

Same Day (Rapid) Start for Oral HIV PrEP

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Module 2: [HIV PrEP In-Depth Topics](#)

Lesson 5: [Same Day \(Rapid\) Start for Oral HIV PrEP](#)

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<https://www.hivprep.uw.edu/go/hiv-prep-depth-topics/same-day-rapid-start-hiv-prep/core-concept/all>.

Background

In the United States, HIV transmission continues to occur at a significant rate and the number of people utilizing HIV preexposure prophylaxis (PrEP) remains low compared to the estimated number of individuals who meet criteria for HIV PrEP. Multiple barriers exist along the HIV PrEP care continuum (e.g., linkage to care, attending appointments, filling prescriptions, and adherence with HIV PrEP), 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 taking PrEP.[5,6] Rapid initiation of HIV PrEP decreases 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 by expediting the achievement of protective tenofovir levels in serum and tissues. The following discussion will focus on rapid initiation of the oral PrEP regimens tenofovir DF-emtricitabine (TDF-FTC) and tenofovir alafenamide-emtricitabine (TAF-FTC). This topic will not include discussion of the use of long-acting injectable cabotegravir (CAB-LA) for rapid HIV PrEP, due to lack of data for rapid start with CAB-LA, variable funding barriers related to immediate access of CAB-LA, and the need to perform HIV-1 RNA testing prior to starting CAB-LA.

Definitions for Same-Day and Standard HIV PrEP

The following definitions are important to recognize when discussing same-day or rapid HIV PrEP with TDF-FTC or TAF-FTC.

- **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 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 picking up the medication at a pharmacy or through a clinic-dispensed starter-pack.

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 HIV PrEP

Several descriptive studies regarding the implementation and outcomes of same-day HIV PrEP are summarized below. At this time, all available data related to same-day (rapid) HIV PrEP pertains to oral HIV PrEP.

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](#)).[\[7\]](#) The investigators delayed HIV PrEP 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, 97% of persons evaluated qualified for immediate HIV PrEP and 3% (50 of 1,437) for standard HIV PrEP.[\[7\]](#) Individuals were promptly contacted and reevaluated after receiving an initial HIV PrEP prescription if subsequent 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 of prescription in 4 (0.2%) individuals due to a contraindication (2 persons had a positive HIV nucleic acid test [NAT] and 2 persons had an eGFR less than 60 mL/min).[\[7\]](#) An additional 6 individuals had a positive HBsAg and continued HIV PrEP. Among the individuals assigned to receive standard HIV PrEP, only 15 (35%) of those without medical contraindications started HIV PrEP at the New York City sexual health clinic site within 60 days of the initial visit.[\[7\]](#) The authors concluded that clinical assessment appeared adequate to identify patients eligible for immediate HIV PrEP, medical contraindications to HIV PrEP among immediate HIV PrEP-eligible patients were very rare, and loss to follow-up was significant when HIV PrEP was delayed.[\[7\]](#)

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: known HIV infection, 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, met with a benefits navigator to assist with enrollment into health insurance and cost-assistance programs, and received screening with a point-of-care (POC) HIV-1/2 antigen-antibody test, a blood draw (for creatinine and HBsAg), and a urine pregnancy test (for persons with a uterus).[\[8\]](#) 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.[\[6\]](#) If 2 weeks elapsed between the HIV test and HIV PrEP initiation, a new HIV test and HIV PrEP prescription were required. 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. All persons were offered assistance with insurance navigation and access to manufacturer medication assistance programs.[\[6\]](#) If the cost of the laboratory work was not covered by insurance, the participants could receive a point-of-care creatinine test in lieu of phlebotomy and laboratory-based studies. 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 to individuals at high risk for HIV acquisition.[10] Between November 2018 and May 2019, individuals with a negative rapid HIV-1/2 antigen-antibody test at a non-clinical testing site 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 53 (77%) filled the prescription; 87% of the prescriptions were filled within 1 week. Among the 53 individuals who filled the prescription, only 23 (43%) returned for follow-up, despite the pharmacist contacting patients weekly for 1 month if they did not pick up the prescription or attend the clinical appointment (Figure 4).[10] Overall, among the 69 who were referred to a pharmacist for same-day HIV PrEP, only 23 (33%) attended a clinical appointment within 6 weeks. Prescriptions were not refilled if patients did not attend their follow-up appointment.[10] This study demonstrated the feasibility of same-day HIV PrEP prescribing outside of a clinic setting, although the relatively low follow-up rates underscored the need for programs to support retention in HIV PrEP care.

