



HIV PrEP Framework Federal Activities

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Table of Contents

Policy, Practice Guidelines, and Program Guidance	1
Communications to the General Public and Persons at Increased Risk of Acquiring or Transmitting HIV	2
Training and Technical Assistance to Health Care Providers, Grantees, and Others	4
PrEP Programs to Improve Access, Use, and Adherence	6
PrEP Readiness, Linkage, and Navigation Programs	6
PrEP Medication and Clinical Services	7
PrEP Adherence Programs	7
Monitoring and Evaluation	8
Research	9
Financing	10
Department and Agency Acronyms	11



Policy, Practice Guidelines, and Program Guidance

Policies make it possible for agencies, programs and providers to deliver PrEP and for individuals to receive it. Policies also help clarify positions on PrEP issues and can be used to support action, address funding/reimbursement, remove barriers, etc.

Practice guidelines and program guidance provide more specific direction to health care providers, grantees, and/or government employees about the delivery of PrEP services and the establishment and operation of programs to support PrEP awareness, use, and adherence.

AGENCY	SELECTED ACTIVITIES
CDC	<p>CDC issued Public Health Service PrEP clinical practice guidelines for the use of daily oral PrEP to reduce the risk of acquiring HIV infection in adults.</p> <p>CDC released a PrEP guidance letter to CDC-funded health department HIV prevention programs which outlines how funds may be used in implementing program activities to support PrEP.</p>
HRSA	<p>The Bureau for Primary Health Care (BPHC) is developing a Technical Assistance Resource (TAR), due to be released in early December 2016, that communicates BPHC policies and guidelines regarding PrEP and provides guidance and links to resources on PrEP implementation at Federally Qualified Health Centers (FQHCs).</p> <p>The HIV/AIDS Bureau (HAB) issued a Dear Colleague Letter (HRSA Program Letter) and updated the HRSA Application Guide which accompanies all HRSA FOAs to provide guidance to recipients on the use of Ryan White HIV/AIDS Program (RWHAP) funds for PrEP services and service delivery within the parameters of the RWHAP legislative authority.</p>
IHS	<p>In early October 2016, the IHS Chief Medical Officer released PrEP guidelines (policy, practice guidelines, and program guidance) templates to all IHS Area Clinical Directors across the country to assist clinical staff in understanding PrEP eligibility, patient needs, clinical algorithms, and best practices. Sites were invited to use the guidelines templates and customize them as needed for facility-level use.</p>
ONDCP	<p>ONDCP supports the use of PrEP for persons who may benefit from its utilization, including persons who inject drugs.</p>
SAMHSA	<p>Providers are required to provide PrEP education and linkage to clinical services for clients who request PrEP as outlined in the SAMHSA Targeted Capacity Expansion: Substance Use Disorder Treatment for Racial/Ethnic Minority Populations at High-Risk for HIV/AIDS, Minority AIDS Initiative Continuum of Care Pilot, other discretionary grant programs, and FOAs.</p>
VA	<p>Current scientific evidence about and recommendations for the use of PrEP in the Veterans Health Administration (VHA) has been made available on the VA's website. This information has also been made available to VHA clinicians and Pharmacy Directors in compliance with applicable Federal and pharmacy protocols and regulatory standards.</p>



Communications to the General Public and Persons at Increased Risk of Acquiring or Transmitting HIV

Social marketing campaigns and educational materials increase knowledge and awareness of PrEP among the general public and persons living with HIV as well as promoting use among persons at increased risk of HIV infection.

Information in existing campaigns, prevention programs, and patient education materials may need to be updated to ensure they include accurate and relevant information about PrEP.

