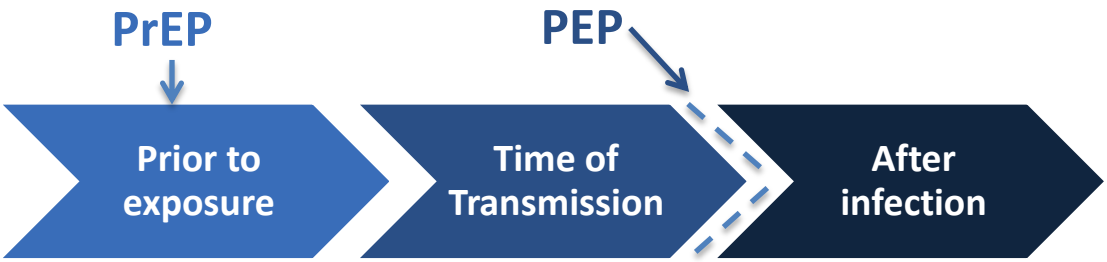
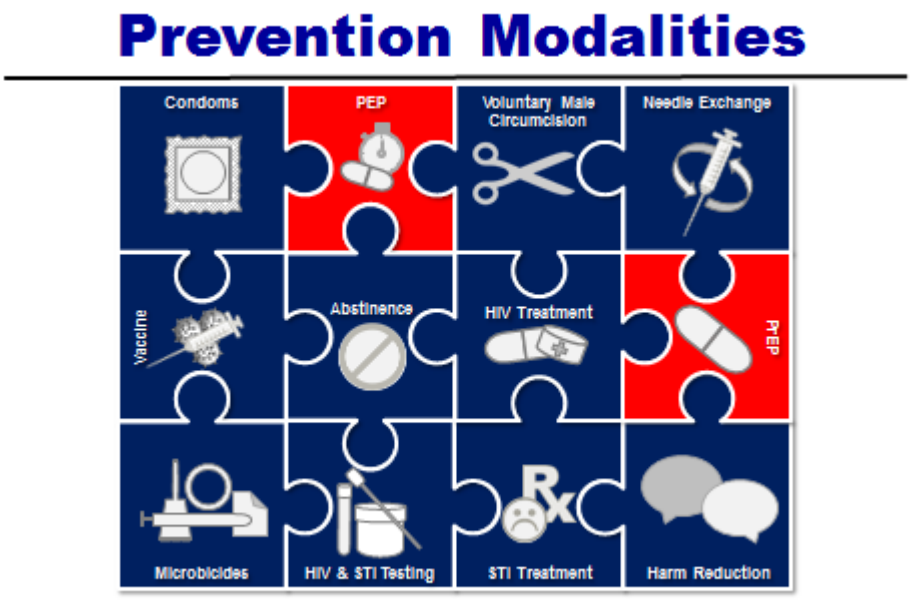
HIV Biomedical Prevention Framework for Los Angeles County

Introduction

Antiretroviral drugs are an increasingly important component of HIV prevention, as they can reduce viral loads and infectiousness of persons living with HIV (i.e., “treatment as prevention”) and help prevent HIV acquisition in uninfected persons (i.e., “biomedical prevention”). Post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) are two forms of HIV biomedical prevention. PEP is 28 day course of an antiretroviral regimen taken within 72 hours of a high risk HIV exposure to prevent HIV sero-conversion. PrEP is a daily pill taken by individuals who are HIV-negative before they are potentially exposed to HIV. PrEP has been shown to reduce the risk of HIV infection by up to 92% when taken consistently.



DPH is committed to support the delivery of a full range of prevention services for HIV-negative individuals at risk of HIV infection that includes PrEP and PEP, health education and risk reduction counseling, condom use, HIV testing, STD testing and treatment, and referrals for appropriate social and support services such as substance abuse treatment and mental health services.



Courtesy of Dr. Raphael Landovitz, UCLA CARE Center.