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. Of the 1,387 patients who attended an initial HIV PrEP visit between October 2014 and December 2019, 1,190 (86%) initiated HIV PrEP.[11] Of those 1,190 who initiated HIV PrEP, 488 (41%)

had discontinued HIV PrEP by the end of the analysis period.[\[11\]](#)

Providing Same Day HIV PrEP

Settings Amenable to Same-day 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 an HIV-1/2 antigen-antibody test. If same-day results can be obtained with a laboratory-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 and HIV testing 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 HIV PrEP

Same-day HIV PrEP should not be considered if the clinic does not have the capacity to provide same-day PrEP services as outlined above. In addition, same-day 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 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 HIV PrEP

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

- Rapid HIV test (ideally an 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.
- Point-of-care pregnancy test for persons with a uterus
 - Oral HIV PrEP is safe for individuals who are pregnant, but ascertaining whether someone is pregnant or not is important prior to initiating HIV PrEP, especially for counseling purposes. For individuals who have a positive pregnancy test, shared decision-making should then be used to determine whether HIV PrEP is continued.

Required Laboratory Tests to be Drawn on Same-Day as Prescribing 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.
- Hepatitis B 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.

Recommended Laboratory Tests to be Drawn on the Same Day as Prescribing HIV PrEP

The following laboratory studies are strongly recommended on the day of PrEP prescription:

- Syphilis serologic testing
- Gonorrhea and chlamydia nucleic acid amplification testing (from urine, rectum, and oropharynx, as indicated based on body sites involved in sexual activity)

Medication Options for Same-Day HIV PrEP

At this time, same-day HIV PrEP is recommended only with oral HIV PrEP (TDF-FTC or TAF-FTC). Note that TAF-FTC should not be used in cisgender women to prevent HIV acquisition through receptive vaginal sex. Same-day HIV PrEP with CAB-LA is not recommended due to multiple logistic issues that make it extremely difficult to start on an initial HIV PrEP visit.

Initial 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, many settings allow for a maximum of 2 refills when an initial 30-day supply has been given to ensure individuals 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.[\[12\]](#)

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 tenofovir levels in serum and tissues. Nevertheless, several barriers and concerns remain when using same-day HIV PrEP.

Lost 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 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 and normal creatinine clearance obtained 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 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 oral HIV PrEP. Depending on the patient's insurance plan, obtaining coverage for HIV PrEP can take several days 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 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.
- Available data and experience using same-day HIV PrEP is limited to oral HIV PrEP regimens (TDF-FTC or TAF-FTC). There are currently no data on the use of CAB-LA for same-day HIV PrEP.
- Prior to prescribing same-day HIV PrEP, a rapid HIV test (ideally an HIV-1/2 antigen-antibody test) and point-of-care pregnancy test (for persons with a uterus) must be performed if not done within the preceding 7 days.
- The quantity of oral HIV PrEP medications prescribed will vary by clinical setting; however, most same-day HIV PrEP programs described in the literature report providing a 30-day HIV PrEP prescription at this 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 quite rare, as was a creatinine clearance level low enough to necessitate discontinuation of HIV PrEP.

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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.

