Preparing for HIV Pre-Exposure Prophylaxis
Lessons Learned from Post-Exposure Prophylaxis

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Introduction

Although RCTs have not been conducted to establish the efficacy of non-occupational post-exposure prophylaxis (nPEP), studies[1,2] in non-human primates have demonstrated protection with nPEP; observational data[3] support the efficacy of PEP for occupational exposures; and several studies[4–6] have established the feasibility of nPEP delivery in various settings. Based on these data, the CDC and public health and professional organizations in many other western countries have issued recommendations regarding nPEP use.[7–10] The efficacy of pre-exposure prophylaxis (PrEP) for the prevention of HIV infection has now been demonstrated in several RCTs,[11–13] the CDC has issued guidance on PrEP use,[14] and demonstration projects are being planned to evaluate PrEP implementation in real-world settings. Lessons learned from nPEP programs could greatly inform these demonstration projects and the implementation of PrEP.

San Francisco City Clinic, the only municipal sexually transmitted disease (STD) clinic in San Francisco, has maintained an nPEP program since 2002. This decade of experience provides a unique perspective on implementation of biomedical HIV prevention interventions. Here, the authors' programmatic experience with nPEP is highlighted, in order to consider lessons learned from its delivery in a public health clinic. Consideration is given in this paper to five key areas that influence the successful delivery of nPEP (Table 1): (1) knowledge of the intervention; (2) risk perception, risk evaluation, and the decision to initiate prophylaxis; (3) adherence; (4) risk compensation; and (5) access. Also highlighted are some of the key differences between nPEP and PrEP that underscore the distinct challenges of PrEP implementation (Table 2).

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Description of San Francisco City Clinic Program

San Francisco City Clinic provides nPEP services to approximately 300 clients per year. nPEP is offered on a drop-in basis during clinic hours to HIV-uninfected patients who report having a high-risk exposure within the preceding 72 hours to a person known to be HIV-infected or at high risk for HIV infection. High-risk exposures include unprotected anal or vaginal intercourse, sharing needles, blood-to-blood contact, and other needle stick exposures. Patients either present to clinic requesting nPEP or are identified by the clinician as an nPEP candidate during the standardized behavioral risk assessment during a clinic visit. Final eligibility for nPEP is determined by the clinician working together with the patient.

Patients deemed eligible for nPEP are referred to a counselor for HIV testing and client-centered risk reduction counseling before receiving medication. Counselors meet with patients and discuss how to obtain and use the medication, possible side effects, and adherence tools. They also provide written materials to reinforce these messages.

Eligible patients who elect to initiate nPEP are provided with a free 2-day course of co-formulated emtricitabine plus tenofovir while in the clinic and are given a written prescription for the remainder of a 28-day course of this regimen. Uninsured patients are referred to public medication assistance programs, based on income and residency requirements. Patients are contacted by counseling staff 2–3 days after their clinic visit to assess clinical problems, prescription fulfillment, and medication adherence. Approximately 2–3 weeks after completion of the 28-day course, the patient is advised to return for an HIV antibody and RNA test and assessment of regimen completion.

Lessons Learned and Implications for Pre-Exposure Prophylaxis

Knowledge and Uptake

Although the CDC issued recommendations on nPEP for HIV prevention in 2005, uptake has been modest. Lack of knowledge about nPEP among both potential users and providers and limited availability in clinical settings have

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Table 1. Key facilitators of nPEP implementation