Key PrEP Service Elements

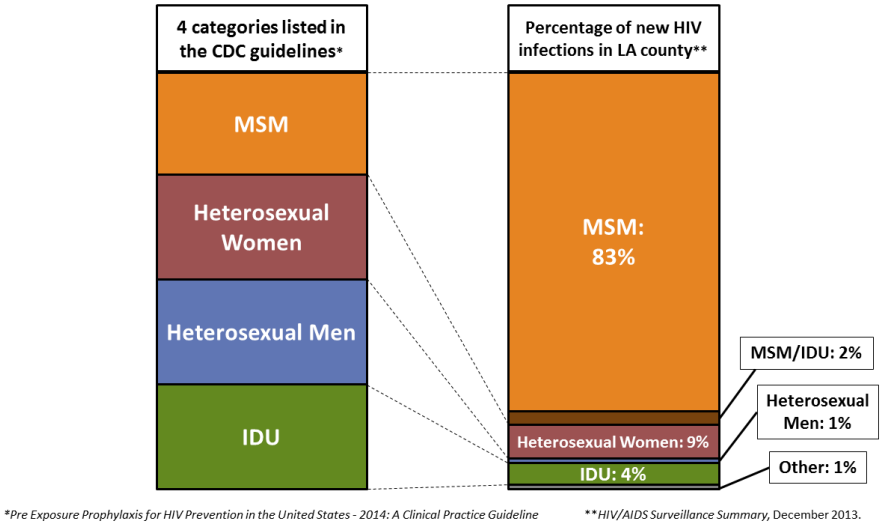
Effective delivery of PEP and PrEP goes beyond the provision of antiretroviral medication. It includes a comprehensive prevention package for at-risk HIV-negative individuals that will not only increase the likelihood of individuals staying HIV-negative but also result in better engagement in regular preventive healthcare services, linkage to appropriate social services, and better health outcomes. Studies and experience with PEP provision have demonstrated the need for an accompanying comprehensive HIV prevention package that includes the following:

- Medical visits- six or more times a year
- Anti-retroviral medications
- Lab tests (HIV, STD, Hepatitis, kidney function)
- STD treatment and recommended vaccinations (Hepatitis, Meningococcal)
- Care coordination and referrals to support services (e.g., mental health, substance abuse)
- Medication adherence support and education
- Risk reduction counseling

Who Can Benefit from PrEP?

In May 2014, the Centers for Disease Control and Prevention (CDC) issued its first PrEP guidance that recommended consideration of PrEP in certain high risk groups. The LAC DPH has cross-referenced this guidance to the epidemiology of new cases of HIV in LAC (Figure 1). Good candidates for PrEP include partners of HIV-positive persons, men who have sex with men (MSM) with a recent STD, women with certain risk factors, and injection drug users who share equipment.

Figure 1. CDC Guidelines vs. Percentage of New HIV Cases in LA County



*Pre Exposure Prophylaxis for HIV Prevention in the United States - 2014: A Clinical Practice Guideline

**HIV/AIDS Surveillance Summary, December 2013.

Current State of PEP and PrEP in LA County

Due to the time sensitive nature of PEP, patients seeking it must often turn to an emergency room or urgent care providers, whose knowledge or experience with non-occupational PEP may be limited. To enhance access to PEP for persons with non-occupational exposures and to provide more comprehensive prevention services to these high-risk individuals, DPH currently funds a PEP service at the Los Angeles LGBT Center. In 2014, 1118 clients accessed this service.

Since the FDA approval of Truvada for PrEP use in 2012, interest, acceptance, and use of PrEP has increased in Los Angeles County (LAC). Many individuals in LAC have obtained PrEP through research studies or through their private provider, when he/she is willing to prescribe it. (PrEP services are currently not funded by DPH, although we are partners with UCLA on a local

demonstration study.) In many cases, PrEP is being delivered in a disjointed manner, with individual providers prescribing PrEP to patients without protocols or the appropriate support services to ensure optimal outcomes. In addition, several factors affect the full uptake and delivery of PrEP, limiting the potential impact of PrEP in reducing HIV incidence in LAC.

- **Many of the highest risk residents, which include gay men of color, are less likely to know about or seek PrEP.** While approximately 7% of African American men who have sex with men in LAC seroconvert to become HIV positive every year, they remain the group the least likely, among MSM, to have heard of PrEP use or express interest in taking PrEP.

