Same Day (Rapid) Start for HIV PrEP

This is a PDF version of the following document:
Module 2: HIV PrEP In-Depth Topics
Lesson 4: Same Day (Rapid) Start for HIV PrEP

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Background

In the United States, HIV transmission continues to occur at a significant rate and HIV preexposure prophylaxis (PrEP) remains underutilized. Multiple barriers exist along the HIV PrEP care continuum and data indicate that many individuals fall out of care before ever filling their prescription.[1,2,3,4] Indeed, patients have cited a need for multiple clinic visits as a major barrier to initiating HIV PrEP.[5,6] Rapid initiation of HIV PrEP has to potential to decrease barriers to HIV PrEP uptake and thereby reduces the number of people who drop out of the HIV PrEP care cascade even before filling the first HIV PrEP prescription.[5,6] Furthermore, rapidly starting HIV PrEP in persons at risk of acquiring HIV minimizes their time at risk. The following discussion will primarily focus on rapid initiation of the oral HIV PrEP regimens tenofovir DF-emtricitabine (TDF-FTC) and tenofovir alafenamide-emtricitabine (TAF-FTC). The discussion will include a more limited discussion of rapid start with long-acting cabotegravir (CAB-LA) and lenacapavir subcutaneous injection (LEN-SQ), since there is less evidence for same day HIV PrEP with injectable medications and more logistical and implementation challenges.

Definitions for Same-Day and Standard HIV PrEP

The following definitions are important to recognize when discussing same-day or rapid HIV PrEP initiation.

- **Standard HIV PrEP**: When a person is evaluated and an HIV PrEP prescription is provided after laboratory results have returned, typically within 7 days of the initial visit.
- **Same-day HIV PrEP Prescription**: When HIV PrEP is prescribed the same day of the initial visit, but the person does not start HIV PrEP medications until the initial HIV test results have returned.
- **Same-day HIV PrEP Start**: When HIV PrEP is prescribed and initiated the same day as the initial visit, either by (1) picking up the medication at a pharmacy or through a clinic-dispensed starter pack for oral HIV PrEP; (2) administering the oral loading dose of lenacapavir and the first injection of LEN-SQ; or (3) administering the first dose of intramuscular CAB-LA. Often, same-day PrEP starts are done after rapid, blood-based, point-of-care HIV testing is documented to be negative and laboratory-based blood testing for HIV is drawn.

The following figure summarizes timelines related to standard HIV PrEP, same-day HIV PrEP prescription, and same-day HIV PrEP start (Figure 1).

Experience for Same-Day Oral HIV PrEP

Several descriptive studies regarding the implementation and outcomes of same-day HIV PrEP are summarized below. At this time, available data related to same-day (rapid) HIV PrEP pertain to oral HIV PrEP, but clinical trials and experience of same-day (rapid) initiation with LEN-SQ and/or CAB-LA may occur in the future.

New York City Sexual Health Clinic

In an observational study, a New York City sexual health clinic evaluated 1,437 persons for immediate HIV PrEP, in which TDF-FTC was given on the same day as the visit after a negative rapid HIV test, but before results of other recommended lab testing returned (Figure 2).[7] Rapid HIV PrEP was not started if any of the following were present: symptoms consistent with acute HIV, history of kidney disease, or history of active hepatitis B virus (HBV) infection.[7] From January 2017 to June 2018, among persons evaluated, 97% qualified for immediate HIV PrEP and 3% for standard (delayed) HIV PrEP.[7] Individuals were promptly reevaluated if laboratory results indicated HIV infection, a glomerular filtration rate less than 60 mL/min, and/or a positive hepatitis B surface antigen (HBsAg) test. Immediate HIV PrEP was discontinued within 10 days in only 4 individuals due to a contraindication: 2 had a positive HIV nucleic acid test (NAT) and 2 had an eGFR less than 60 mL/min).[7] Six individuals had a positive HBsAg test and continued HIV PrEP.[7] Among the 50 individuals who received standard HIV PrEP, most did not start HIV PrEP within 60 days of the initial visit.[7]

Denver Metro Health (Sexual Health) Clinic

At the largest sexual health clinic in metropolitan Denver, Colorado, 100 individuals 18 years of age or older who met CDC indications for HIV PrEP were enrolled in a pilot program to receive a 30-day starter pack of TDF-FTC.[8] Individuals were excluded if any of the following were present: signs or symptoms suggestive of acute HIV, active indication for HIV postexposure prophylaxis (PEP), history of renal dysfunction, chronic HBV, or current pregnancy.[8] Prior to receipt of TDF-FTC, individuals were evaluated by a clinician, received screening with a point-of-care (POC) HIV-1/2 antigen-antibody test, had a blood draw (for creatinine and HBsAg), and underwent a urine pregnancy test (for women).[8] Of the 100 participants in the study, 78% completed a follow-up visit 1 month after the initial visit, and 57% completed two follow-up visits within 180 days of enrollment (Figure 3).[8] Following the pilot program, a permanent program was implemented in which a prescription for HIV PrEP is given, instead of a starter pack, to be filled on the day of the visit.[6] In the pilot and permanent program, there were no participants who needed to stop HIV PrEP due to laboratory abnormalities, and no cases of acute HIV were diagnosed based on laboratory studies obtained at the time of HIV PrEP initiation.[6]