AGENCY	SELECTED ACTIVITIES
CDC	<p>CDC published PrEP educational fact sheets, infographics, brochures, and Vital Signs on its websites. PrEP is also incorporated in social marketing campaigns including <i>Act Against AIDS</i> and <i>Start Talking. Stop HIV</i>.</p> <p>CDC developed the HIV Risk Reduction Tool which enables users to compare the risks created by different sexual activities and to see how one or a combination of prevention methods – such as condoms, PrEP, or ART – could reduce the risk of HIV.</p> <p>CDC is reviewing and updating prevention messages that are delivered in CDC-funded programs to ensure inclusion of PrEP.</p>
DOD	<p>DoD Navy and Marine Corps Public Health Center Navy Sexual Health and Responsibility Program (SHARP) has made HIV PrEP information available on the Navy Marine Corps Public Health Center website for Service Members.</p> <p>Army Public Health Center HIV and STD Prevention Education Resources have included links to the Navy and Marine Corps SHARP information and HIV Prevention Resources, as well as links to external HIV PrEP resources (e.g., CDC).</p>
HRSA	<p>HRSA prepared multiple messages on PrEP that were disseminated via social media, newsletters and listservs. That information may be used to tailor messages for clients who access services at HRSA-funded programs and from HRSA-funded providers.</p>
IHS	<p>IHS is collaborating with tribal entities that have targeted and culturally appropriate social media messaging as a core competency to include PrEP messaging at both national and regional levels.</p>
NIH	<p>NIH has provided online information about PrEP including a description of PrEP research findings and an infographic describing research on long-acting forms of PrEP.</p> <p>NIH has conducted webinars and Facebook Live chats to share PrEP research findings with the general public.</p> <p>NIH is disseminating press releases regarding PrEP research through its websites and on Twitter.</p>

Updated the AIDS.gov PrEP topic page, including infographics. The page has received 239,931 visits in 2016, making it the 11th most popular page this year.

OHAIDP

Published 11 blog posts about PrEP, each disseminated via GovDelivery reaching 43,000 subscribers.

Addressed PrEP in 3 videos produced by AIDS.gov.

Shared infographics about PrEP on AIDS.gov social media channels.

ONDCP

ONDCP includes information about PrEP in speeches and presentations regarding its potential benefits for HIV prevention among persons who inject drugs.

VA

VHA has developed PrEP fact sheets and FAQs for its website. In addition, PrEP messages are included in social media and awareness campaigns for World AIDS Day and HIV Testing Day.



Training and Technical Assistance to Health Care Providers, Grantees, and Others

Training and technical assistance increases the knowledge, skills, ability, and capacity of health care providers, the federal workforce, and grantees to identify candidates for PrEP, deliver PrEP, and expand PrEP use and adherence.

AGENCY	SELECTED ACTIVITIES
CDC	<p>CDC has funded PrEP technical assistance grantees for clinical care organizations (on how to deliver PrEP care), health departments (on increasing community awareness of PrEP, identifying and training PrEP providers, and monitoring its use), and community based organizations (on educating, linking, and supporting persons at risk in PrEP and other HIV prevention services).</p> <p>CDC hosted a “Pre-Exposure Prophylaxis (PrEP) for Prevention of HIV Infection” Public Health Grand Rounds to explore the opportunities for using PrEP as tool to prevent the transmission of HIV and discuss the challenges to effective implementation that must be addressed to make PrEP a success.</p>
DOD	<p>DoD SHARP has HIV PrEP products for clinicians including but not limited to fact sheets, webinars, briefings, posters, as well as a link to the University of California, San Francisco Clinician Consultation Center (CCC) PrEPline, a resource staffed with an expert team of HIV clinicians to advise healthcare professionals on the indications for and proper implementation of PrEP.</p>
HRSA	<p>BPHC and CDC are partnering in the Partnerships for Care (P4C) to integrate HIV care into primary care at FQHCs. HRSA BPHC, through its P4C HIV Training, Technical Assistance and Collaboration Center (HIV TAC) developed a four-part PrEP Community of Practice (CoP). This CoP included learning sessions that provided training to health centers on guidelines for prescribing PrEP and other issues regarding PrEP implementation (e.g., strategies to manage PrEP with other medications and PrEP engagement and retention in care).</p> <p>BPHC is providing funding for The National LGBT Health Education Center at the Fenway Institute. The Center provides TA to FQHCs on PrEP delivery and other topics related to LGBT health. These TA activities which target BPHC grantees, specifically providers, support improved patient-provider communication about PrEP, screening for eligible patients, and the full continuum of care related to PrEP delivery.</p> <p>On August 2, 2016, the HAB held a technical assistance webcast attended by more than 500 recipients to review the Dear Colleague Letter PrEP guidance and to provide examples for PrEP services within the RWHAP legislative authority, for the use of the RWHAP for PrEP. Another webcast is being planned for this winter, scheduled for December 14th, and will provide RWHAP recipient examples of PrEP implementation.</p> <p>During the 2016 National Ryan White Conference on HIV Care and Treatment in August 2016, HRSA held a workshop with RWHAP recipients and providers to detail its support of PrEP as a priority NHAS 2020 action item, and related guidance on PrEP from BPHC and HAB.</p>