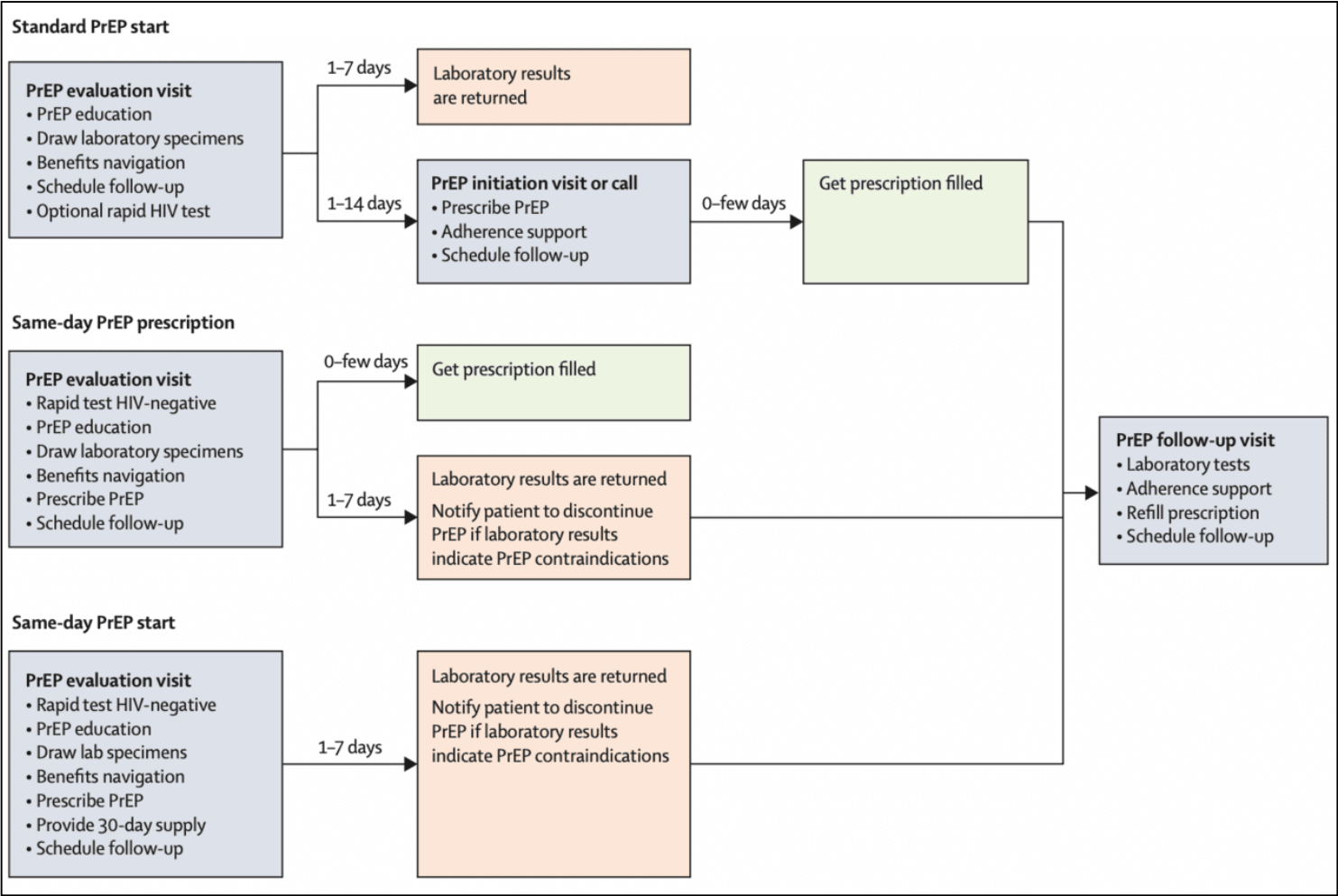


Figure 2 Immediate HIV PrEP Initiation at New York City Sexual Health Clinics

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.