Facilitator	Interventions to facilitate and support
Knowledge	
Awareness of nPEP as prevention tool among those who may benefit	Community engagement, advocacy, education, and marketing for MSM; victims of sexual assault; and individuals with sex partners who are HIV infected or at high risk for HIV
Awareness of nPEP as prevention tool among potential prescribers	Advocacy and education for clinicians, especially ER providers, primary care and urgent care providers, and clinicians in STD clinics
Knowledge of where and how to access nPEP	Community engagement, advocacy, education, and marketing
Risk perception, risk evaluation, and the decision to initiate prophylaxis	
Risk perception by exposed individual	Education of potential nPEP candidates about risk factors for HIV transmission
Individual decision to initiate nPEP	Counseling interventions to guide individual choice to initiate nPEP
Risk assessment by healthcare provider	Provider education to improve patient–provider communication around sexual health and sexual history-taking; development and dissemination of HIV-risk calculation tools for use in clinical settings
Adherence	
Adhering to nPEP and managing side effects	Adherence support
Risk compensation and prevention synergy	
Sexual risk behaviors and use of other HIV-prevention strategies	Risk-reduction counseling, condom provision
Access	
Availability of nPEP	Identification and support of sites of nPEP delivery (e.g., ER, urgent care, STD clinics); ensuring adequate funding for nPEP program—safety net, third-party payers, drug manufacturers' patient-assistance programs
nPEP delivery	Onsite HIV testing and counseling; prescription of nPEP
Obtaining nPEP	Reducing pharmacy barriers

ER, emergency room; MSM, men who have sex with men; nPEP, non-occupational post-exposure prophylaxis; STD, sexually transmitted diseases

contributed to this underutilization.[17–20] Given the time-sensitive nature of nPEP initiation, a potential nPEP user must have pre-existing knowledge of when and where to access nPEP. Education and advocacy work of gay-community organizations have successfully increased awareness and prevalence of nPEP use in some settings.[21] Developing promotional and educational messages about PrEP for both users and providers should be a focus of the PrEP implementation science agenda.

Risk Perception, Risk Assessment, and the Decision to Initiate Non-Occupational Post-Exposure Prophylaxis

The authors' experience in San Francisco has illustrated that the decision to initiate nPEP is highly personalized and unique for each individual and each encounter. Perceived risk of HIV infection varies from person to person.[22–25] For example, the authors found that some patients do not consider unprotected insertive anal intercourse to be high risk and do not seek nPEP for such encounters. Studies also have shown that some men who have sex with men (MSM) do not perceive substantial HIV exposures as posing enough risk to trigger nPEP, particularly if the exposure involves a steady partner.[24] In a study of nPEP in Brazil, ten HIV seroconversions occurred among 200 MSM who chose to not start nPEP because they underestimated the risk of their exposure.[24]

On the other hand, some patients overestimate their risk for HIV infection. In the authors' experience at San Francisco City Clinic, approximately one third of patients who request nPEP have not had an exposure that meets risk criteria to warrant the intervention. Of 608 unique patients who requested nPEP at San Francisco City Clinic between 2007 and 2009, a total of 407 (67%) received nPEP. In most instances in which nPEP was requested but not prescribed, the patient reported a sexual exposure not considered to be high enough risk to warrant nPEP, such as unprotected oral sex or unprotected vaginal sex

Table 2. Selected differences between nPEP and PrEP

nPEP	PrEP
Evidence base	
Animal studies, case–control studies, feasibility studies	Animal studies, RCTs
Recommended medication	
A variety of anti-retrovirals have been studied. Two- or three-drug regimen recommended depending on setting[7,15,16]	Co-formulated emtricitabine/tenofovir, other medications are being studied
Frequency of intervention	
Episodic	Daily (only currently proven regimen)
Duration of intervention	
28 days	Ongoing during patterns of risk
Precipitating event	
Single high-risk exposure	Pattern of ongoing risk behavior
Lab monitoring	
HIV test at baseline, baseline labs (creatinine and/or LFTs) depending on the nPEP regimen used	Baseline HIV test, HBsAg and creatinine, quarterly creatinine and HIV testing
Follow-up care	
1-month follow-up for repeat HIV testing and counseling	Quarterly visits for side-effect assessment, rapid HIV testing, kidney function monitoring, adherence and risk-reduction counseling
Requirements for site of delivery	
Onsite rapid HIV testing; HIV risk-reduction counseling; prescribing provider	Onsite rapid HIV testing; HIV risk-reduction counseling; prescribing provider; adherence counseling; phlebotomy; lab monitoring; capacity for continuity care with patient on PrEP

HBsAg, hepatitis B surface antigen; LFTs, liver function tests; nPEP, non-occupational post-exposure prophylaxis; PrEP, pre-exposure prophylaxis

with a heterosexual partner at low risk for HIV infection (SEC, unpublished observations, 2012). Whether the "worried well" or those at high risk for HIV infection will seek PrEP is unclear and will be addressed in PrEP demonstration projects.