Washington University Adult Infectious Diseases Clinic

A same-day HIV PrEP program was launched at an adult infectious diseases clinic at Washington University in St. Louis, Missouri, in 2014.[6] The protocol included clinical screening, a rapid HIV antibody test, and a blood draw, with the results reported within 1 day. Participants received a 30-day prescription of oral HIV PrEP with one refill, and follow-up appointments at 1 and 3 months were scheduled. If more than 7 days elapsed between initial HIV testing and HIV PrEP initiation, a repeat HIV test was required prior to HIV PrEP medication dispensation.[6] Between 2014 and 2018, a total of 334 individuals received a prescription for HIV PrEP, 93% of whom received a same-day prescription, with the intent that the individual would start taking HIV PrEP immediately.[6] Among those who received a same-day prescription, 97% started HIV PrEP, and 78% continued HIV PrEP for at least 3 months.[6] In the same-day HIV PrEP cohort, there were no HIV PrEP discontinuations due to baseline laboratory abnormalities (e.g., positive baseline HIV test or abnormal baseline creatinine). Similarly, there were no positive HIV tests during the first 90 days of follow-up, suggesting that HIV PrEP was not initiated in the setting of an existing, undiagnosed HIV infection.

Howard Brown Health FQHC in Chicago

Investigators from Howard Brown Health, a Federally Qualified Health Center (FQHC) network of 6 sites in Chicago, retrospectively reviewed outcomes from their HIV PrEP programs.[9] All participants in the same-day HIV PrEP program received standard-of-care baseline laboratory testing and were given a 30-day prescription of TDF-FTC, with a plan for re-engagement within 30 days.[6] The clinic partnered with local pharmacies to have a “bottle-in-hand” system with a starter-pack option, and patients took the first PrEP dose in the presence of clinic staff.[6] Between 2012 and 2017, an average of 62% of HIV PrEP prescriptions were prescribed on day 0, with the proportion of same-day prescriptions increasing annually, from 0% in 2012 to 72% in 2017.[6] In this program, as of 2017, there was only one documented case in which a person with an unknown diagnosis of HIV was prescribed HIV PrEP, and that individual was ultimately switched to a full antiretroviral regimen when the diagnosis of HIV was made, without any evidence of emergent HIV drug resistance.[6]

Pharmacist-Led Same-Day HIV PrEP in Jackson, MS

In Mississippi, a pharmacist-led, same-day HIV PrEP program successfully provided timely HIV PrEP.[10] Between November 2018 and May 2019, individuals with a negative rapid HIV-1/2 antigen-antibody test who met the criteria to start HIV PrEP were referred to an on-site clinical pharmacist, who evaluated the patients for medical contraindications but did not obtain baseline labs.[10] On the same day, a 60-day HIV PrEP prescription was sent to the patient’s preferred pharmacy, and a follow-up appointment was made to see a clinician and to obtain baseline laboratory studies (within 6 weeks of receiving the HIV PrEP prescription).[10] All 69 individuals evaluated received an HIV PrEP prescription and 77% (53 of 79) filled the prescription; 87% of the prescriptions were filled within 1 week. Among individuals who filled the prescription, only 43% (23 of 53) returned for follow-up, despite the pharmacist contacting them weekly for 1 month if they did not pick up the prescription or attend the clinical appointment (Figure 4).[10] Overall, among all individuals who were referred to a pharmacist for same-day HIV PrEP, only 33% (23 of 69) attended a clinical follow-up appointment within 6 weeks.[10] Prescriptions were not refilled if patients did not attend their follow-up appointment.[10]

Navigator-Led Model for HIV PrEP – Public Health – Seattle & King County

Between October 2014 and December 2019, a total of 1,387 patients attended an initial HIV PrEP visit at Public Health – Seattle & King County’s (PHSKC) Sexual Health Clinic.[11] At the HIV PrEP initiation visit, all patients were tested for HIV with a rapid HIV-1/2 antibody test (*INSTI/BioLytical Laboratories, Richmond, BC*), and a phlebotomy sample was obtained to test for syphilis, creatinine, HBV, and HIV (using a laboratory-based HIV-1/2 antigen-antibody immunoassay).[11] Patients who tested negative for HIV via the rapid HIV-1/2 antibody test and did not have symptoms of acute HIV were given a 30-day prescription for oral HIV PrEP with one refill to be filled at the pharmacy of their choosing.[11] Disease intervention specialists served as HIV PrEP coordinators and navigators and verified that patients filled their HIV PrEP prescription within 14 days; if the HIV PrEP prescription was not filled in this time period, patients were asked to return for follow-up testing before HIV PrEP initiation. Among all patients who attended an initial HIV PrEP visit between October 2014 and December 2019, initiation of HIV PrEP occurred in 86% (1,190 of 1,387).[11] In the subset who initiated HIV PrEP, 41% (488 of 1,190) discontinued HIV PrEP by the end of the analysis period.[11]

