October 2021

Rapid ART:
An Essential Strategy for Ending the HIV Epidemic

Ending the HIV Epidemic

TAPin Technical Assistance Provider innovation network

Summary of Insights from November 19, 2020 Webinar by HRSA's TAP-in, Technical Assistance Provider innovation network

A Project of CAI

Introduction

About this Resource

This resource outlines what HIV care providers need to do to strengthen or develop a rapid ART program that will provide antiretroviral therapy to patients quickly—ideally on the same day they receive their HIV diagnosis. The focus of this resources is on "how to" strengthen or establish rapid ART services. It provides concrete information in terms of steps to take, protocols to modify and use, and other tasks that are necessary to put a program in place. Tips and ideas are often bulleted. Appendices provide samples that can be readily modified. As a result, there is minimal descriptive information about agencies and programs, while steps were taken to avoid overly general suggestions (e.g., meet clients where they are).

This document complements the presentations and slides from the webinar, Rapid ART: An Essential Strategy for Ending the HIV Epidemic found on the TargetHIV website. Presented in this resource is a broad overview of rapid ART, the technical assistance and training services available to Ending the HIV Epidemic (EHE) jurisdictions, and rapid ART components for sites considering starting or enhancing rapid ART. These components were primarily identified by two main sources:

1. Agencies that presented their rapid ART implementation programs at the 2020 National Ryan White Conference on HIV Care and Treatment (2020 Ryan White Conference)

2. Insights from the expert panel. Users are encouraged to access the resources in the Appendices for more in-depth information on specific rapid ART topics

EHE jurisdictions seeking to develop or enhance rapid ART strategies are encouraged to seek technical assistance (TA) from the HRSA-funded Technical Assistance Provider innovation network (TAP-in) at TAP-in@caiglobal.org. Learn more about TAP-in at https://targethiv.org/ta-org/tap-in

This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $3,750,000 with 0% financed with non-governmental sources. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, HRSA, HHS or the U.S. Government.

Table of Contents

Overview of Rapid ART

Definition of Rapid ART

Rapid ART is the administration of antiretroviral therapy (ART) "as soon as possible after the diagnosis of HIV infection, preferably on the first clinic visit- and even on the same day as the HIV diagnosis."[1] That definition is reflected in HHS guidelines, which have adopted recommendations for progressively earlier ART. Rapid ART has also been adopted by numerous local/state health departments and international bodies, including WHO and the International Antiviral Society-USA. Several states and localities have also designated rapid ART as the standard of care.

Most rapid ART programs in the United States define rapid ART as starting ART at the first clinic visit after HIV diagnosis and aim to have the first clinic visit within 7 days of diagnosis (sooner if possible).

Efficacy of Rapid ART

Rapid ART is now the standard of care for people with new diagnoses of HIV, based on persuasive data on its efficacy, as demonstrated in several randomized controlled trials in non-U.S. settings and observational trials in the United States. These studies demonstrate decreases in time from HIV diagnosis to HIV care, to ART start, and to viral suppression; increased uptake of ART; high rates of viral suppression; and excellent patient acceptability. Some have also shown increased retention in care.

In contrast, the efficacy of rapid re-initiation of ART for patients re-engaging in HIV care has not yet been well studied. However, the adoption of this intervention is based on good clinical practices to remove barriers and re-engage patients immediately into care, and recommendations from major health department programs.

RAPID ART IS THE STANDARD OF CARE FOR HIV INFECTION.

[1] Immediate ART Initiation: Guide for Clinicians. Susa Coffey, MD (Author); Oliver Bacon, MD, MPH (Author). AETC NCRC. 2/14/19. https://aidsetc.org/resource/immediate-art-initiation-guide-clinicians

Rapid ART: A Priority for EHE Jurisdictions

Because of its efficacy, the "Treat" strategy of the ***Ending the HIV Epidemic in the U.S.*** initiative states: "Treat people with HIV rapidly and effectively to reach sustained viral suppression." Additionally, rapid ART promotes U=U (Undetectable equals Untransmittable): individuals with a sustained undetectable viral load do not sexually transmit HIV.

