

Rapid Start Protocol

I. Description of Intervention

Definition:

Rapid Start is an intervention whereby a newly diagnosed person living with HIV (PLWH) initiates care and treatment immediately after diagnosis or as soon as possible thereafter; this is unless the client is not ready to initiate care and treatment.¹ The timeframe for initiating Rapid Start is the same day as the client's HIV diagnosis or within at least 7 days of diagnosis.²

Purpose:

The purpose of Rapid Start is to provide one-on-one, client-centered support to connect newly diagnosed PLWH to care and treatment services in a timely and expeditious manner. The intervention involves assisting newly diagnosed PLWH to obtain same day/next day access to medical appointments and to a provider; insurance navigation and approval; pre-approved antiretroviral therapy (ART) regimens; if possible, a 5-day starter pack of medications and observed administration of the first dose; and follow-up.³

Goal:

The goal of Rapid Start is to decrease the time between an HIV diagnosis and viral suppression in order to achieve positive health outcomes.⁴

Prerequisites for Implementation

- i. Knowledge of the State of Louisiana's Prevention Counseling, Rapid Testing and Referral Services (CTRS) Protocol;
- ii. A single point-of-contact to accept and coordinate Rapid Start referrals, as well as to assist newly diagnosed PLWH to navigate, access, and obtain care, treatment and support services;
- iii. Documented and established relationships with medical providers who can provide care and treatment services in a timeframe (same day/next day medical appointments or appointments within 7 days) and manner consistent with Rapid Start.
- iv. Knowledge of health benefits navigation (e.g. Medicaid, the Health Insurance Marketplace, and Louisiana Health Access Program (LA HAP)); and

¹ Michael S. Saag, MD, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infections in Adults 2018 Recommendations of the International Antiviral Society-USA Panel. JAMA. 2018; 320(4):379-396. doi:10.1001/jama.2018.8431

² World Health Organization. Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy, July 2017. Geneva: World Health Organization; 2017.

³ Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. J Acquir Immune Defic Syndr. 2017;74(1):44-51, as updated by RAPID Program staff as San Francisco General Hospital in November 2018.

⁴ Jeffery Crowley and Sean Bland. Leveraging The Ryan White Program to Make Rapid Start of HIV Therapy Standard Practice, December 2018. The Ryan White Policy Project of the O'Neill Institute for National and Global Health Law

- v. Ability to provide a warm handoff to Ryan White case management to provide follow-up and ongoing support as needed.

II. Key Staff:

Patient Navigator: charged with serving as the single point-of-contact to accept and coordinate Rapid Start referrals and linkage; establishing a close relationship with partner agencies and clients initiating Rapid Start; scheduling initial Rapid Start/first care appointment; providing HIV counseling and education; providing insurance navigation and assistance with enrollment; assessing potential barriers to care and connecting clients to Ryan White case management; and conducting follow-up after the initial Rapid Start/first care appointment.

Prescriber: charged with establishing a rapport with clients; assessing and evaluating clients' medical history; assessing clients for contraindications; requesting labs; offering/prescribing Rapid ART; scheduling following visits; and providing ongoing care and treatment services.

III. Implementation

Referral:

A client will be referred for Rapid Start on the basis of a positive HIV test result (either 2 positive rapid HIV tests or a positive lab-based HIV test), and the client's willingness to initiate Rapid Start.

Linkage to Navigation:

The Patient Navigator will establish contact, either in-person or by phone and engage the client at the time of the client's HIV diagnosis or within 24 hours of the client's HIV diagnosis. At this time, the Patient Navigator will assess the client's readiness to initiate Rapid Start; manage the expectations of the client by defining what the Rapid Start process entails and the amount of time the process will take; the health benefits Rapid Start and its relationship to Undetectable = Un-transmittable (U=U); and schedule the client's Rapid Start/first care appointment within 0-7 days of the client's HIV diagnosis. Please note: Rapid Start/first care appointments generally take between 3 - 4 hours as the client will complete labs and be seen by the Patient Navigator and a Medical Provider.

A Breakdown of Typical Rapid Start Appointment

- ✓ Patient Navigator: 1 - 2 hours + follow-up
- ✓ Medical Provider and labs: 1 - 2 hours
- ✓ Total Time: approximately 3 - 4 hours

Rapid Start/first care appointment (Patient Navigator):

During the client's Rapid Start/first care appointment, the Patient Navigator will conduct HIV counseling and education, as well as assess potential barriers to care and make appropriate referrals to Ryan White case management and other support services. Moreover,

the Patient Navigator will assist the client with insurance navigation and/or complete the LA HAP Rapid Start application process, which is as follows:

1. Ask client if the client has health care coverage.
 - If the client has Medicaid, the medication claim can be adjudicated under Medicaid. A nominal copay of 50 cents-\$3.00 may apply.
 - If the client has Medicare or private insurance, the medication claim can be adjudicated through that insurer. Any deductible, copay or coinsurance that applies can be adjudicated through LA HAP following the completion of the LA HAP Rapid Start application.