Providing Same-Day Start with HIV PrEP

Settings Amenable to Same-day Oral HIV PrEP

Any setting with the following three capabilities can implement same-day oral HIV PrEP: (1) access to point-of-care HIV testing (ideally with an HIV-1/2 antigen-antibody immunoassay); (2) the ability to order creatinine and lab-based HIV testing; and (3) the capacity to provide prescriptions and appropriate follow-up and/or referral.[12] Examples include primary care clinics or community health centers, sexual health clinics, pharmacies, public health clinics, and syringe service programs. In addition, any person with an indication for HIV PrEP who wishes to receive HIV PrEP and has a recent (within 1 week) documented baseline negative HIV test can be a candidate for same-day HIV PrEP. More specifically, any facility offering same-day HIV PrEP services should have the capacity to do the following:[12]

- Identify persons for HIV PrEP candidacy.
- Perform point-of-care HIV testing, ideally with a blood-based HIV-1/2 antigen-antibody test. If same-day results can be obtained with a laboratory blood-based HIV-1/2 antigen-antibody test, this is preferable to a point-of-care HIV test. Oral fluid HIV testing should not be used to determine HIV status when starting HIV PrEP.
- Draw blood for laboratory-based serum creatinine, HIV testing, and hepatitis B virus (HBV) serologic studies, if same-day testing for these labs is not available. If point-of-care serum creatinine testing is available, this may be done in place of lab-based serum creatinine testing.
- Clinicians should be available to dispense or prescribe oral HIV PrEP medications.
- Ideally, have the ability to screen for sexually transmitted infections at the initial visit, but this is not a requirement for starting same-day HIV PrEP.
- Provide assistance for navigating payment options, insurance, or financial assistance programs.
- Schedule longitudinal follow-up or provide appropriate referral to persons receiving HIV PrEP.

Exclusions for Same-Day Oral HIV PrEP

Same-day oral HIV PrEP should not be considered if the clinic does not have the capacity to provide same-day oral HIV PrEP services as outlined above. In addition, same-day oral HIV PrEP should not be administered in the following situations:[6]

- Persons with a preliminary or confirmed diagnosis of HIV
- Persons with signs or symptoms consistent with acute HIV
- No contact information for the person starting HIV PrEP or inability to follow up for test results (in the event that HIV PrEP discontinuation was recommended based on the laboratory results)
- Inability to have blood work done on the day of the visit (unless a negative laboratory HIV test and normal creatinine were obtained within the previous week)
- Persons who express ambivalence about starting HIV PrEP
- Persons with a history of renal disease (conditions that predispose the patient to renal disease may be considered on a case-by-case basis)
- Persons who do not have insurance, drug coverage, or another means to pay when picking up their HIV PrEP prescription

In addition, same-day oral HIV PrEP may not be appropriate for:

- Persons for whom nonoccupational HIV PEP is indicated, including those with condomless sex with a person of unknown HIV status (a person with HIV who has a detectable or unknown viral load), or receptive syringe and/or injection works sharing in the prior 72 hours
- Persons who may be more difficult to contact for follow-up discussion of test results
- Persons with anticipated major problems with HIV PrEP adherence and/or follow-up

Baseline Laboratory Studies

Required Tests Prior to Prescribing Same-Day Oral HIV PrEP

The following testing must be obtained and reviewed prior to prescribing same-day HIV PrEP:

- Rapid HIV test (ideally a blood-based HIV-1/2 antigen-antibody test)
    - A negative point-of-care rapid HIV test allows for same-day HIV PrEP prescription but must be followed by a same-day order for a laboratory-based HIV-1/2 antigen-antibody immunoassay.
    - Oral fluid HIV testing should not be used as the rapid HIV test in this context.

Required Laboratory Tests to be Drawn on Same Day as Prescribing Oral HIV PrEP

Because HIV PrEP will be prescribed prior to obtaining the required laboratory test results, a plan must be in place to contact the patient or have them return within 1 week for test results. The following laboratory testing should be drawn on the day the HIV oral PrEP prescription is provided:

- Laboratory-based HIV-1/2 antigen-antibody immunoassay test: Administering HIV PrEP is contraindicated if a person has a positive HIV test.
- Serum creatinine level: The use of TDF-FTC is contraindicated with a creatinine clearance less than 60 mL/min, and TAF-FTC is contraindicated with a creatinine clearance less than 30 mL/min.
- HBV serologic studies (HBsAg, hepatitis B core antibody, and hepatitis B surface antibody): The oral HIV PrEP medications TDF, TAF, and FTC have activity against HBV. Persons taking HIV PrEP with concurrent chronic HBV should be counseled that abrupt discontinuation of oral HIV PrEP can result in an HBV flare, potentially manifesting as acute hepatitis. Individuals without active or past HBV should receive hepatitis B immunization.
- Point-of-care pregnancy test for women: Oral HIV PrEP is safe for women who are pregnant, but ascertaining whether a woman is pregnant or not is important for counseling purposes. For women who have a positive pregnancy test, shared decision-making should then be used to determine whether HIV PrEP is continued.