Support for EHE jurisdictions in implementing rapid ART is available from the HRSA-funded Technical Assistance Provider-innovation network (TAP-in), as part of a full range of support for EHE jurisdictions. This document is but one form of technical assistance to EHE jurisdictions (and other HIV care agencies) on rapid ART implementation within their current HIV care programming.

EHE jurisdictions seeking to develop or enhance rapid ART strategies are encouraged to seek technical assistance (TA) from the HRSA-funded Technical Assistance Provider innovation network (TAP-in) at TAP-in@caiglobal.org.
Learn more about TAP-in at https://targethiv.org/ta-org/tap-in

HRSA and EHE Guidance on Rapid ART

HRSA Policies: Paying for Rapid ART

HRSA's Ryan White HIV/AIDS Program (RWHAP) issued a policy notice[2] and a program letter[3] in 2019 to align with treatment guidelines establishing rapid ART as the standard of HIV care. In summary, both documents:

① Clarify the legislative requirement that RWHAP is the payer of last resort.
② Provide recipients with flexibility and guidance on how they may provide rapid ART services prior to the establishment of a patient's RWHAP eligibility.
③ Explain that it is the responsibility of the recipient to recoup costs for patients later determined not eligible for RWHAP services.

RWHAP agencies should read the documents in full. Below is an excerpt from the 2019 program letter:

> "HRSA RWHAP remains the payor of last resort. As such, recipients and subrecipients must certify and document a client's eligibility and recertify the client's ongoing eligibility to receive HRSA RWHAP services. In the context of a public health program and understanding that HIV treatment is prevention, HIV care and treatment services may be provided to PLWH before HRSA RWHAP eligibility is documented, on a time-limited basis as defined by the recipient. The HRSA HIV/AIDS Bureau (HAB) defers to the recipient to determine if and which services they are willing to provide to clients during the time-limited rapid eligibility determination period. Use of RWHAP funds for services to PLWH who are ultimately determined to be ineligible for RWHAP are unallowable and must be recouped by the program from an alternate payment source.
> HRSA HAB continues to expect RWHAP recipients to establish and monitor procedures to ensure funded providers verify and document client eligibility, as described in HRSA HAB PCN 13-02." Rapid Eligibility Determinations and Ryan White HIV/AIDS Program, Program Letter, 5/2/2019

State and local health coverage programs for uninsured individuals and pharmaceutical assistance programs are potential avenues for securing payment for rapid ART services. While some agencies utilize "starter packs" provided by pharmaceuticals, others prohibit their use.

[2] Clarifications on Ryan White Program Client Eligibility Determinations and Recertifications Requirements, Policy Clarification Notice (PCN) #13-02 (Revised 5/1/2019) Relates to Policy Notice #16-02. Rapid Eligibility Determinations and Ryan White HIV/AIDS Program, Program Letter, 5/2/2019 https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters

[3] Rapid Eligibility Determinations and Ryan White HIV/AIDS Program, Program Letter, 5/2/2019 https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters

Use of EHE Funds: Innovation and Creativity

Initial rapid ART activities were launched around the country as early as 2013. Efforts ramped up significantly in 2019 with an endorsement in the HHS clinical guidelines and rollout of the Ending the Epidemic (EHE) initiative and Pillar 2: Treat goal to "treat people with HIV rapidly and effectively to reach sustained viral suppression." EHE efforts are to: encourage prompt initiation of HIV care and treatment to achieve viral suppression and stop transmission; increase capacity by funding RWHAP Parts A and B in the EHE jurisdictions; provide workforce capacity development through the RWHAP Part F AIDS Education and Training Centers (AETC) Program; and provide technical assistance to the identified jurisdictions.

RWHAP Part A and Part B EHE jurisdictions were awarded funding under HRSA-20-078, which explained that recipients were "encouraged to propose methods that are innovative and creative; the methods are not limited to the current RWHAP service categories or eligibility requirements (except for an HIV diagnosis), and there is no requirement to spend at least 75 percent of the award on core medical services."

TA services for HRSA-20-078 funded jurisdictions are provided through TAP-in and can be accessed via TAP-in@caiglobal.org. Recipients can seek TA on a broad range of issues, including flexibility of EHE funds.