HRSA	<p>The HRSA PrEP Workgroup developed a three-part interactive PrEP training webinar series for federal staff in conjunction with SAMHSA, IHS and AHRQ. Two trainings were held on July 7 and September 20. The third will be completed around World AIDS Day.</p> <p>The HRSA HIV/AIDS Bureau AIDS Education and Training Centers (AETCs) provide consultative technical assistance and prevention education to clinicians across the nation through the CDC-funded PrEP Warmline. In addition, AETCs have RWHAP legislative authority to provide training to HIV medical providers on prevention, including PrEP.</p>
OHAIDP, OMH, ONAP, CDC, NIH	<p>OHAIDP and OMH co-hosted a June 2016 federal staff webinar about PrEP that reached more than 600 listening sites spanning 6 federal departments (DOL, ED, HHS, HUD, State, VA) and at least 13 agencies.</p>
SAMHSA	<p>SAMHSA is using multiple forums such as webinars and workshops at annual grantee meetings to provide education and training on PrEP.</p>
IHS	<p>IHS held a Grand Rounds webinar on PrEP in June of 2016 for IHS clinicians. The Grand Rounds provided current evidence for PrEP, protocols, and details for receiving technical support from IHS Headquarters.</p>
VA	<p>VHA has developed several provider fact sheets that are available on its website.</p> <p>PrEP telephone consultation line has been made available to providers to help answer any questions they may have about prescribing and monitoring patients on PrEP.</p> <p>Funded 10 quality improvement projects designed to incorporate evidence-based interventions to connect HIV-positive Veterans to care and target at-risk HIV-negative Veterans for focused interventions.</p>



PrEP Programs to Improve Access, Use, and Adherence

Distinct programs and resources support PrEP readiness, linkage and access to PrEP, delivery of PrEP medication and services, and adherence.



PrEP Readiness, Linkage, and Navigation Programs

PrEP programs identify an individual's indications for PrEP, assess readiness, link to clinical screening, and provide navigation for obtaining PrEP.

AGENCY	SELECTED ACTIVITIES
CDC	CDC has funded health departments, community based organizations, and demonstration projects to offer these services.
IHS	IHS has formed an ongoing PrEP Collaborative with a cluster of early adopter IHS hospitals and external experts on PrEP program implementation, at this time centered primarily in the US Southwest.
NIH	NIH advanced a comprehensive care model to facilitate and support PrEP use among Black MSM through the HPTN 073 study. NIH-sponsored research is also developing a model program to facilitate PrEP screening and uptake among Black women in primary care settings.
OPA	OPA, through funding from the Secretary's Minority AIDS Initiative Fund (SMAIF), has developed and disseminated an evidence-based algorithm to provide PrEP services within Title X funded family planning services projects.
SAMHSA	The SMAIF supported project, Advancing Prevention and Care Services in At-Risk Urban Communities, is seeking to improve health outcomes through drug treatment, HIV and viral hepatitis screening, and accessing PrEP services in conjunction with syringe services programs.



PrEP Medication and Clinical Services

Clinical services including patient screening, monitoring, and evaluation are critical for the initiation and use of PrEP.

AGENCY	SELECTED ACTIVITIES
CDC	<p>CDC is supporting activities to provide patient screening, monitoring, and evaluation for the initiation and use of PrEP in public STD clinics (although CDC does not pay for the medication).</p> <p>The President's FY17 Budget Request includes \$20 million in additional grant resources for a new demonstration project to increase availability and improve utilization of pre-exposure prophylaxis (PrEP) in high-burden communities. This demonstration project will allow health departments to use up to 30 percent of these available funds to pay for PrEP medications as the payer of last resort.</p>
IHS	PrEP Collaborative is implementing clinical PrEP services in participating hospitals.
NIH	NIH has supported research to improve PrEP prescribing among persons at increased risk of HIV infection. One current NIH study is testing a multi-level structural intervention to integrate PrEP delivery within FQHCs that care for underserved communities in the Bronx, NY, which may provide a model for FQHCs in other areas.