Medication Options for Same-Day Oral HIV PrEP

At this time, oral TDF-FTC or oral TAF-FTC are the primary options used for same-day (rapid) HIV PrEP initiation. Note that TAF-FTC is not FDA-approved for use in women to prevent HIV acquisition through receptive vaginal sex, and it is not recommended for prevention of HIV through injection drug use.

Initial Oral HIV PrEP Prescription

The quantity of HIV PrEP prescribed and whether it is prescribed the same day or soon thereafter will vary based on the clinical setting. For example, some settings may offer a same-day HIV PrEP prescription while counseling the patient to await a follow-up call regarding laboratory results before filling the prescription and initiating the HIV PrEP medication. Meanwhile, other settings may offer same-day HIV PrEP starts, meaning HIV PrEP is dispensed to the patient with the intent that the patient starts taking the HIV PrEP medication on the day of the visit. Most of the same-day HIV PrEP programs described in the literature report giving a 30-day HIV PrEP medication prescription at this initial visit, although some programs give a prescription that is longer, such as a 60- or 90-day prescription.[6] The number of refills also varies, though following a negative HIV-1/2 antigen-antibody assay for HIV, typically allowing for 2 refills on the 1-month supply. Some settings allow for 6 months of prescribed medication (5 refills on a monthly supply), balancing the need to ensure the patient has sufficient medication with the need to return for HIV and STI testing on a regular basis.

Follow-Up

Initial follow-up for patients initiating same-day HIV PrEP will vary based on the clinical setting. Many clinics will schedule short-term follow-up, either in person or via phone or video, to review baseline laboratory results. In addition, most same-day HIV PrEP clinical models described in the literature require the patient to return for a subsequent prescription within the first 4 to 6 weeks of HIV PrEP start.[6,9,10] Once an individual who has done a rapid HIV PrEP start with oral HIV PrEP and is established on HIV PrEP, follow-up should occur at 3-month intervals to repeat laboratory-based HIV and STI testing, similar to recommendations for persons who have a standard HIV PrEP start.[12] Some clinics have a model with oral HIV PrEP that has patients undergo lab testing every 3 months and clinic visits every 6 months.

Same-Day Start with Injectable HIV PrEP

For individuals who would benefit from HIV PrEP, offering same-day (rapid start) with either CAB-LA or LEN-SQ is a potential option, but often with significant logistical challenges. The consideration of rapid start with injectable HIV PrEP is most likely to arise for individuals with a high need for HIV PrEP, but who have difficulty taking oral pills as prescribed. With a rapid start of CAB-LA or LEN-SQ, it is reasonable to perform a rapid, point-of-care blood-based HIV antigen-antibody test, and if negative, obtain a blood draw for laboratory-based HIV antigen-antibody and HIV-1 RNA testing. The injectable HIV PrEP can be administered while the laboratory-based testing is pending.[13] If same-day, rapid initiation of CAB-LA or LEN-SQ is planned, the necessary criteria for starting the medication are similar to the criteria for rapid start of oral HIV PrEP, except that results from baseline renal function are not necessary for persons who will receive either of these options. Baseline tests should be drawn for HBV, hepatitis C virus (HCV), and bacterial STIs, but a rapid start with CAB-LA or LEN-SQ can proceed while results from these tests are pending.

Rapid Start with CAB-LA

If CAB-LA is given as same-day HIV PrEP, the standard dose of a single 600 mg (3 mL) intramuscular injection should be given, with a repeat dose in 1 month (or 4 weeks). Use of CAB-LA rapid start is not applicable if the plan is to administer the oral lead-in with oral cabotegravir. When planning to use CAB-LA rapid start, it is important to ensure the availability of trained staff to provide the cabotegravir intramuscular injections.

Rapid Start with LEN-SQ

If lenacapavir is given as same-day HIV PrEP, the full initiation-phase dosing of lenacapavir must be administered: day 1 lenacapavir subcutaneous injections (total dose 927 mg) and oral lenacapavir (total dose 600 mg), followed by day 2 oral lenacapavir (total dose 600 mg) (Figure 5).[13] Same-day rapid start with lenacapavir may have substantial barriers, including delays in obtaining insurance approval (due to the very high cost of this medication), difficulty accessing oral lenacapavir, necessity to carefully review all potential drug interactions that can occur with lenacapavir, and availability of trained staff who can appropriately administer the lenacapavir subcutaneous injections.

Potential Concerns with Same-Day HIV PrEP

In general, rapid HIV PrEP initiation, and more specifically same-day HIV PrEP, is advantageous in that it can decrease barriers to HIV PrEP uptake and can increase the likelihood that persons will start HIV PrEP.[5,6] Same-day HIV PrEP can also decrease the chance of acquiring HIV, as it minimizes delays in HIV PrEP initiation and promotes faster achievement of protective medication levels in serum and tissues. Nevertheless, several barriers and concerns remain when using same-day HIV PrEP.