HRSA Rapid ART Initiatives

In 2020, HRSA funded a Special Projects of National Significance (SPNS) initiative to explore rapid ART best practices. Funds were awarded on September 1, 2020. The program is called Building Capacity to Implement Rapid ART Initiation for Improved Care Engagement. The University of California San Francisco is the evaluation center. There are also 15 demonstration sites under this effort. Learn more about SPNS.

Also, in 2020, HRSA funded the SPNS Rapid ART Dissemination Assistance Provider that will compile information on rapid ART activities around the country to identify evidence-based models. This work is being conducted through Cicatelli Associates Inc. (CAI), which is also the TAP-in technical assistance (TA) provider. Learn more about the TAP-in Project or contact kbrooks@caiglobal.org.

Prioritizing Rapid ART: Decision Steps

Why Rapid ART is Adopted by Sites

RWHAP rapid ART sites report various reasons why they pursue rapid ART. Logically, sites are simply following the science: rapid ART is the standard of care. Additional motivators include promotion by clinic champions; responsiveness to patient interests and demands; inclusion of strategy in local EHE plans; and responses to community feedback from planning groups, special workgroups, and consumer advisory boards.

The most important step to undertake in deciding on rapid ART is to examine local HIV data: who is getting tested, who is falling out of care, who is achieving viral suppression, where is there room for improvement?

Often, rapid ART is first undertaken by clinics with existing capacity in the form of, for example, clinical expertise, HIV testing services, and linkage to care activities. That's because rapid ART requires the ability to deliver ART the same day or soon after and, ideally, support patients over time.

Determine the Need for Rapid ART

To determine the need for rapid ART, first collect epidemiological data from the health department and HIV surveillance team in terms of:

- Who is getting tested for HIV, and testing positive, but not getting linked to care?
- What is the current time from HIV diagnosis to the first HIV care visit, and to ART initiation?
- Who is not being offered ART or facing delays in being prescribed ART?
- Who is discontinuing care?
- What are the current rates of viral suppression?

Next, analyze the data. What's your room for improvement? Are there differences according to patient demographics (e.g., age, sex/gender, sexual minority, race/ethnicity, income level, housing status, resides in an underserved community)?

Determine Readiness to Provide Rapid ART

How can a clinic, or an entire jurisdiction, determine its readiness for rapid ART? Below is a checklist to help guide this assessment. The RAPID Clinical Site Checklist provided on the next page poses the question—Is your clinic ready to offer rapid ART? For this assessment, readiness is defined by the extent to which systems are in place that are necessary to provide rapid ART.

San Francisco's "Getting to Zero" initiative has developed Standard Operation Procedures (SOPs) for the delivery of rapid ART throughout their provider system. Their SOPs include a number of helpful tools that include an Appendix, on page 21, that provides a "Rapid ART Clinical Site Checklist" that assesses readiness in terms of roles and tasks that each staff completes including: front-desk staff, clinical staff (prescribers and nursing staff, social workers and counselors, laboratory staff, participating pharmacies), and resources available for patients.

Instructions for completing The RAPID Clinical Site Checklist: Review the list below to determine the extent to which the site has the components of rapid ART services in place by indicating: in place, somewhat in place, needs to develop, and/or needs technical assistance and training for the component. Once you have completed the assessment, it is important to focus on areas that need to be strengthened (i.e., somewhat in place) or that need to be developed.

Rapid ART Component	In Place	Somewhat in Place	Need to Develop	Need TA, Training, or Other Support (describe)
In-house HIV testing				
Linkage to HIV testing sites				
Providers are interested in providing rapid ART				
Providers trained to provide rapid ART				
Access to ART medications (same-day)				
Workflow and protocols support rapid ART provision				
Systems in place to provide follow-up and supportive services to promote retention (e.g., housing, community health workers (CHW), transportation)				
Other facilitators (e.g., patient education materials, EHR standing orders)				

Setting Up Rapid ART – Focus Areas

This section explores eight areas of focus for strengthening or integrating rapid ART as part of standard of care. The key considerations for each area of focus come directly from the experiences of various sites that have planned and implemented rapid ART programs, as shared at the 2020 Ryan White Conference and other select resources. The eight areas of focus are:

- **Establish Testing and Linkage Networks**
- **Identify a Rapid Champion/Form a Dedicated Rapid Team**
- **Develop a Workflow and Protocol**
- **Secure Buy-In and Deliver Provider Training**
- **Secure Access to Medications**
- **Support Patients at First Appointment and Over Time**
- **Use Data to Support Patients and Track Outcomes**
- **Use Quality Improvement to Make Adjustments**

Establish Testing and Linkage Networks

Rapid ART clinics need to be able to identify and receive individuals who test HIV-positive, either in-house or through referrals.