- **Many LAC residents have had difficulty finding a provider who will prescribe PrEP.** Of the seven PrEP demonstration studies funded in LAC, only two are still enrolling new participants; anecdotally, many participants who desire to continue PrEP after study closure have experienced difficulty finding a provider to continue to prescribe them PrEP. While any licensed medical provider can prescribe PrEP, in reality, many lack knowledge about PrEP, lack experience and are therefore uncomfortable prescribing HIV medications, or hold biases that lead them to withhold prescriptions for PrEP. In addition, some patients and providers are uncomfortable speaking candidly with each other about sexual risk behaviors.

- **Cost for uninsured patients remains a significant barrier to PrEP.** For patients who are uninsured and whose income is <500%FPL, medications can be obtained without cost through manufacturer medication assistance programs (MAP). Use of these programs is dependent on provider willingness to pursue and complete the paperwork. The cost for other components of PrEP delivery, such as laboratory testing, medical visits, and other support services, may be placed upon the patient or remain an unreimbursed cost for the clinic.

- **High co-payments present barriers but resources are available.** While most private insurance plans cover PrEP, some patients are required to pay high co-payments that limit their ability to afford the drug. A manufacturer sponsored co-payment assistance program is available for patients with high co-payments, but access is dependent on provider and pharmacy willingness to pursue and complete the appropriate paperwork.

Cost of PrEP Service Delivery

For the above reasons, additional support with new sources of funding is needed for optimal PrEP implementation. Table 1 summarizes the projected costs of three different models of a DPH-supported PrEP service delivery program, based on historic PEP program expenditures.

Table 1. Projected Annual Costs of a DPH-funded Comprehensive PrEP Service Delivery[*]

# of Clients	Drug Cost per Client	Annual Program & Clinical (Non-drug) Cost per Client	Total Cost per Client	Total Projected Cost
DPH funds all costs of service				
250	$5,211	$3,600	$8,811	$2,202,750
500				$4,405,500
DPH funds "everything except meds"				
250	Insurance/MAP	$3,600	$3,600	$900,000
500	Insurance/MAP	$3,600	$3,600	$1,800,000
DPH funds "everything except meds and medical visits"[¥]				
250	Insurance/MAP	$1,800	$1,800	$450,000
500	Insurance/MAP	$1,800	$1,800	$900,000

[*] Assumes high capacity site, use of 340B drug pricing, and patients needing six medical visits per year.
[¥] Assumes medical visits, laboratory expenses, vaccinations, and STD treatment covered by insurance.

It is important to note that Ryan White Program funds cannot be used to fund PEP and PrEP. Alternatively, CDC HIV prevention funds can be used for some PEP and PrEP-related activities such as administrative costs, risk reduction counseling, and HIV and STD screening services. Any drug costs for an LAC-supported PrEP program would need to be funded with net County funds.

Table 2 describes a potential reimbursement structure based on the third model, where drug costs are covered by either health insurance or MAPs, and health insurance is fully leveraged for reimbursement for medical care for insured clients. DPH would fund the cost of medical care for uninsured or underinsured patients and salary support for a PrEP coordinator to ensure appropriate screening, intake, assessment, and linkage to prevention, benefits, and other social services.

Table 2. PrEP Service Elements and Potential Reimbursement under County Program

PrEP Service Element	Staff Responsible	Eligible Clients
Entry into PrEP		
Risk behavior screening	PrEP Coordinator	Any insurance status
Risk reduction counseling including PrEP education	PrEP Coordinator	Any insurance status
Intake and Assessment	PrEP Coordinator	Any insurance status
Benefits navigation	PrEP Coordinator	Any insurance status
PrEP Intake and Medical Visit		
Medical Visit- Initial - HIV/STD/Hepatitis testing - Safety labs/medical clearance	Medical Provider	Uninsured/underinsured only
STD treatment	Medical Provider	Uninsured/underinsured only
Vaccinations	Medical Provider	Uninsured/underinsured only
PrEP Medications - Medication Assistance Program - Prior authorization forms	Medical Provider/Other	Any insurance status
Complementary services at visit - PrEP education - Risk screening, substance use, mental health needs - Targeted adherence counseling	PrEP Coordinator	Any insurance status
Follow-up PrEP Services		
Medical Visit- Follow-up (6+ total) - HIV/STD/Hepatitis testing - STD treatment - Safety labs - Adherence counseling - Discuss desire to continue PrEP	Medical Provider	Uninsured/underinsured only
Other PrEP follow-up between visits - Coordinate monthly refills for MAP patients	PrEP Coordinator	Any insurance status
Program Administration		
Program oversight and reporting	Administrator	Any insurance status