Loss to Follow-Up

Although same-day oral HIV PrEP gives individuals faster access to HIV PrEP and minimizes the drop-off between being prescribed HIV PrEP, filling HIV PrEP prescriptions, and initiating HIV PrEP, some studies have shown that rates of follow-up after rapid HIV PrEP initiation remain low.[6,10] Further studies are needed to better understand the impact same-day HIV PrEP may have on retention in HIV PrEP care and HIV PrEP persistence, particularly when compared to standard HIV PrEP prescribing.

Lack of Resources for Rapid HIV Testing

Some practice settings may not have the capacity to perform rapid blood-based HIV testing. Unfortunately, if obtaining a rapid HIV test is not feasible, then same-day HIV PrEP should not be dispensed, unless the person had a negative laboratory HIV test within 1 week prior to HIV PrEP initiation.[6]

Abnormal Laboratory Results

Even in settings where rapid HIV testing is available, medical providers may worry that baseline laboratory results will ultimately reveal a contraindication to HIV PrEP (e.g., positive laboratory-based HIV-1/2 antigen-antibody Immunoassay, or for oral HIV PrEP, an elevated serum creatinine). These concerns are particularly pronounced when persons starting same-day HIV PrEP have unpredictable or intermittent contact information and/or are experiencing considerable social instability and thus may be hard to reach when laboratory results become available. Although the potential for abnormal baseline laboratory results should be taken into consideration prior to prescribing same-day HIV PrEP, it should also be noted that in many studies of same-day HIV PrEP, undiagnosed HIV in the setting of a negative rapid HIV test and/or abnormal baseline elevated serum creatinine levels were rare, and results of laboratory-based testing rarely changed HIV PrEP management.[6,7,9]

Payment for HIV PrEP Medications

An additional barrier is the financial cost of HIV PrEP. Depending on the patient's insurance plan, obtaining coverage for HIV PrEP can take several days (or longer) and may require considerable coordination with pharmacies, insurance companies, and/or patient assistance programs. This may present a logistical barrier to implementing same-day HIV PrEP, particularly when financial and social work support are not readily available. To circumvent this potential barrier, some locations have partnered with pharmacies to provide starter packs of oral HIV PrEP or to employ HIV PrEP navigators to assist with pharmaceutical cost assistance programs, although this may not be feasible in all locales.[9]

Summary Points

- Rapid initiation of oral HIV PrEP decreases barriers to HIV PrEP uptake and reduces the number of people who drop out of the HIV PrEP care cascade before they fill the first HIV PrEP prescription.
- Any setting with access to point-of-care HIV testing (ideally with an HIV-1/2 antigen-antibody test), as well as the capacity to provide prescriptions and appropriate follow-up and/or referral, can implement same-day oral HIV PrEP.
- To date, available data and experience using same-day HIV PrEP are primarily limited to the oral HIV PrEP regimens TDF-FTC and TAF-FTC.
- Theoretically, CAB-LA or LEN-SQ could be started as same-day, rapid HIV PrEP, though data and experience are minimal, so these options should be offered with careful counseling and shared decision-making, with consideration of potential logistical barriers.
- Prior to prescribing same-day HIV PrEP, a negative result on a rapid HIV-1/2 antigen-antibody test must be documented; a negative result on a test drawn within the preceding 7 days is acceptable.
- Although the quantity of oral HIV PrEP medications prescribed with rapid HIV PrEP may vary by clinical setting, most often a 30-day HIV PrEP prescription is provided at the initial visit.
- Although the potential for abnormal baseline laboratory results should be taken into consideration prior to prescribing same-day HIV PrEP, in most studies of same-day HIV PrEP, undiagnosed HIV at the time of screening in the setting of a negative rapid HIV test was rare.

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Figures

Figure 1 Standard Versus Same-Day HIV PrEP Timelines

Source: Rowan SE, Patel RR, Schneider JA, Smith DK. Same-day prescribing of daily oral pre-exposure prophylaxis for HIV prevention. Lancet HIV. 2021;8:e114-e120.