- For new HIV diagnoses, clinics need close linkages with testing sites and efficient referral protocols.
- For persons who previously tested positive and are not on ART (never started ART, or started but later stopped), clinics will need methods to identify them and engage/re-engage them in care.
  - Methods to maintain engagement in care can include: more frequent clinic visits, paying for transportation to the clinic with gift cards or rideshares, regular phone calls or texts, remote adherence monitoring (e.g., with Bluetooth medication caps, phone calls), in-clinic medication storage, peer navigation, and enlisting patient friend and family support if appropriate.

With both types of clients, clinics should establish a workflow that includes a single point of contact to accept referrals, arrange the rapid intake visit, and activate the rapid ART team. Clinics should have services and referrals systems for patients who have challenges (e.g., lack of stable housing) that will likely hinder the ready adoption of rapid ART and ongoing engagement in HIV care.

Assign a single point of contact to handle referrals and care engagement.

Laboratory Versus Point of Care HIV Testing

Rapid HIV treatment initiation may be offered after a positive HIV test, regardless of the type of test used.

- Sites that send HIV tests to laboratories can initiate or refer for treatment immediately upon receipt of the confirmed positive test result and arrange to obtain specimens for recommended baseline lab tests such as viral load, genotyping for drug resistance, and tests of kidney function.
- Sites that perform rapid point of care HIV 1/2 antibody screening can (1) await confirmatory test results; (2) consider using a different, 2nd rapid test after an initial reactive test to improve the positive predictive value of the 1st test before initiating or referring for ART the same day; or (3) refer for or initiate ART while awaiting the results of a confirmatory test and other lab work.

Deciding whether to initiate rapid ART based on a reactive rapid test before confirmation depends on circumstances specific to each program:

- The likelihood that a reactive rapid test result is truly positive is high in persons with recognized risk factors for HIV and in communities of high prevalence.
- Initiating rapid ART after a reactive rapid test result reduces loss to follow-up from persons who might not return for their confirmatory result.
- Rapid ART initiation also has the potential to reduce the time during which people with newly diagnosed HIV can transmit HIV.
- For the small percentage of persons who turn out to be uninfected, ART can be stopped upon receipt of the definitive HIV test results. Studies of uninfected health care workers who initiate post-exposure prophylaxis and uninfected pregnant women with false-positive rapid test results have shown no adverse effects from a short course of ART.
- Sources of support to pay for ART medications for persons who prove to be HIV-negative can pose additional challenges.

Some clinicians may be uncomfortable prescribing an ART regimen before lab results establish whether the patient has confirmed HIV infection, renal insufficiency, or medication-resistant virus. However, clinical experience with immediate ART suggests that providers seldom have to stop or alter the initial regimen.

Identify a Rapid Champion and Form a Dedicated Rapid Team

Rapid ART programs often build upon existing successful clinical programs (e.g., an HIV screening program, HIV clinic, PrEP program, sexual health clinic). The expertise and passion of the existing staff are a natural foundation for adding rapid ART to clinic operations. Often, one individual on staff acts as the rapid ART champion. A dedicated rapid team of multidisciplinary professionals is best for design and implementation purposes so that varied insights and skills can be incorporated into the rapid ART program.

Develop a Workflow and Protocol

At the 2020 National Ryan White Conference, a number of rapid ART sites presented information on their goals, staffing, and steps for engaging and working with patients. Typically, programs established formal workflows and protocols to outline these elements. Below are highlights.

