP in the United States.[3] In a sample of clients at health departments across three cities nationwide, self-referrals for PrEP were associated with being white and having a college degree or higher.[4] Unfortunately and as such, the populations most burdened by HIV, specifically, young Black and Latino men who have sex with men (MSM),[5] are lagging behind in PrEP uptake. This report addresses various structural barriers associated with the uptake of PrEP and makes recommendations for the implementation of PrEP on a national scale.



YOUNG BLACK AND LATINO MSM, THE MOST BURDENED BY HIV, ARE LAGGING BEHIND IN PrEP UPTAKE

NUMBER OF PEOPLE ON PrEP IN THE U.S. BETWEEN JANUARY 2011 AND MARCH 2013

Accessibility

The breadth of the literature on PrEP focuses primarily on issues surrounding its accessibility –meaning, the degree to which PreP is available to as many people as possible. On both ends of the patient-provider relationship, a lack of accessible information and services impede PrEP uptake and prescription by both patients and providers. This lack of accessibility seems to be a large part of the reason behind PrEP's slow take-off.

On the consumer end of the relationship, it is crucial to engage with those populations who could benefit most from PrEP. Issues around cost and awareness can limit access to PrEP for certain populations. In terms of awareness, prior knowledge of the drug appears to be one factor related to its uptake.[6] With the release of the iPrEX clinical trial results, awareness seems to continue to increase, however, PrEP awareness is still as low as 19% in some places while only as high as 63% in others.[6]

ON THE CONSUMER SIDE, THERE IS A SLOW INCREASE OF PrEP AWARENESS

In the United States, PrEP can cost anywhere from $0 per month to $2,000 per month depending on whether one has health insurance and/or is participating in a research study.[7] Although there have been no reports of PrEP being denied coverage by public and private health insurance companies,[8] Medicaid coverage does vary from state-to-state.[9] For many people, especially those populations most burdened by HIV, the high price of the drug can play a factor in their decision to get on PrEP.[10]

In addition to the cost of the drug itself, frequent copays and lab work can make PrEP uptake and retention prohibitive for some.[11] To offset the cost, Gilead, the manufacturer of Truvada for PrEP, has created a co-pay assistance program for eligible persons. For every prescription filled, the Gilead Co-pay Coupon Card covers up to $200 of the copay,[12] making the drug virtually free for some. Those with no insurance can get the drug for free or at low cost by participating in a clinical trial pending eligibility, through a program called Healthy San Francisco, or by enrolling in Gilead's US Advancing Access Program.[7]

COST OF PrEP AND COPAY VARIES DEPENDING ON THE TYPE OF INSURANCE; BUT IT IS MOSTLY FREE

In regards to healthcare providers, one of the greatest barriers to providers prescribing PrEP is a lack of knowledge on the existing PrEP research.[13] Over 78% of providers in a New England study said a lack of awareness of PrEP was a barrier to prescribing it.[13] In a PrEP readiness survey distributed by the Commission at the 2014 U.S. Conference on AIDS, only 68% of 69 respondents knew that PrEP was taken *before* exposure to the HIV virus.[14] This result highlights the lack of knowledge and misinformation that exists regarding PrEP.

A phenomenon of silence exists between healthcare providers and their patients regarding HIV risk. Research shows that many healthcare providers do not bring up HIV risk with their patients, and many individuals are reluctant to bring up risk behaviors with their providers.[6] Because they are in a position to effect behavior change, nurse practitioners, physician assistants, and doctors have the opportunity to disseminate information on PrEP and recommend it to those who are eligible for it. In an analysis of US PrEP utilization outside of clinical trials, researchers concluded that PrEP users were more likely to be women under the age of 25 who lived in the South and were treated by non-Infectious Disease physicians.[15] In this same analysis, they also found that nurse practitioners, physician assistants, internal medicine, and emergency medicine specialists prescribed the majority of PrEP (46% of all prescribers), while only 12% of PrEP providers were infectious disease specialists and 16% were family practice specialists.[15] These preliminary results paint a different landscape for real-world PrEP use than what researchers may have expected.