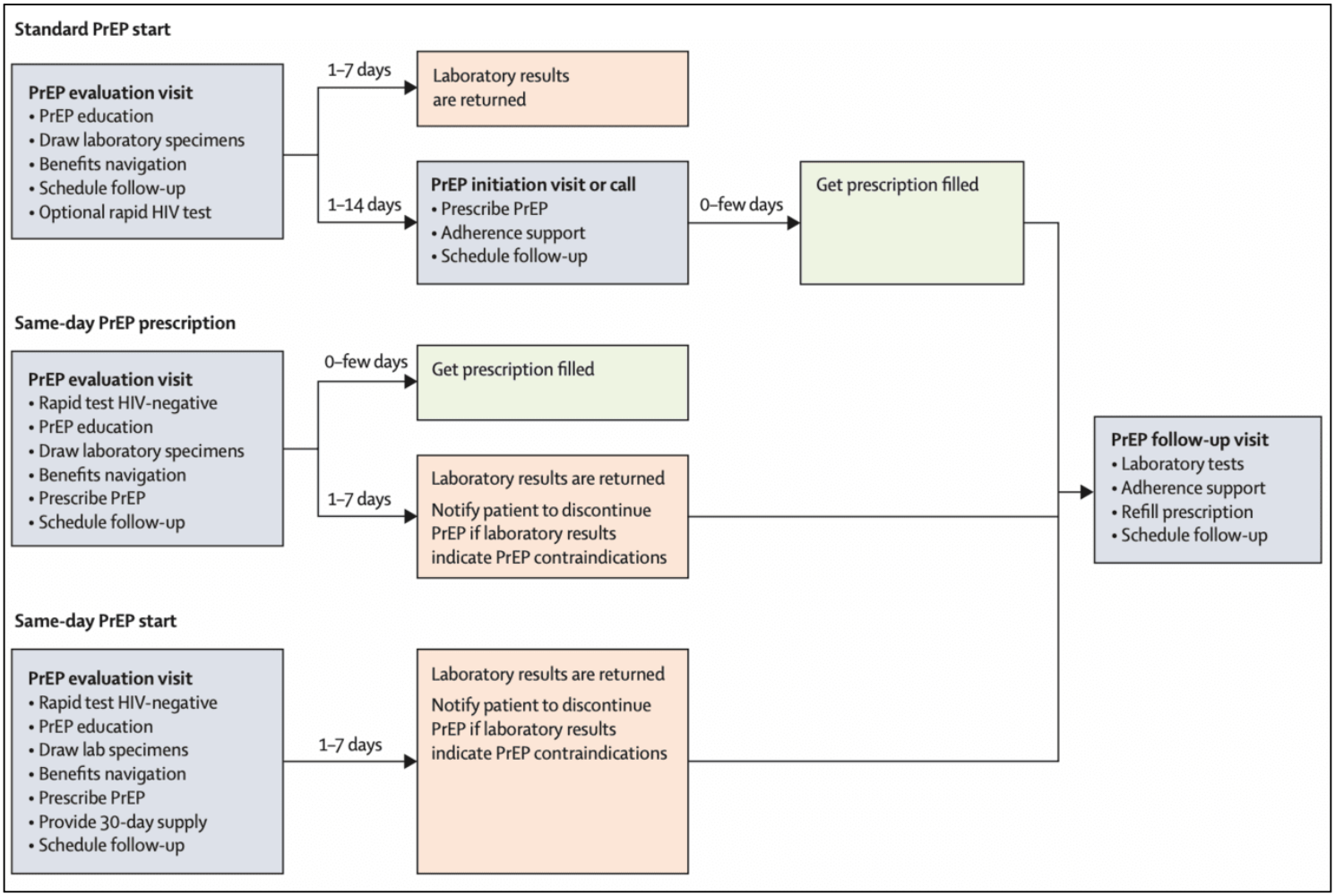


Figure 2 Immediate HIV PrEP Initiation at New York City Sexual Health Clinics

Source: Mikati T, Jamison K, Daskalakis D. Immediate PrEP initiation at New York City sexual health clinics. Program and abstracts of the 2019 Conference on Retroviruses and Opportunistic Infections; March 4-7, 2019; Seattle, WA. Abstract 962.