If a client has no coverage:

- Complete the Rapid Start LA HAP application
- Fax application to LA HAP at 504-568-3157
- Call LA HAP staff at 504-568-7474 and let them know that a Rapid Start application has been submitted
- The person who submitted the application will receive a call from LA HAP staff within 4 hours to approve or deny the application
- Wait 30 minutes between approval and attempting to access coverage at a pharmacy to allow for updates to client record to be communicated to pharmacy. All information necessary to communicate to the pharmacy including Member ID, Group Number, BIN, and PCN can be found on the client’s LA HAP card, which can be printed from the Ramsell system or (if printing/viewing card is not available) obtained from LA HAP staff.

Applications submitted by 3 pm should be approved or denied the same day. After 3 pm SHP cannot guarantee completion of the process before the office closes. If applications are incomplete the approval process may take longer.

All Rapid Start agencies are required to hold 3 days’ worth of medications on site in the case that approval is not possible within a timely manner.

Rapid Start/first care appointment (Medical Provider):⁵

The Medical Provider will conduct a medical history and exam, assess client for indications of previous ART, PrEP, PEP use, sexual and drug exposure, co-morbidities, medications, allergies, and symptoms for opportunistic illnesses. The medical provider will request the following baseline labs:

Table of Baseline Labs for Rapid Start Patients

Confirmatory HIV testing (if needed)	HAV IgG antibody
HIV RNA PCR viral load	Hepatitis B serology (HBV cAb HBV sAb HBVsAg)
HIV genotype	HCV antibody reflex to RNA
CD4+ T cell count	GC/CT – NAAT (Urine and Extragenital)

⁵ AIDS Education & Training Center (AETC) Pacific. Clinical Essentials: HIV testing, Rapid ART, PEP, PrEP. Updated November 2018

Complete blood count with differential and platelet level	syphilis screening (+ Nx – RPR, - Nx reverse sequence)
Comprehensive metabolic panel (including creatinine and liver function)	A pregnancy test (if applicable)

Once the Medical Provider has completed his/her examination and assessed for contraindications, the Medical Provider will prescribe an ART regimen based on his/her best medical judgement. The following ART regimens are based on 2018 recommendations of the International Antiviral Society – USA Panel:

Generally Recommended Initial Regimens (Listed in Alphabetic Order by InSTI Component)

- Bictegravir/TAF/emtricitabine
- Dolutegravir/abacavir/lamivudine
- Dolutegravir plus TAF/emtricitabine

Recommended Initial Regimens for Individuals for Whom Generally Recommended Regimens ARE Not Available or Not an Option (Listed in Alphabetic Order by First Component)

- Darunavir/cobicistat plus TAF (or TDF)/emtricitabine
- Darunavir boosted with ritonavir plus TAF (or TDF)/emtricitabine
- Efavirenz/TDF/emtricitabine
- Elitegravir/cobicistat/TAF (or TDF)/emtricitabine
- Raltegravir plus TAF (or TDF)/emtricitabine
- Rilpivirine/TAF (or TDF)/emtricitabine (if pretreatment HIV RNA levels is <100,000 copies/mL and CD4 cell count is >200 ul)

TDF is not recommended for individuals with or at risk for kidney or bone disease (osteopenia or osteoporosis)

Initial 2-drug regimens are only recommended in the rare situations in which a patient cannot take abacavir, TAF, or TDF

Recommended Regimens for Individual Who Are Pregnant

- Abacavir/lamivudine (or emtricitabine) if patient tests negative for HLA B*5701 or TDF/emtricitabine

For a complete list of antiretroviral on Louisiana AIDS Drug Assistance Program (ADAP), visit <http://www.ramsellcorp.com/PDF/Louisiana%20HAP%20Uninsured%20Drug%20Class.pdf>.

The Medical Provider will schedule the client to return within 7-14 days for a follow-up visit to review previous labs, draw new labs, and provide a medical examination.

Follow-up:

The Patient Navigator will follow-up with the client within 2-3 days of the client's Rapid Start/first care appointment. During follow-up, the Patient Navigator will assess how the client is doing post appointment, ensure client's understanding of what happened post Rapid Start/first care appointment, inquire about any complications or issues, determine client's need for other supports, support client in addressing barriers, and outline any next steps.