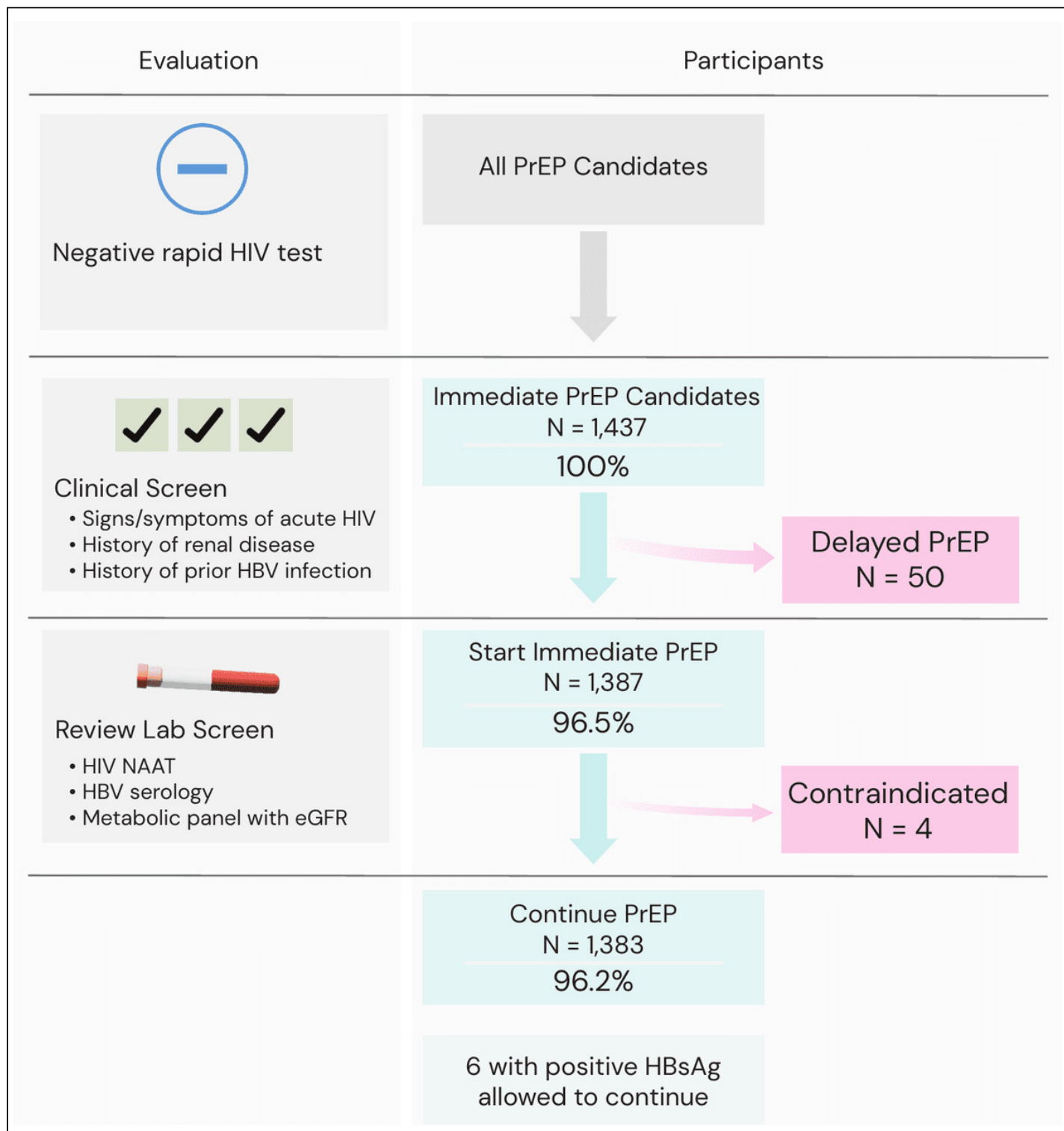


Figure 3 Follow-Up HIV PrEP Care Cascade After Same-Day Initiation

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.

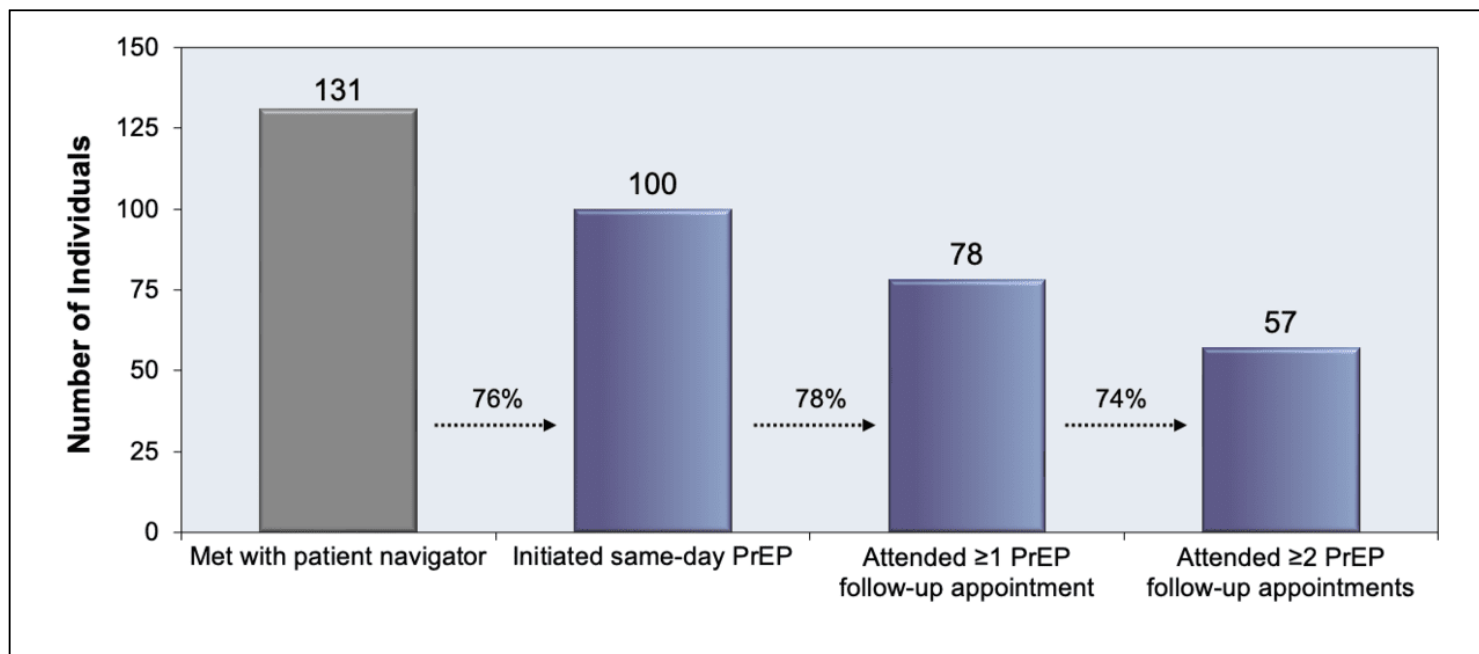


Figure 4 Number and Percentage of Patients Retained Along Steps of the Same-Day HIV PrEP Continuum

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.