Finally, the "cost" of an intervention includes not only financial cost, but also the time and effort required to maintain it. PrEP providers perceive the cost and monitoring of PrEP use to be a barrier in its prescription.[13] With the new International Classification of Disease and the enactment of the Affordable Care Act, coding and sequencing practices for PrEP among insurance companies and healthcare providers will need to be created.[11]

Acceptability

In order for an intervention such as PrEP to be successful, it must first be deemed acceptable as a means of prevention to both community members and service providers. In the case of community members, there is some evidence of its acceptability. In a racially/ethnically diverse sample of men who have sex with men (MSM) in Boston, 74% reported being more willing to use PrEP after being educated about its potential for preventing HIV infection. Of those who reported being willing to use PrEP, 78% of non-whites were likely to intend to use PrEP.[10] These results hold promise for PrEP uptake by key Black and Latino populations.

HIV-related stigma has been shown to negatively impact HIV testing, status disclosure, and treatment.[6] Studies have established correlations between HIV-related stigma and avoidance of testing, selective disclosure in situations where there may be negative consequences, and suboptimal adherence to drug treatment.[16]

This same stigma can be detrimental to PrEP's acceptability. In fact, many individuals report feeling stigmatized for being on PrEP.[6] In a survey by POZ magazine, 72% of respondents said that there is stigma attached to taking PrEP.[18] Stigma and discrimination present a number of factors that increase both risks and barriers to prevention, treatment, care, and support.[10] Individuals on PrEP report that their peers believe they will engage in more risky sexual activity and divert resources from HIV+ patients in need of treatment.[6] Patients also report that doctors appear judgmental about their decision to get on PrEP and are unwilling to prescribe it.[6] This guilt and lack of social support from key figures can affect PrEP uptake and adherence; adherence in particular is a key issue, as inconsistent use of PrEP decreases its effectiveness in HIV prevention. Additionally, if PrEP is targeted only to high-risk groups, which tends to be those most stigmatized, then this might also contribute to PrEP stigma.[10] In general, the stigma associated with HIV could contribute to providers being even less receptive to messages surrounding PrEP and its dissemination.[6]

In the case of service providers, physicians do seem to express interest in prescribing PrEP. One survey of Massachusetts HIV specialists and generalist physicians found that almost 75% of providers would be willing to prescribe PrEP to high risk MSM based off the results from one of the clinical trials - the iPrEX study.[19]

At the same time, studies have also shown that providers are concerned about risk compensation by individuals on PrEP[6] and this may in turn affect how they prescribe PrEP to patients. Risk compensation occurs when an individual increases "risky behavior" following a decrease in perceived risk.[20] Some providers are concerned that the decreased risk of acquiring HIV while on PrEP will cause individuals to change other behaviors such as decreasing condom use or increasing the number of casual sex partners. While the potential for risk compensation has not been found in most studies,[13] it can be a barrier to prescribing PrEP because providers may already hold beliefs about the drug and its perceived association with risk compensation. The concept of risk compensation is not limited to the HIV prevention field. For example, risk compensation can occur when an individual spends more time in the sun because they believe that wearing sunscreen will prevent melanoma.[20] In order for PrEP uptake to occur more easily by high-risk populations, healthcare providers will need to accept this biomedical intervention and adopt it as a part of their practice.

Availability

Ensuring adequate clinical capacity and delivery of PrEP is essential to its uptake and adherence. It is unknown how available PrEP is in most communities; however, the San Francisco City Clinic – the city's main STI clinic – experienced a waitlist of several dozen clients from 2012 – 2013.[6, 21] Some healthcare providers and AIDS service organizations have begun compiling lists of PrEP providers for their clients. While most of the providers identified thus far are located in more urban areas, the availability of PrEP in more rural and suburban areas is still unknown.

One other concern regarding availability is the increase in non-prescribed use and sharing of medications between MSM.[22] Since 2007, reports have circulated of tenofovir's unregulated use at circuit parties and by doctors who prescribe it to HIV negative patients.[23] Although the Food and Drug Administration (FDA) has recently established guidelines for the latter,[2] future research will need to elucidate patterns of PrEP use and non-prescribed use among MSM populations.

