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# Antiretroviral Drugs as the Linchpin for Prevention of HIV Infections in the United States

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Recent advances in the use of antiretroviral drugs for the prevention of HIV infection present a historic opportunity to better control the spread of the disease. Despite an estimated 18% decline in the number of annual HIV infections between 2008 and 2014 (http://bit.ly/2ftovat), there were approximately 38 000 new infections in 2014, 70% of which were among men who have sex with men (MSM). As a consequence of improved survival with antiretroviral therapy (ART), the number of persons living with HIV has increased to 1.1 million. However, all of these persons are a potential source of new infections to their partners, particularly the 15% who do not know that they are infected, as well as those who know their HIV status but have not achieved a suppressed viral load (i.e., as a result of ART). Each infected person incurs $402 000 in discounted lifetime costs.[1]

## THE INNOVATION

Whereas ART initiation was once reserved for HIV-infected persons who had sustained an immunologic decline, it has since been demonstrated that “early” ART markedly reduces onward HIV transmission.[2] The real-world prevention effects of increased access to treatment were documented in Vancouver, British Columbia, between 1996 and 2012. Moreover, there is solid evidence that early initiation of ART is associated with reductions in severe health outcomes and mortality. Nevertheless, an estimated 61% of HIV transmissions in the United States occur from persons who had been diagnosed with HIV but who were not retained in care.[3] For the prevention of HIV infection in high-risk individuals, several trials and demonstration projects have proven the benefit of oral anti-retroviral drugs for pre-exposure prophylaxis (PrEP) among high-risk MSM, heterosexual men, and women, as well as injection drug users.[4] Ongoing preclinical and clinical research holds the promise of more adherence-friendly PrEP agents.

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***Note***. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Historically, control of infectious diseases has been advanced by chemotherapeutic programs as evidenced by declines in syphilis in the 1940s, tuberculosis in the 1960s, and gonorrhea in the 1980s. An HIV-specific example has been the success of the prevention of mother-to-child transmission of HIV. Although a vaccine and a cure for HIV remain elusive, the daily accumulation of approximately 130 new infections and the opportunity afforded by the innovations of early ART and PrEP demand a concerted effort to maximize the tools we have in hand with a bold and sustained campaign.

In 2011, the Centers for Disease Control and Prevention's (CDC's) Division of HIV/AIDS Prevention (DHAP) implemented a High-Impact Prevention strategy through which combinations of scientifically proven, cost-effective, and scalable interventions were targeted to the right populations in the right geographic areas.[5] National prevention efforts have focused on four key areas: widespread testing and linkage to care for infected persons to begin early treatment, support for these persons to adhere to ART, universal viral suppression, and PrEP services for persons at high risk of HIV acquisition. The national goals are to achieve viral suppression in at least 80% of persons living with diagnosed HIV and reduce the annual number of new diagnoses by 25%. While the federal government's national goals have been articulated and High-Impact Prevention expresses our agency's strategy, in this article we share a vision for how DHAP intends to more systematically promote the use of antiretroviral drugs to reduce new HIV infections.

## AN ANTIRETROVIAL DRUG PREVENTION FRAMEWORK

Thomas R. Frieden, the former CDC director, described a six-component wheel as a comprehensive approach to control disease.[6] At its hub, this wheel has innovation as its driving force. In applying this framework for HIV prevention, our innovation consists of anti-retroviral drugs used in two ways: early ART for preventing HIV transmission and PrEP for the prevention of HIV acquisition. The four spokes of the wheel are the technical package, communication, partnership, and effective performance management, and the wheel's rim and sixth component is political commitment.

The technical package consists of a limited number of high-impact interventions that together are expected to control HIV. Communication of accurate and timely information to the health care community, decision-makers, and the public is intended to engage civil society, influence decision-makers, and affect behavior change. Partnerships and coalitions are forged with both public- and private-sector organizations, which includes DHAP-funded health departments and community-based organizations. Effective performance management is carried out through real-time program monitoring, evaluation, and program improvement. Finally, political commitment is necessary to obtain the resources and support for action.

## COMPONENTS OF THE FRAMEWORK

Here we focus on the four spokes or components of the innovation wheel to maximally use antiretroviral drugs for HIV prevention. All these components are necessary for the prosecution of successful public health interventions. Table 1 shows selected elements and their status within the four components. Some elements consist of published normative

documents requiring periodic updates. Other elements might require funding, the pursuit of new or broader lines of action, or additional research to improve uptake of PrEP and treatment. A notable need is in the strengthening of partnerships and greater coordination between government-to-government and government-to-nongovernment entities. The effort to treat HIV-infected persons and control the epidemic has had political commitment (the rim of the wheel) at the national level. This is evidenced by a $20 billion budget for domestic HIV care and treatment in 2016, and a stable $0.9 billion per year for domestic HIV prevention between 2011 and 2016.

## THE WAY FORWARD

Despite the fact that CDC is in control of neither the funding or the distribution of medications related to treatment or PrEP, most elements are within CDC's sphere of either control or influence. The success of the campaign to prevent the transmission of HIV from infected mothers to their children demonstrates that such an approach is feasible. CDC is committed to addressing the outstanding elements in the spokes of the innovation wheel within the context of High-Impact Prevention. There will be increased internal coordination at DHAP to advance the components of the wheel, including regular data-driven reviews to help focus DHAP's efforts and understand successes and challenges in the field.