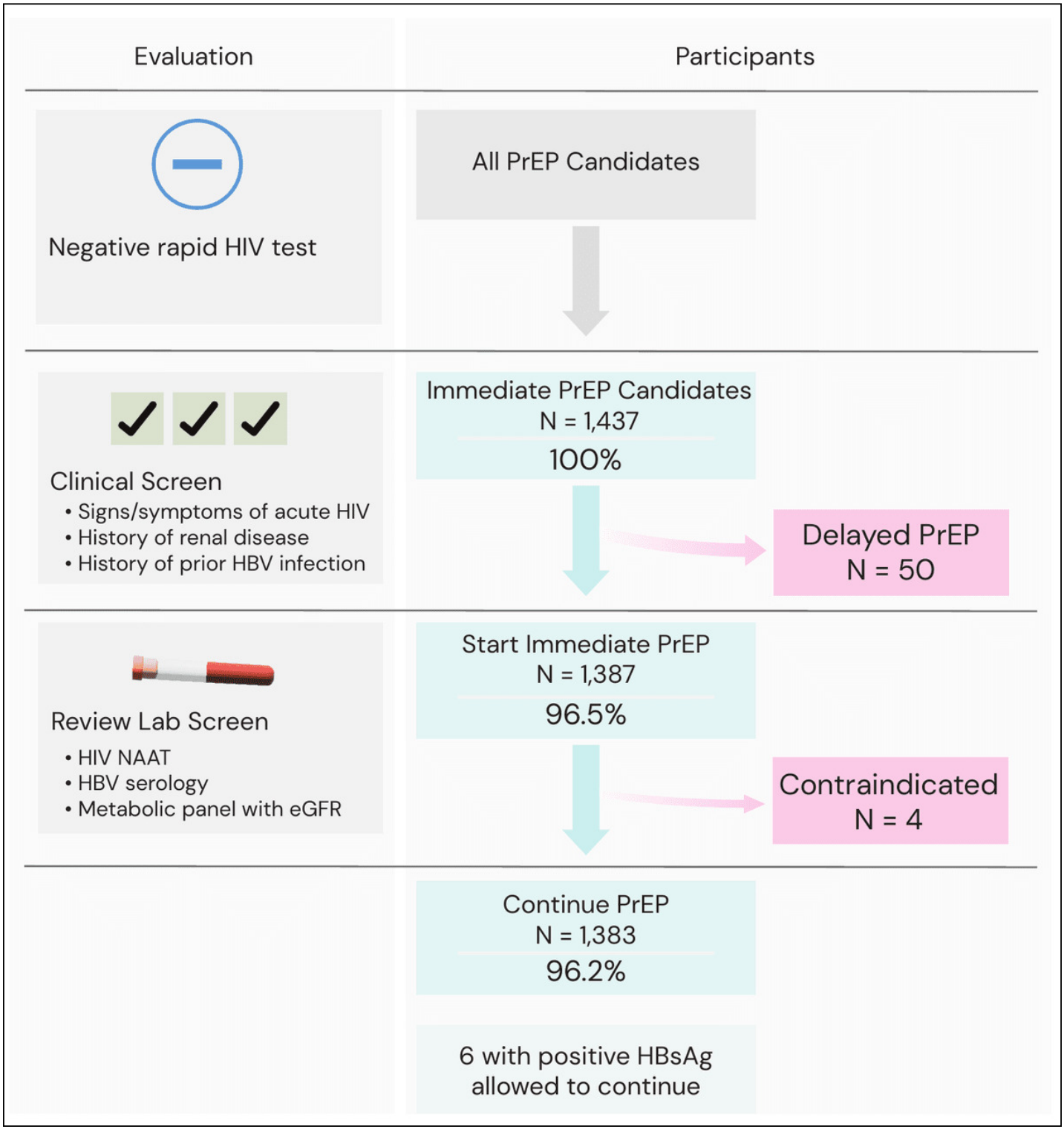


Figure 3 Follow-Up HIV PrEP Care Cascade After Same-Day Initiation

Source: Kamis KF, Marx GE, Scott KA, et al. Same-Day HIV Pre-Exposure Prophylaxis (PrEP) Initiation During Drop-in Sexually Transmitted Diseases Clinic Appointments Is a Highly Acceptable, Feasible, and Safe Model that Engages Individuals at Risk for HIV into PrEP Care. Open Forum Infect Dis. 2019;6:ofz310.

