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Getting PrEP to the people: opportunities, challenges, and emerging models of PrEP implementation

Patrick S Sullivan[A] and **Aaron J Siegler**[B]

[A]Department of Epidemiology, Rollins School of Public Health, Emory University

[B]Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory University

Abstract

Background/Purpose: Pre-exposure prophylaxis with TDF/FTC is now accepted as an efficacious approach to preventing HIV acquisition among people at high risk for HIV infection, but in most places, PrEP uptake to date has not been sufficient to make large impacts on HIV incidence.

Approach: Here we consider several key elements of the effort to expand PrEP uptake for at-risk populations who would benefit most: Increasing ***access*** to PrEP, ***integrating*** PrEP programs with other services, promoting PrEP ***persistence***, and developing systems for ***monitoring*** PrEP use.

Outcomes/Impact: Access to PrEP includes regulatory issues and geographic proximity to PrEP providers. Integrating PrEP programs with other comprehensive sexual health services, through clinic-based programs or through technology-based approaches, offers opportunities to identify PrEP candidates and improve linkages to PrEP care. Once at-risk people are prescribed PrEP, lowering barriers to persistence on PrEP is critical to realizing the most population benefits. To understand progress and identify under-served groups and communities, systems to monitor the uptake of PrEP are needed.

Significance/Innovation: We argue that making the most of a new biomedical intervention tool requires ongoing research about implementation, scaleup through multiple channels, including community-based organizations, and high-quality monitoring of uptake. We must turn to questions of PrEP implementation and continue to seek innovative approaches to reduce barriers to PrEP uptake and persistence on PrEP.

It is now clear that daily pre-exposure prophylaxis with TDF/FTC is effective in reducing HIV acquisition for men who have sex with men (MSM), people who inject drugs, and heterosexual couples. The public health impact of PrEP on HIV epidemics will be largely driven by the extent of uptake of PrEP for people at substantial risk for HIV infection. Modeling studies conducted to estimate the impact of varying levels of PrEP on HIV incidence in MSM suggest that 30%−50% coverage of PrEP among MSM with PrEP indications would be required to achieve reductions in HIV incidence of 25%.(1–3) Few health jurisdictions have achieved this level of PrEP coverage; in a national sample of MSM in the United States, less than 10% of surveyed MSM in 2014 reported ever having used PrEP. Some jurisdictions, such as Seattle (4), San Francisco(5), Sydney, Melbourne(6), and Chicago(7) have reported PrEP uptake as high as 16–30% in specific service populations.

Despite increases in PrEP use and moderate levels of coverage in some cities, significant barriers to increasing PrEP among those at substantial risk for HIV remain. A case series of MSM who became newly infected with HIV while they were in a research study in which PrEP was offered to participants every 3–6 months, lack of risk perception and lack of understanding of PrEP indications (e.g., STI diagnosis) were common reasons for not starting PrEP when it was recommended. Further, the 2014 Public Health Service PrEP guidelines may be less sensitive for identifying Black MSM at risk for HIV infection, compared to sensitivity for identifying white MSM at risk.(8) For women at risk for HIV, concerns about stigma and medication costs and fear of reactions of family members and health care providers have been identified as barriers to uptake.(9)

Getting PrEP to the people who need it will require a coordinated, multisectoral response. Here, we will consider several aspects of a wholistic approach to expanding PrEP uptake by at-risk populations, including increasing access to PrEP, integration with other sexual health services, improving persistence on PrEP, and systems for monitoring PrEP uptake. We conceptualize this within the frameworks of the Continuum of PrEP Care as proposed by Kelley et al (10) and Nunn et al. (11)

Improving access to PrEP: Regulatory policies and access to healthcare

The Kelley (10) and Nunn (11) frameworks both identify facilitating PrEP access as key continuum elements. PrEP access is substantially influenced by regulatory policy. Despite the endorsement of PrEP by the World Health Organization,(12) most UN member nations (155/193) have not provided regulatory approval for PrEP.(13) Thus, greater than 78% of the world's population, 5.9 billion people, live in countries without approval. Encouragingly, some of the countries that have approved PrEP have high need, accounting for 58% (21.3 million/36.7 million) of people living with HIV at the end of 2016.(14) Yet, in absence of regulatory approval, PrEP access in countries without approval will be limited, and PrEP will accrue only to individuals with the financial resources and international connections to procure antiviral medication. Data demonstrating the substantial effectiveness and cost-effectiveness of TDF/FTC for PrEP for indicated individuals provide incontrovertible support for its regulatory approval. Countries without approval should seek to identify remaining barriers to approval, and systematically address them through either collecting relevant data or marshalling political support.