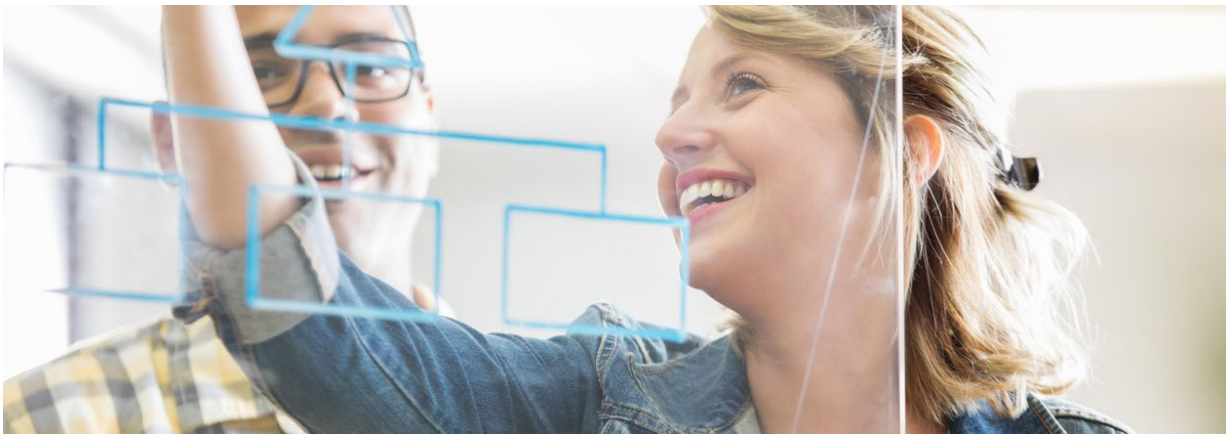
Staffing. Sites need to have staff who are readily available for at-a-moment attention to rapid ART patients (e.g., walk-ins). Staff roles also need to be clearly outlined, both for in-house clinic staff and outside staff (e.g., health department navigators, in cases where clinics lack these positions).

Workflow and Staff Roles

Designate the process for intake and processing, which typically covers:

- Activation of the rapid team/process, including:
  - Roles of clinical staff who interface with patients.
  - A description of who will perform essential activities during the rapid ART visit, and in what order.
- Timing of eligibility determinations and benefits optimization (e.g., benefits assessment worker, social worker, and/or case manager), according to clinic/RWHAP policy and use of EHE funds.
- Ensuring access to medications (e.g., direct dispensing or via a pharmacist).
- Mechanisms for continuing patient support (e.g., navigator, adherence counselor).

Workflows should strive to minimize the number of people interacting with a new patient and emphasize warm handoffs.