Recommendations

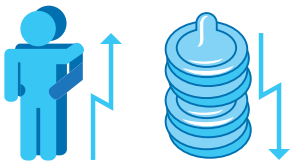
1. **Expand PrEP knowledge amongst both high-risk populations and healthcare providers.** It seems wise to strategically market PrEP to these two key populations because a tailored approach might facilitate a smooth transaction between the patient and provider. AIDS service organizations should also create a list of PrEP providers in the community to be utilized by clients and healthcare providers. Great efforts should also be made to identify and reach out to those who would be eligible candidates for PrEP.
2. **To ensure equal access, states should expand Medicaid coverage of PrEP.** In order for PrEP to be considered a method of prevention for those with public insurance, it will be necessary for state Medicaid programs to cover PrEP so that lower income, higher-risk populations are able to access the drug.[10] All high-risk populations should have affordable access to PrEP, regardless of the state or territory in which they live.
3. **Implement programs that aim to reduce PrEP stigma.** Individuals should not be stigmatized or labeled for taking preventive measures that protect their health. Reducing HIV-related stigma in different communities, particularly ethnic and racial minority communities, can promote PrEP uptake.
4. **Increase acceptability of PrEP among healthcare providers.** One way to get healthcare providers on board with PrEP is to use results from numerous PrEP clinical trials, as this has been shown to be effective.[19] Talking about sex and HIV are sometimes difficult conversations for some providers to have with their patients, as such medical schools and training programs should further incorporate education around behavioral risk assessment and cultural competency into their curricula.
5. **Continue to fund research on PrEP, especially community-based participatory research.** *Community-based participatory research* is particularly important moving forward because it can address questions that are of high priority in the community while further developing the knowledge base for policy, organizational and community change. There is still much to be discovered about PrEP, such as the effect is has on the female body[24] and its effectiveness in real world settings.[25] Studies should also aim to determine optimal dosages of PrEP and attempt to develop interventions that enhance adherence to the drug.[26] More fundamentally, research should explore the psychosocial aspects of using this new prevention method.[27]
6. **Dismantle institutional/structural barriers that prevent access to care and utilization of services by populations at higher risk for HIV.** Making PrEP more accessible to those with less educational attainment[16] and non-whites and are necessary measures to take. Continuing to expand access to stable housing and mental health services will also help the most marginalized populations maintain

LACK OF PrEP RESEARCH KNOWLEDGE HINDERS THE ABILITY OF PROVIDERS TO PRESCRIBE IT

74% PERCENTAGE OF MSM WHO WERE WILLING TO USE PrEP AFTER BEING EDUCATED ABOUT IT

75% PERCENTAGE OF PROVIDERS WHO WERE WILLING TO PRESCRIBE PrEP UPON RESULTS OF CLINICAL TRIALS

PrEP USERS HAVE REPORTED BEING STIGMATIZED; WHICH COULD POTENTIALLY AFFECT UPTAKE AND ADHERENCE



PROVIDERS ARE CONCERNED THAT PATIENTS ON PrEP MIGHT INCREASE RISKY BEHAVIORS (LESS CONDOMS, MORE SEXUAL PARTNERS) DUE TO A DECREASE IN PERCEIVED RISK

adherence to medication.[28] Respondents to the PrEP readiness survey identified mental health, substance abuse, and housing as the top 3 needs for Gay/Bi/MSM.[14] Providers and AIDS service organizations can help by initiating conversations about PrEP and navigating with those unfamiliar with the new healthcare structure under the Affordable Care Act. Lawmakers and lobbyists can advocate for more accessible housing and mental health services.

7. **Strengthen partnerships with community members and other AIDS service providers.** In order to stay relevant, it is crucial that service providers maintain those with HIV/AIDS or those at high risk for it as their number one priority. On behalf of those with an investment in HIV/AIDS research/services, individuals in leadership positions should advocate to those with political power for continued support.
8. **Continue to prioritize funding for those currently living with HIV/AIDS.** Continuing to make treatment and services more affordable to those currently living with HIV/AIDS is important to dispelling fear and stigma around PrEP. If we want to put an end to HIV/AIDS, we should not view said funding as a diversion of resources.

Concluding Remark

All in all, PrEP holds promise for moderating the HIV/AIDS epidemic. Though much work has already been invested in PrEP, stakeholders must continue to collaborate in order to take full advantage of these new biomedical advances. In order for PrEP to have the meaningful impact on the HIV/AIDS epidemic that we believe it is capable of, it must first be made more accessible and available to people at high risk for acquiring HIV. Stigmatization of PrEP must be lessened so that there is more acceptance of those choosing to adopt this new intervention. With this said, PrEP should be discussed with and made available to those who are resource-deprived, namely young Black and Latino MSM, so that ethnic and racial HIV disparities can be reduced.

PrEP REPRESENTS AN OPPORTUNITY TO DECREASE THE SPREAD OF HIV AMONG POPULATIONS AT HIGH RISK OF INFECTION

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