Other recommendations include:

- Repeat HIV RNA PCR viral load six weeks post initial visit and again three months later
- Repeat CD4+ T cell count six months post initial visit

Resources:

1.) Benefits of Rapid Start

https://journals.lww.com/aidsonline/FullText/2018/01020/Benefits_and_risks_of_rapid_initiation_of.3.aspx

<https://www.ncbi.nlm.nih.gov/books/NBK475972/>

https://www.gettingtozerosf.org/wp-content/uploads/2017/05/RAPID_Provider_final_v2_high-res-1.pdf

2.) HIV Training Modules

<https://www.hiv.uw.edu/alternate>

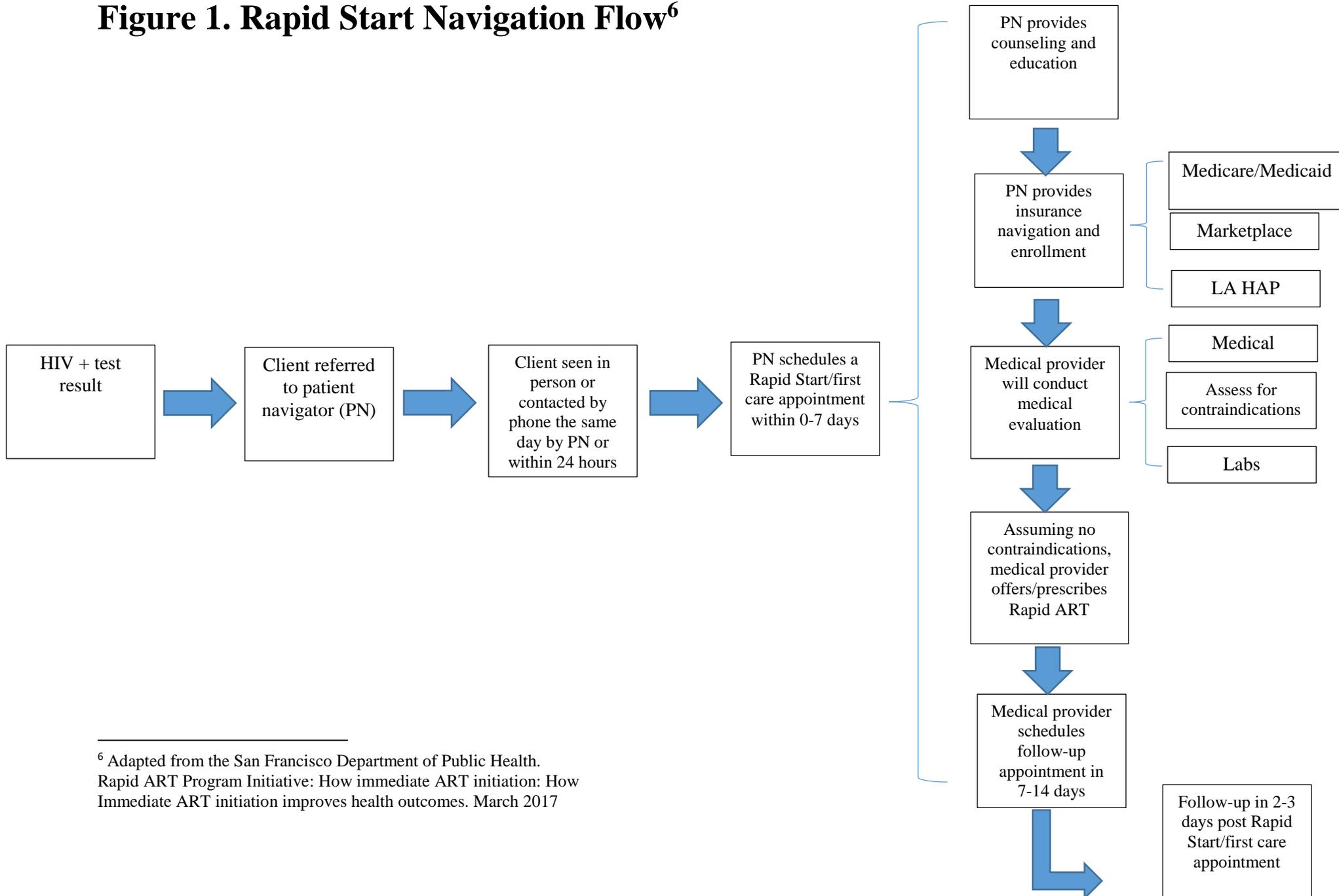
https://www.iapac.org/files/2018/05/HIV_Manual-111915b.pdf

<https://aidsetc.org/nhc>

<https://www.hiv.uw.edu/go/basic-primary-care>

Appendix: Test and Treat Application

Figure 1. Rapid Start Navigation Flow⁶



⁶ Adapted from the San Francisco Department of Public Health. Rapid ART Program Initiative: How immediate ART initiation improves health outcomes. March 2017