Just as patients differ in their evaluation of risk, providers may differ in the counseling messages they deliver around nPEP and the way in which they "frame" a recommendation for or against nPEP. Clinical data on HIV transmission risk from patients with an undetectable viral load have further complicated risk assessment and guidance around nPEP.[8,26] In San Francisco, whether clinicians recommend nPEP and whether patients choose to use nPEP for unprotected "high risk" sexual acts with sex partners known to be HIV-infected but receiving anti-retroviral therapy varies from clinician to clinician and patient to patient.

Deciding whether to initiate PrEP will likely be an even more nuanced and complex decision for patients and providers than decisions regarding nPEP. Rather than simply considering a single encounter, PrEP risk assessment should include patterns of behavior such as frequency of high-risk encounters, substance use, and HIV prevalence in the patient's sexual network. In a recent Internet survey by Krakower et al.,[19] less than half of MSM had discussed HIV prevention strategies with their provider, suggesting the importance of provider education and sensitivity training around discussing these topics. Simple screening tools for use during the clinical encounter may help providers assess whether nPEP or PrEP are appropriate for individual patients, and developing these tools should be a goal of implementation research.

Retention and Adherence

Several studies have reported high levels of loss to follow-up or failure to complete a full course of nPEP.[27–29] This may be due to multiple factors, including a changing self-perception of HIV risk.[30] Side effects from the nPEP medications frequently lead to nPEP discontinuation. The tolerability and simplicity of the nPEP regimen is associated with adherence.[15,16] One RCT suggested that an intensive adherence-counseling intervention may im-

prove nPEP adherence.[28] San Francisco City Clinic counseling staff routinely "check in" with patients shortly after they initiate nPEP to assess side effects and adherence, but no data are available on whether this intervention is associated with improved adherence.

Ensuring high levels of adherence to PrEP may be even more difficult. nPEP is an acute and short-term intervention, whereas PrEP requires ongoing participation. Adherence to PrEP in the iPrEx study varied by geographic region but was low overall, with drug detected in less than half of the blood samples from study participants in the active arm.[11,31] Poor adherence in the FEM-PrEP study (a clinical trial led by Family Health International to assess the effectiveness and safety of Truvada® in preventing HIV acquisition in women) likely contributed to premature study discontinuation because of futility.[32] Although HIV resistance was not seen among participants who seroconverted during the iPrEx trial,[11,33] the use of PrEP sporadically could lead to individuals becoming infected and subsequently developing HIV resistance, particularly in the setting of less-frequent HIV testing.

Identifying barriers to adherence and designing interventions to assess and support adherence clearly will be essential for successful PrEP implementation. Addressing medication-related obstacles to adherence is also important. Although co-formulated emtricitabine/tenofovir generally is well tolerated, it can cause nausea and other gastrointestinal side effects, particularly during PrEP initiation.[11] Patient education and anticipatory guidance around potential side effects and strategies to mitigate symptoms may be helpful in improving PrEP adherence.[34]

Risk Compensation

Researchers, clinicians, and community members have raised concerns that PrEP could lead to an increase in high-risk behavior because of a reduced perception of HIV risk.[34,35] This process, known as risk compensation, also has been raised as a possible consequence of nPEP availability and use.[36–38] Although some nPEP users continue to have high-risk sexual encounters after a course of nPEP, there are no data to suggest that the availability or use of nPEP leads to an *increase* in prevalence of high-risk sex.[36,39] In an nPEP feasibility study in San Francisco that included five sessions of risk-reduction counseling, there was a significant reduction in the overall practice of high-risk acts in the year following nPEP use. In an nPEP cohort in Australia, there was no significant increase or decrease in HIV risk behavior after nPEP use.[40]