PrEP Adherence Programs

Adherence programs support the ongoing use of PrEP to achieve maximum prevention benefit and reduce the risk of selecting for a drug-resistant virus if non-adherence leads to HIV acquisition.

AGENCY	SELECTED ACTIVITIES
CDC	CDC has funded health departments, community based organizations, and demonstration projects to offer these services.
IHS	PrEP Collaborative is implementing clinical PrEP services in participating hospitals.
NIH	NIH has funded research to improve PrEP adherence measurement and support. One NIH initiative advanced research to develop innovative measures of PrEP medication adherence, and the resulting research grants are currently developing and validating novel drug assays, ingestion sensors, and wireless technologic approaches for clinical monitoring of PrEP adherence.



Monitoring and Evaluation

Ongoing evaluations and monitoring of PrEP uptake, awareness and knowledge of PrEP, and populations at-risk help inform and improve the efforts of the PrEP framework.

AGENCY	SELECTED ACTIVITIES
ONAP	ONAP NHAS indicator.
CDC	CDC is monitoring awareness and use of PrEP in high risk populations (e.g., NHBS) and is evaluating PrEP programs in demonstration projects. CDC is monitoring PrEP prescriptions nationally to assess disparities in demographic and geographic uptake relative to the distribution of new HIV diagnoses.
IHS	IHS is monitoring facility level reporting from 'early adopter' PrEP services in key hospitals.
NIH	NIH has supported research awards to establish metrics and systems for monitoring PrEP implementation in several U.S. municipalities, including Chicago, Detroit, and San Francisco.
VA	VA has a planned evaluation effort to determine the uptake of PrEP in various patient populations nationally.



Research

Research to expand the number of new drugs, delivery mechanisms, dosing protocols, and ongoing cost effectiveness studies increases the availability of PrEP. Likewise, understanding the determinants for use and adherence helps target efforts in scaling up PrEP. Further, implementation research helps determine and identify best practices and evidence-based models for PrEP delivery.

AGENCY	SELECTED ACTIVITIES
CDC	<p>CDC is conducting laboratory studies of new PrEP agents and delivery mechanisms.</p> <p>CDC is conducting implementation studies of FDA-approved PrEP agents, analyses of financing issues, and implementation research studies funded by NIH's National Institute for Mental Health (NIMH) in collaboration with demonstration project sites funded by CDC to improve delivery of PrEP.</p> <p>CDC is modeling the impact of PrEP (alone and in conjunction with other prevention strategies) to assess potential impact on new HIV infections.</p>
DOD	<p>USAF physicians participated in a cross-sectional survey regarding knowledge, attitudes, and beliefs toward HIV PrEP.</p>
NIH	<p>NIH has designated PrEP as a high priority area for HIV/AIDS research funding and is currently supporting pre-clinical and clinical research to develop the next generation of long-acting PrEP, including injectable, implantable, and intravaginal ring formulations.</p> <p>NIH has also advanced an implementation science research initiative to study PrEP planning, outreach, and delivery activities for MSM and transgender women at CDC-funded US health departments.</p>



Financing

Financial decisions and efforts address coverage and cost of medication as well as clarify payer sources and other related funding opportunities and mechanisms for PrEP.

AGENCY	SELECTED ACTIVITIES
HRSA	BPHC is encouraging FQHCs to use 340B pharmacy discounted drug pricing to improve access to PrEP medication.
VA	Truvada approved and on formulary for PrEP. Veterans' co-pays vary based on their service connection and VA disability rating.

Department and Agency Acronyms

CDC	Centers for Disease Control and Prevention, HHS
CMS	Centers for Medicare and Medicaid Services, HHS
DOD	Department of Defense
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration, HHS
IHS	Indian Health Service, HHS
NIH	National Institutes of Health, HHS
OASH	Office of the Assistant Secretary for Health, HHS
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy, HHS
OMH	Office of Minority Health, HHS
ONAP	Office of National AIDS Policy, The White House
ONDCP	Office of National Drug Control Policy, The White House
OPA	Office of Population Affairs, HHS
OWH	Office on Women's Health, HHS
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
VA	Department of Veterans Affairs

To learn more about the Federal HIV PrEP Framework,
visit www.AIDS.gov.