DPH HIV Biomedical Prevention Program

DPH fully supports and endorses the use of biomedical interventions as critical components of Los Angeles County's overall HIV prevention strategy. DPH is part of a diverse set of stakeholders working to ensure that we have a responsive local system for providing HIV biomedical prevention services. DPH does not currently fund PrEP. However, DPH, in partnership with the Commission on HIV and community partners, is working to support the targeted use of PrEP by individuals in LA County at high risk of acquiring HIV. DPH also recognizes that the County cannot be the sole solution to a robust, County-wide PEP and PrEP interventions and that increasing provider capacity in primary care and other settings must be part of a wider HIV biomedical prevention implementation strategy.

Main Goals of the DPH HIV Biomedical Prevention Program

- **Increase consumer knowledge about HIV biomedical prevention**
    - PrEP training for CBO provider partners who serve high risk individuals to ensure that appropriate patients are informed about PrEP and know where to access it.
    - Targeted social marketing campaign with posters, postcards, pamphlets
        - Disseminate to healthcare providers, HIV prevention providers, DPH field staff
- **Ensure access to quality comprehensive HIV biomedical prevention services in LAC**
    - Formalize LAC referral network/directory of providers already offering PrEP and PEP
    - Increase PrEP provider capacity through education and outreach
        - Explore the use of "Public Health Detailing" to increase PrEP and PEP service capacity within primary care/MSM sexual health care centers. Involves a data-driven approach to target providers serving highest risk groups, sending detailers to do a 5-10 minute presentation to providers, and one follow-up visit to provide additional support and evaluate whether practice pattern has changed.
        - Identify providers who are interested in offering PrEP but who need additional training and provide training and technical assistance to them. Work with local AID Education and Prevention Training Centers to provide PrEP trainings for healthcare partners on best ways to operationalize PrEP service delivery.
    - Deploy safety-net HIV biomedical prevention services
        - DPH will implement PrEP in public health STD clinics in high impact areas by summer 2015. Goal is to provide PrEP services and medications at no-cost but with goal of transitioning patients to primary care provider for PrEP and ongoing medical care by 12 months.
        - DHS is exploring ways to continue to provide PrEP through clinics currently offering it as part of a research study or other appropriate clinics.
        - DPH will explore procurement options for additional PEP and PrEP delivery sites to be operated by medical clinics of local community based organizations through a solicitations process. Services will be deployed in areas of the County based on local epidemiology and need.

PEP Update

Table 3 summarizes cost data from DPH's PEP program. Given the time-sensitive nature of PEP, which must be started within 72 hours of exposure, there is a stronger role for DPH to support a safety net PEP program to ensure timely access to PEP medications and medical services. The first two rows summarize the costs of providing the comprehensive PEP service, including drug costs, at a high volume setting based on the current and potential increased enrollment based on the current LA County PEP protocol, which has relied on a two drug regimen. The second set of rows describes the costs associated with providing a comprehensive PEP service, including a three drug regimen consistent with anticipated revisions to the CDC non-occupational PEP guidelines.

Table 3. Current and Future Costs of Comprehensive PEP Service Delivery*

	# of Clients	Drug Cost per Client	Program & Clinical (Non-drug) Cost per Client	Total Cost per Client	Total Projected Cost
Current Two-drug Regimen for 28 Days					
Current Enrollment	794	$434.51	$600	$1,034.51	$821,401
Increase Enrollment by 25%	993				$1,027,268
Future Three-drug Regimen for 28 Days					
Current Enrollment	794	$1,035.27	$600	$1,635.27	$1,298,404
Increase Enrollment by 25%	993				$1,623,823

*Based on 2013-14 contract year data and assume high capacity site and use of 340B pricing.