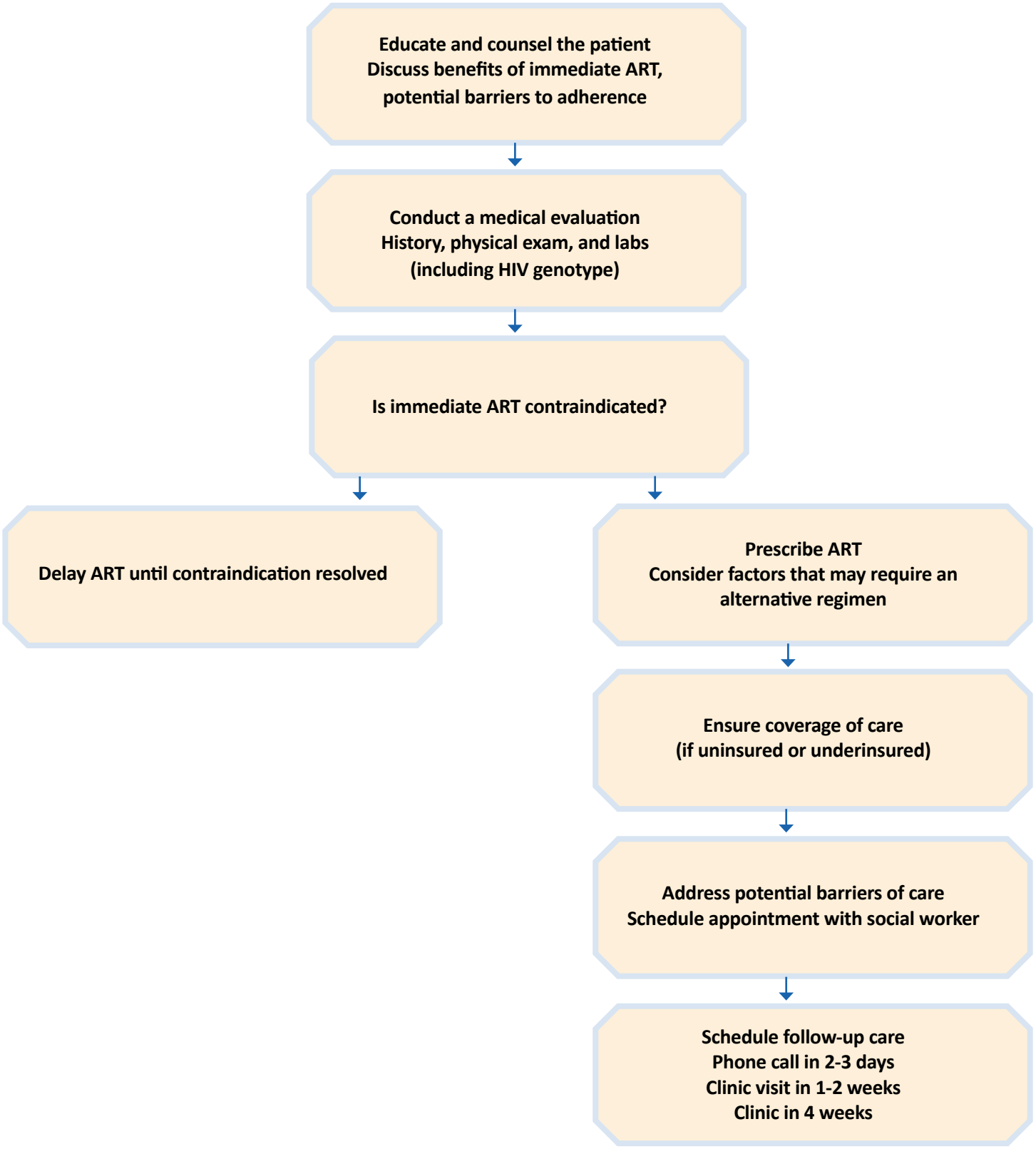


Essential steps include:

- Review HIV test results with the patient. Determine if the patient has a confirmed HIV test result or a rapid HIV screening test result that requires additional testing.
- Educate the person about treatment options, including rapid ART, and assess willingness to start.
- Assess eligibility for immediate start of ART. The main contraindications are:
  - Signs or symptoms of a central nervous system opportunistic infection (in this case, ART may be delayed until during the initial treatment of the opportunistic infection)
  - Liver or renal disease that might affect medication dosing
- Determine patient preferences (such as where they wish to receive care—at the clinic location or another site).
- Establish or optimize insurance coverage, if needed.

Workflow steps may differ for newly diagnosed vs. previously diagnosed patients not engaged in care, or for walk-in patients tested elsewhere.

Clinical Steps in Same Day Initiation of ART. Sample Rapid ART Workflow. Adapted from New York City Rapid ART Guidance for Clinicians