A major share of DHAP's funding for HIV prevention is aimed at diagnosing people with HIV and ensuring that they are swiftly linked to and retained in care so that they can achieve and maintain viral suppression. PrEP has been designated as a priority, particularly as a targeted prevention initiative for MSM and transgender individuals. Using routine monitoring and evaluation as well as special studies, DHAP will rapidly disseminate information on the status of PrEP use, early ART initiation, target population behaviors associated with these innovations, and updates on the HIV care continuum. Data-to-care is a public health strategy that uses HIV surveillance data for public health purposes, especially to identify HIV-diagnosed persons not in care and link them to care.

Questions remain about how best to implement early HIV treatment and PrEP. For this reason, research is needed to optimally implement various aspects—including behavioral and structural interventions—to overcome barriers to early treatment and PrEP. CDC will continue to augment public–private partnerships and coordinate with funders of public health–oriented research such as the National Institutes of Health. All six components of the innovation wheel will be needed to attain a vision of the United States as a place where "new HIV infections are rare, and when they do occur, every person … will have unfettered access to high-quality, life-extending care."[7(pA3)]

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**TABLE 1**

Components and the Status of Selected Elements of the Four "Spokes" of the Antiretrovirals for HIV Prevention Innovation Wheel

| Component | Selected Elements | Status and Potential Actions |
|---|---|---|
| Technical package<br>Guidelines<br>HIV and other laboratory tests, including sexually transmitted infections<br>Tools for reaching target population<br>Best practices for HIV testing, linkage to care, retention in care, re-engagement in care, and adherence<br>Risk-reduction services | Publication and dissemination of guidelines: PrEP, nPEP, ART. | Published (updated periodically). |
| | Laboratory guidelines for HIV and STI testing. | Published (updated periodically). |
| | Identify target populations. | Continue research to close the gap of PLWH unaware of their diagnosis; continue research to better identify high- risk persons who would most benefit from PrEP. |
| | Recommended approaches to optimize HIV testing, adherence support (for both PrEP and treatment), linkage to care, retention in care, re-engagement in care. | Partially complete: Web-based training in evidence-based prevention services; grantees to use the Antiretroviral Treatment Access Study and Retention-in-Care methodologies to promote linkage to care and retention in care for PLWH, respectively; additional research ongoing to improve linkage, adherence, and re- engagement in HIV care as well as initiation and retention to PrEP. |
| | Recommended risk-reduction services, syringe services programs, condoms, behavior change interventions, referral to mental health and substance abuse therapy. | Published (updated periodically). |
| Communication<br>Best practices in use of new media<br>Education of health care providers and beneficiaries | Educate potential patients (PLWH and high-risk negatives) on the benefits of PrEP and early initiation of ART. | Planned or ongoing but need to ensure quality, monitor, and enhance as needed. |
| Stakeholder engagement including high-risk communities | Educate communities in which there are high prevalences of HIV and communities of high-risk persons on the benefits of PrEP and early initiation of ART. | Planned or ongoing but need to ensure quality, monitor, and enhance. |
| | Educate primary health care workers on the benefits of PrEP and early initiation of ART and encourage uptake of guidelines. | Continue and expand funding and support. |
| | Inform stakeholders of the benefits of PrEP and early initiation of ART. | Planned or ongoing but need to ensure quality, monitor, and enhance. |
| | Maximize use of new media (e.g., smart phones) to promote above. | Continue and expand funding and support. |
| Partnerships | Medical associations | Enhance current collaborations; begin new ones. |
| Associations and societies | Federal health agencies | Enhance current collaborations per national goals. |
| Government–government | State and local health departments | Funded to implement HIV prevention programs. |
| Health care system | Clinics and health care organizations | Enhance current collaborations per national goals. |
| Community | Community-based organizations | Funded to implement HIV prevention programs. |
| | Advocacy organizations | Enhance current collaborations per national goals. |
| | Private sector | Enhance current collaborations per national goals. |

| Component | Selected Elements | Status and Potential Actions |
|---|---|---|
| Performance management<br>Monitoring and evaluation<br>HIV surveillance, including the care continuum | Monitor progress of grantees in implementing PrEP and early initiation of ART and document best practices. | Complete best practices in the use of PrEP and early initiation of ART. |
| Behavioral surveillance<br>Best practices documentation | Conduct health services research to assess the impact of the new programs. | Planned or ongoing but need to ensure quality, monitor, or enhance. |
| Research<br>Transmitted drug resistance surveillance | Monitor transmitted drug resistance to ensure that tenofovir/emtricitabine remains the first-choice PrEP agent. | Ongoing program; may require development and funding of surveillance for transmitted drug resistance in PrEP patients. |

*Note.* ART = antiretroviral therapy; nPEP = nonoccupational postexposure prophylaxis; PLWH = persons living with HIV; PrEP = pre-exposure prophylaxis; STI = sexually transmitted infection.

*Source.* The components and innovation wheel concept were described by Frieden.[7]