Although nPEP use may not be associated with an increase in risk behaviors, a continuation of sexual practices that led to an initial nPEP course puts an nPEP user at ongoing risk for HIV infection. A study of MSM nPEP users in Amsterdam found that MSM who were prescribed nPEP had an HIV incidence prevalence 4.8 times that of MSM participating in the Amsterdam Cohort Studies (IRR=4.8; 95% CI=2.0, 11.5).[41] Likewise, in an Australian cohort, MSM who had received nPEP had a significantly higher rate of HIV seroconversion (HR=2.67, 95% CI=1.4, 5.1) compared with those who had not used nPEP.[40]

Repeat nPEP use is not uncommon. Among 355 MSM nPEP users in Amsterdam, 10% received more than one nPEP prescription over a 9-year period.[41] In the authors' program in San Francisco, 38 of 407 (9%) patients received nPEP more than once between 2007 and 2009 (San Francisco City Clinic, unpublished data). These data suggest that although nPEP use is not in and of itself associated with risk compensation, nPEP users are at high risk for HIV infection and need additional HIV prevention strategies. nPEP users with ongoing high-risk behaviors and repeat nPEP users may be particularly good candidates for PrEP.

Several studies have asked MSM to predict their sexual risk practices in the hypothetic context of PrEP use.[42,43] Of 124 substance-using MSM in New York City who reported that they would be likely to use PrEP if it were at least 80% effective, 44 (35.5%) reported that they would be likely to decrease their condom use while on PrEP.[44] In an Internet survey conducted in 2010 of HIV-uninfected MSM recruited from social-networking sites, only 7% of 1155 respondents reported that they would decrease their condom use while on PrEP, knowing that PrEP is 44% effective.[43] Participants who reported difficulty in communicating about safer sex, greater arousal-related barriers to condom use or those whose risk perception directly affected condom use were more likely to predict that their condom-use practices would decrease if they took PrEP.[42,44] Whether sexual risk practices will change in the context of ongoing open-label PrEP use is an important question that will be addressed in forthcoming PrEP demonstration projects.

Access to Non-Occupational Post-Exposure Prophylaxis

In San Francisco, the primary public sites where nPEP is offered are San Francisco City Clinic and San Francisco General Hospital urgent care and emergency room. Some other hospitals and primary care providers in San Francisco offer nPEP on a case-by-case basis. nPEP availability in other jurisdictions in California is also limited. For instance, in Los Angeles County, only 17 (14.5%) of 117 randomly sampled healthcare venues offered nPEP, and only ten sites (8.5%) offered nPEP to uninsured patients.[20]

The cost of nPEP also affects access. Currently, nPEP is covered for uninsured populations in San Francisco

through a sliding-scale public assistance program. Most health insurance covers nPEP, and patient-assistance programs can help with the cost of expensive copayments. Even with insurance coverage or public assistance for nPEP, pharmacy-level barriers can pose challenges to its initiation. Uninsured patients in San Francisco must take a prescription to the public hospital's outpatient pharmacy and complete the necessary paperwork to receive nPEP. These steps add additional layers during which a patient may "fall through the cracks" and fail to initiate their nPEP regimen. Insured patients may not be able to afford expensive copayments, or may be concerned about being identified as being high-risk, which potentially could affect their insurance premiums.

One of the biggest challenges for the successful implementation of PrEP will be identifying who will pay for what may be years of antiretrovirals for high-risk patients. Although some patients may be able to access PrEP through private insurance, and although insurance may be more available through the affordable care act, some form of public assistance will be necessary to ensure that there is equitable access to PrEP for communities most at risk for HIV.

Conclusion

Pre-exposure prophylaxis is an emerging HIV-prevention strategy for MSM and potentially other populations at risk for HIV acquisition. To realize an individual and public health benefit, PrEP must make its way from the research arena into clinical and community settings. Lack of knowledge of the intervention, poor adherence to a full 28-day regimen, and lack of widespread availability have limited the individual and public health benefit of nPEP. For PrEP to be effective, ensuring that individuals at high risk for HIV infection and their healthcare providers know about PrEP will be important. Finding the optimal sites for delivery for PrEP and providing simple tools to support risk assessment, adherence, and risk-reduction counseling also will be critical. The authors anticipate that the NIH-funded PrEP demonstration project currently underway (NCT no. 01632995), and other PrEP demonstration projects around the country, will help to inform best practices in PrEP delivery.

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