Among countries that have approved PrEP, national and local policies can mitigate barriers to access. The cost of seeking PrEP, which can include cash out-of-pocket and time expended seeking care, is often substantial. The prescription for TDF/FTC is often costly, and generic options are not available in many countries. Laboratory and clinician visit costs can also be expensive: PrEP guidelines from WHO4 and CDC (15) call for four visits annually to allow for HIV testing, behavioral surveillance, and testing for sexually transmitted infections (STI) and creatinine levels. Depending on the setting, cost barriers can be addressed at the national or local level. In Brazil, France, and Norway PrEP services and medication are offered at no-or low-cost to end-users.(16) Similar programs are offered in localities such as New York City, San Francisco, Washington State, and the state of Florida. (17–20)

Cost is not the only access barrier to PrEP: patients must also be able to identify a nearby clinician willing to prescribe PrEP. Not all clinicians prescribe PrEP, a challenge that has been described elsewhere as a purview paradox.(21) To begin to address this issue in the United States, we developed a national, online directory of PrEP-prescribing clinics. Launched in late 2016, the database began with over 1200 clinics,(22) but now has expanded to include over 2,100 clinics and is now been combined with a national dataset from the US Centers for Disease Control and Prevention.(23) The front-end website, preplocator.org, has had over 150,000 unique users since launch, and preliminary data indicate that website users make positive progress through the PrEP continuum. Among 54 website users who completed baseline and one-month follow-up surveys, six reported having scheduled an appointment to talk with a PrEP-prescribing clinician at the one-month follow-up survey, and two others reported PrEP initiation.(24)

The geolocated database of PrEP clinics was used to describe access to clinics, and instances where inequities in access were observed.(25) Overall, the median was 2.0 PrEP-prescribing clinics per 1,000 PrEP-eligible MSM in the United States, a supply that may be insufficient to cover long-term PrEP scale-up given that many clinics in the database have limited capacity for new patients. States in the Southeast had fewer PrEP clinics relative to the number of PrEP-eligible MSM. Counties were less likely to have a PrEP clinic in their borders if they had a higher proportion of county residents living in poverty, lacking health insurance, identifying as African American, or identifying as Hispanic/Latino. Thus, the inequities in access to PrEP clinics are occurring in the same populations that are more impacted by the HIV epidemic. A substantial number of PrEP-eligible men live in ‘PrEP deserts,’ facing long commute-time to care.(26) An estimate of over 51,000 have a driving time commute in ideal traffic conditions greater than 1 hour, and over 146,000 have a commute greater than 30 minutes. Census tracts in the South region were more likely to have long commute times to PrEP clinics, even after controlling for urbanicity. It is essential that programs be developed to address unequal geographic and economic access to PrEP. These programs should address barriers to access faced by groups at highest risk, including MSM, and in particular young and minority MSM. Additionally, groups currently accessing PrEP at low rates, including women and younger populations, should be provided with interventions to facilitate access.

In addition to geographic location of clinics, there are important considerations of how to use a variety of potential service provision settings to address gaps in geographic coverage, and to align the clinical workforce with the need to scale up PrEP. There has been an historical “Prevention paradox”, in which neither infectious disease providers nor primary care providers viewed PrEP provision as within their purview.(27) However, a recent review of literature evinced a growing diversity of PrEP provision settings, including sexually transmitted disease clinics, primary care providers, and programs linked to public health functions (e.g., partner notification programs).(28) Calabrese et al have recently advocated that broader adoption of PrEP provision within accessible service settings, such as including primary care, reproductive health, and mental health settings, is necessary to avoid having PrEP lead to exacerbations is health inequities.(29) Existing gaps in PrEP services points could be addressed by strategically recruiting providers in underserved areas within existing accessible structures, including Federally Qualified Health Centers and Health Department

clinics; the World Health organization provides a series of modules addressing the concerns of different types of providers, service settings, and priority populations for PrEP programs.(30)

Persistence on PrEP

Both Kelley (10) and Nunn (11) identify persistence in PrEP care as a key aspect of the PrEP continuum, and or PrEP to have an impact on the HIV epidemic, modeling indicates that sustaining high retention in care will be critical.(31) For instance, the 10-year percent of infections averted for Black MSM was estimated to decrease from 20.0% to 13.7% if the median time on PrEP before discontinuation changed from 3 years to one year. Yet in three PrEP clinical care programs in the US, only 57% of patients were retained in care at six months follow-up.(32) In a community clinic in San Francisco, incidence of PrEP discontinuation at 13 months was 38%.(33) Following participation in the US PrEP Demo Project, only 40% had taken PrEP since study completion, despite 73% indicating being "very interested" in taking PrEP at their end-line PrEP visit.(34) Fall-off from PrEP care has been particularly pronounced among minority MSM,(35) likely due to facing increased barriers to accessing care over time.

Novel, scalable interventions that decrease barriers to staying on PrEP and increase the perceived benefits of care have the potential to improve PrEP persistence. For instance, the PrEP@Home system allows participants to complete three of their four quarterly PrEP visits in the comfort of their own homes.(36) This approach is accomplished with a mailer for participant self-collection of specimens, centralized laboratory testing for returned specimens, and behavioral surveillance. By decreasing time and resources expended in seeking care at four annual clinician visits, the intervention may increase PrEP persistence in care. For technology-based interventions such as this, formative qualitative work can yield substantial changes to the design of the system and should be conducted if possible. In a pilot study following such adaptations for PrEP@Home, participants rated system usability as 'good' on a validated scale. Over 85% would prefer to use it for their next care visit, and over one-third reported that they would be more likely to remain in PrEP care if it was available.(36) The system, as well as an app-based full telemedicine intervention that was adapted from PrEP@Home, are currently being assessed in clinical trials to determine their impact on persistence in care.(37, 38) We envision that the system could eventually used by PrEP providers to reduce the burden of office visits to provide quarterly PrEP monitoring services for patients who prefer home specimen collection.