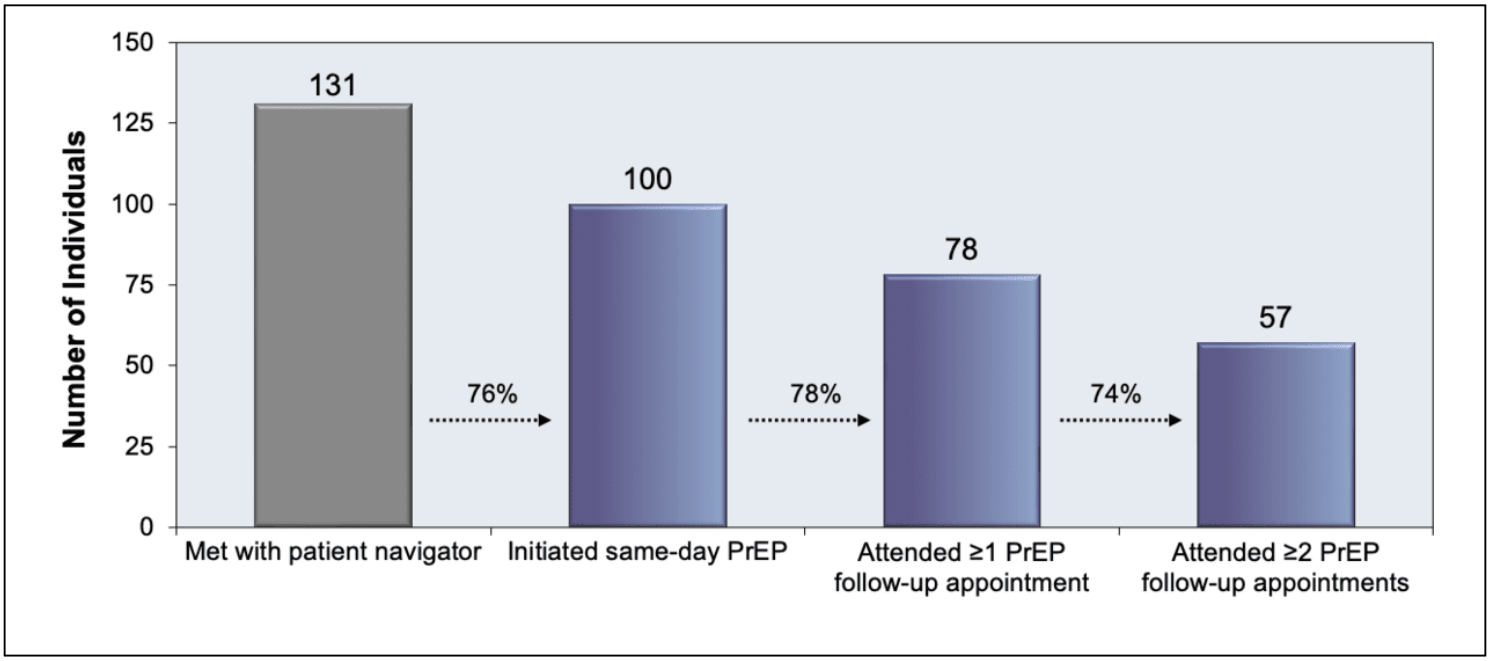


Figure 4 Number and Percentage of Patients Retained Along Steps of the Same-Day HIV PrEP Continuum

Source: Khosropour CM, Backus KV, Means AR, et al. A Pharmacist-Led, Same-Day, HIV Pre-Exposure Prophylaxis Initiation Program to Increase PrEP Uptake and Decrease Time to PrEP Initiation. AIDS Patient Care STDS. 2020;34:1-6.

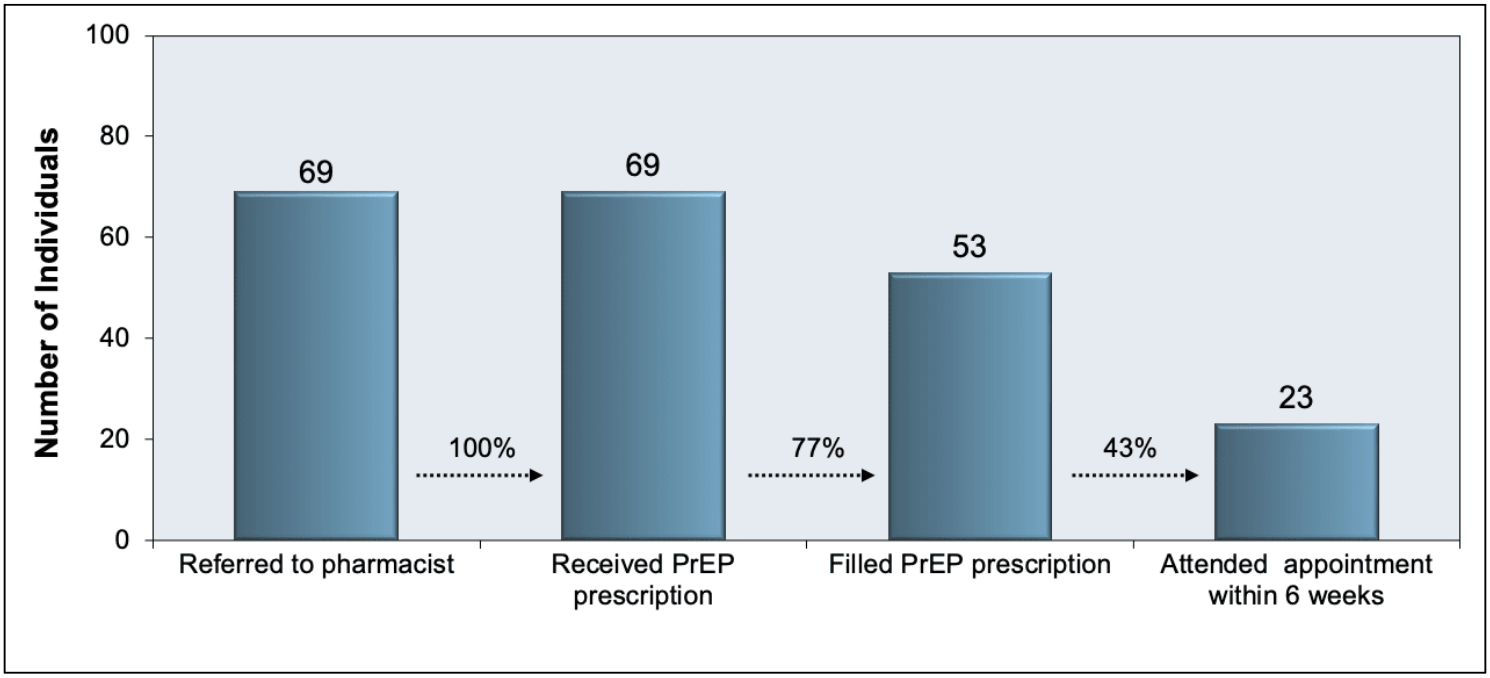


Figure 5 Lenacapavir Dosing Schedule

Illustration: Peter Harrison, MPH and David H. Spach, MD

