How to implement PrEP

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Introduction

Initial results from clinical prevention trials of emtricitabine and tenofovir disoproxil fumarate (FTC-TDF) for pre-exposure chemoprophylaxis (PrEP) of HIV, in oral pill form, indicate that PrEP could be a key part of the “game changer” needed to more effectively fight HIV. PrEP involves taking antiretroviral medications to prevent HIV transmission through unprotected sex or sharing needles. Pre-exposure prophylaxis (PrEP) for HIV prevention has shown efficacy with men who have sex with men (MSM) and heterosexuals. Biomedical prevention interventions such as PrEP have great potential, especially if coupled with expanded testing, diagnosis, and linkage to treatment and care (TLC+). However, a number of potential concerns and barriers must be overcome in order for PrEP to play the potential role it could play in HIV prevention.

Modeling demonstrates the most effective deployment of PrEP will be in combination with scaled-up treatment. This will help reduce incidence in high-prevalence countries and in concentrated epidemics, for example among MSM. The most effective prevention interventions will be those that combine behavioral interventions, structural interventions, and emerging biomedical technologies. A number of studies have shown that, by preventing infections, PrEP could be cost-effective and would save money that would otherwise be spent on HIV care

PrEP must be accompanied by sustained care and behavioral interventions to ensure adherence, minimize risk compensation, and monitor side effects. Because the most at-risk do not access regular clinical care, alternative implementation arrangements will be necessary. National monitoring systems are critical to preventing the spread of drug-resistant HIV.

Provision of PrEP to MSM and transgender women should occur in a broader context of ensuring clinically competent health care for lesbian, gay, bisexual and transgender people. Ensuring insurance coverage of PrEP is essential to ensure it is accessible to those who need it.

Methods

Published, peer-reviewed research related to the implementation of PrEP for HIV prevention was analyzed and key stakeholders were interviewed—researchers, policymakers, providers, funders, and advocates.

Results

PrEP must be accompanied by sustained care, regular HIV and STI testing, and behavioral interventions to ensure adherence, minimize risk compensation, and monitor side effects and drug resistance.

Modeling of PrEP implementation coupled synergistically with scaled-up treatment—focusing on MSM in San Francisco, adults in Botswana, and serodiscordant couples in South Africa—predicts that PrEP could significantly reduce HIV incidence.

If targeted to the highest risk populations—including serodiscordant couples, MSM, sex workers, and young women in hyperendemic countries—and if adherence and efficacy is high enough, PrEP can be cost effective. Assessment protocols will have to be developed to identify those whose characteristics (demographic, behavioral) make them eligible to take PrEP.

While clinical settings are the most feasible sites for PrEP implementation, alternative arrangements should be explored, such as substance use treatment sites.

Research shows widespread willingness to use PrEP among most vulnerable populations, such as MSM.

However, concerns are widespread that PrEP may lead to risk compensation, which should be monitored and challenged through social marketing and behavioral interventions.

Some have raised concerns about PrEP related to potential side effects, risk compensation (the idea that people will stop using condoms if PrEP becomes available), drug resistance, and cost. However, reviews of five major clinical trials involving about 6,000 participants by the Forum for Collaborative HIV Research show no greater risk of side effects, no risk compensation, and no clinically significant development of drug resistance in participants.

Many gay men are unaware of PrEP. Many confuse PrEP and PEP, or are unaware of either. PrEP offers a teachable moment to increase knowledge of and access to PEP.

Training of health providers and non-clinicians in PrEP delivery is a key component of PrEP scale-up.

Results

The experience of providing ARVs in low-income countries with generalized epidemics has highlighted challenges that would likely accompany PrEP scale-up. These include staff development and training; the creation of infrastructure, especially in rural areas; financing the medications; serving areas of high demand; overcoming barriers to accessing care, including stigma; creating monitoring and evaluation systems; maintaining adherence; and monitoring and managing side effects and the emergence of drug-resistant HIV.

Among the greatest barriers to accessing PrEP is cost. The CDC estimates TDF-FTC would cost $8,030 a year; generic TDF-FTC is available in the global south for $108 a year. Currently a number of private insurers and some Medicaid programs are covering PrEP for patients.

The Affordable Care Act mandates coverage of “Essential Health Benefits” (EHBs) by insurance offered in state Health Insurance Exchanges; these include prescription drugs and prevention and wellness programs, which could cover PrEP. The U.S. Department of Health and Human Services has granted significant latitude to states in determining EHBs. Coverage of PrEP by state Medicaid programs is essential to ensuring that those most at risk of HIV, including low-income black and Latino gay and bisexual men and transgender women, are able to access PrEP.

While the cost of PrEP in the U.S. would be substantial, private insurers and state Medicaid departments are open to coverage, and low-cost generic medications could enable access in low-income countries. The prioritization of highly vulnerable populations could increase the cost-effectiveness of PrEP. Providing PrEP is also less expensive than treating someone for HIV over the course of a lifetime.

PrEP will be most effective if coupled with structural level interventions that address factors that increase vulnerability to HIV. This could include social exclusion and isolation caused by anti-gay prejudice, whether in the form of family rejection or harassment in schools or other institutions.

Conclusions and recommendations

The U.S. FDA approved FTC-TDF for use as PrEP for HIV prevention in July 2012. The U.S. CDC issued interim guidance for PrEP with MSM in January 2011, and similar guidance for PrEP with high risk heterosexuals and serodiscordant couples in August 2012. The WHO issued “rapid advice” on PrEP for HIV prevention in July 2012. The U.S. Public Health Service is expected to issue guidance soon.

Conclusions and recommendations

Demonstration projects are underway or set to launch soon in California, Miami, in sub-Saharan Africa, and elsewhere

Recommendations

Public health entities should educate most vulnerable populations about the difference between PrEP and post-exposure prophylaxis (PEP), and use the emergence of PrEP to educate people about PEP. People seeking PEP and/or HIV testing after a possible risk exposure should be prioritized for PrEP coupled with sustained behavioral interventions.

Funders should support community education and engagement campaigns to increase community literacy about PrEP and other biomedical interventions, and to enhance community involvement in scale-up and roll-out of PrEP and other interventions.

Pharmaceutical companies should be encouraged to offer PrEP at a discount to low- and moderate-income people in high-risk groups and to create a Patient Assistance Program.

States should provide access to PrEP as an Essential Health Benefit. State Medicaid programs should also cover PrEP as a cost-saving measure that will improve public health.

Global funders of HIV prevention and care should make resources available for PrEP and treatment as prevention (TasP). The WHO, PEPFAR, UNAIDS, and the Global Fund should provide the latest research to country planners to help policy makers strike the right balance between funding for PrEP, other prevention services, and treatment.

U.S. HRSA and CDC should also work closely in developing implementation plans for PrEP, as PrEP will be most effective if combined with TasP and TLC+.

References and contact information

Based on Cahill S., *Pre-exposure prophylaxis for HIV prevention: Moving toward implementation*, Boston: Fenway Institute, July 2012. Endnotes are available there, pp. 45-64. Available at **http://www.fenwayhealth.org/site/DocServer/PolicyFocus_PrEP_v7_02.21.12.pdf?docID=9321**

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