As individuals persist in PrEP care over time, issues regarding costs may arise. A change or loss of employment can lead to a change or loss of health insurance coverage. Moreover, copayment assistance programs may cover the costs of medication in the United States, but do not always cover other costs associated with PrEP such as lab and clinical service costs.(39, 40) In one of our studies, a participant tested positive for HIV after entering a high-risk period of sexual activity, but delaying PrEP re-initiation because his patience assistance program eligibility had ended.(41) Programs that support individuals in overcoming financial barriers to PrEP will be essential to support not only initiation, but also persistence on PrEP.

Monitoring uptake of PrEP

PrEP programs are a clear public health example of the adage, “If you can’t measure it, you can’t improve it”. We have both indications of how much PrEP coverage will be needed among vulnerable populations to make substantial impacts on new HIV diagnoses in India, Peru, South Africa, and the United States (for example, 30%−50% coverage for behaviorally eligible MSM(42, 43)). In the United States, there is a national strategic goal to increase PrEP uptake by 500% from 2012–2016(44), which has been achieved. To strive for levels of PrEP coverage that will have public health impact and to continue goal setting and monitoring, approaches are needed to measure the extent of PrEP uptake among eligible persons.

There are several sources of data to monitor PrEP uptake in populations, including surveys of populations with possible PrEP indications, electronic medical records or other health records (especially in countries with government-provided health care) and pharmacy data. In countries with national health care systems, if information about PrEP prescription and indication is systematically captured, PrEP uptake and uptake among those with indications may be analyzable directly from administrative databases. In most other settings, questions about completeness of data on PrEP pharmacy data and biases in surveys of high-risk populations create more uncertainty about how robust estimates might be.

In terms of measuring PrEP uptake, there are several possible metrics that could be considered. A basic measure is the number of PrEP uses over a period of time. For example, new PrEP starts have been reported over time since PrEP was approved for prophylaxis in the United States in 2012(45); this is a cumulative measure and reflects cumulative potential impact of PrEP over time, but does not account for people who might stop PrEP (46). Annual prevalence of PrEP use derived from commercial insurance data accounts for PrEP “stops” and has been used as a developmental indicator for PrEP monitoring in the US National HIV/AIDS Strategy.(44) Data on period (annual or quarterly) PrEP use have been reported for US states over time.(47, 48) Prevalence measures have reported the number of PrEP users per 100,000 population to allow comparison of relative uptake in different subgroups. These data highlight, for example, that increases in PrEP use among US men have been consistent from 2012–2017, but the uptake in women has been at a lower level, and at a lower rate of increase in rates.(47)

Surveys have also been used to assess PrEP use among key populations. Notable among these are the US National HIV Behavioral Surveillance System (NHBS), which collected data from MSM, high-risk heterosexuals, and people who inject drugs in 21 US cities in three-year cycles.(49) PrEP questions have been asked in these surveys since 2014; the most recent triannual cycles reported the period prevalence of PrEP use in the 12 months prior to survey as 3.0% for MSM (2014)(50); 0.3% for people who inject drugs (2015)(51); and 0.2% for urban heterosexual men and women at increased risk for HIV (2016) (52). The American Men’s Internet Survey (53) has collected data from 10,000–12,000 US MSM since 2013 on PrEP awareness, interest and uptake; results showed increasing lower uptake in rural areas, lower uptake among Black respondents in data cycles through 2015, and an overall lifetime PrEP experience of 2.8% in 2015.(54) In other cases, research studies that

collect data from key populations at multiple time points can also provide information on the prevalence of PrEP uptake, and on trends in PrEP uptake. For example, a national online cohort of MSM were reported to have 13% PrEP prescription and initiation, and 9% retention in PrEP through 2015 (55).

Conclusion

Realizing the potential of PrEP in ending HIV epidemics will require getting PrEP to those who need it most. Accomplishing this will require a multisectoral effort that increases access to PrEP, national policies supportive of access to healthcare for those in most need, and new partnerships. Here, we have described a partnership of academic research, using data on PrEP clinic locations and PrEP uptake to identify inequities in access, and innovative approaches to overcoming geographic barriers to access. The potential public health impact of PrEP is currently unrealized. Disparities in PrEP care must also be addressed, with the service made available to groups at highest-risk for HIV transmission. The principles of successful public health campaigns provide a framework for PrEP roll-out and scaleup: increased access, increased maintenance in care, and monitoring should all be key components of a unified effort to ensure that the public health benefits of PrEP are realized with equity.

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