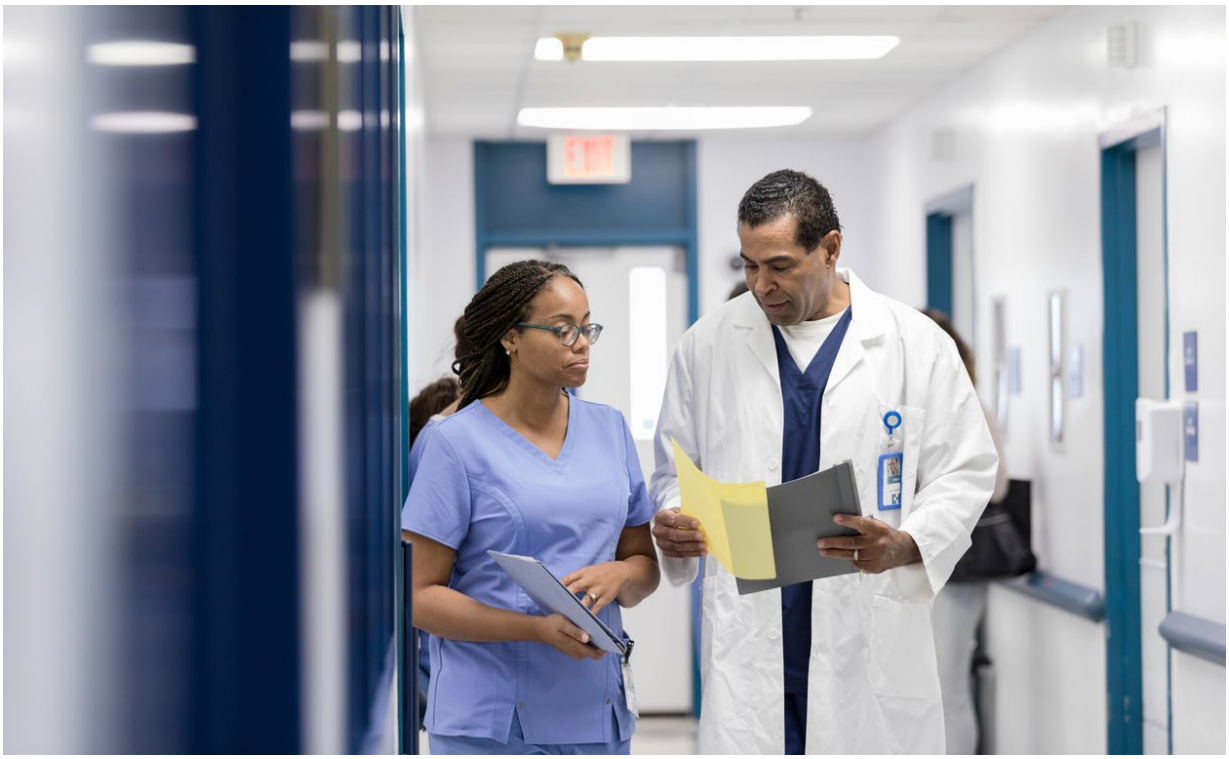


Protocol

Rapid ART protocols differ from workflows in that they provide greater detail. Protocols are tailored to a clinic's circumstances and outline:

- **Roles of staff members.** (Note: Some protocols incorporate task-shifting roles for registered nurses or medical assistants to operate under an expanded scope of practice or to use standing orders to better support a rapid program's components.)
- **Activities in the initial rapid visit** (e.g., insurance/benefits enrollment/optimization, patient screening, medical history and physical exam, laboratory work, support/education, providing prescriptions).
- **Designated pre-selected ART regimens** (prescription options, use of starter packs if available and allowable).
- **Plans for patient follow-up** (e.g., frequency, persons responsible).
- **Where to secure expert consultation** (e.g., to interpret confusing test results, design individualized ART regimens, discuss medical/psychiatric comorbidities). One key resource is the HRSA-funded AETC National Clinician Consultation Center. https://nccc.ucsf.edu

See the Resources in the appendix for sample workflows and protocols.



Secure Buy-in and Deliver Provider Training

Buy-in

Rapid ART is a relatively novel approach to HIV care and treatment. It can, therefore, be challenging to managers, seasoned HIV clinicians, and other staff. Some rapid ART sites report that resistance to rapid ART may exist among experienced staff members who are accustomed to reviewing a battery of diagnostic test results and to an extended assessment of readiness before prescribing ART. Therefore, it is crucial to secure buy-in from clinic leadership, since they set the tone for the rest of the staff on why rapid ART is essential. Options for seeking and securing leadership buy-in include:

- Presenting data on the benefits and efficacy of rapid ART.
- Outlining how rapid ART can be incorporated within a clinic's current operations (e.g., through a working group of staff, adoption of protocols from other sites).
- Describing successful examples of other rapid ART programs in the community.

Training

Train all staff who see rapid ART patients, including front desk staff, laboratory personnel, and clinicians. This helps ensure that patients have a seamless experience at the initial visit. Also, rapid ART is best administered via a team, which may include the clinician(s), counselor, benefits counselor, and navigator.

Consider variable formats and methods for training providers. Examples include:

- In-service staff training.
- Brochures/flyers for staff, placed in staff areas.
- Individual meetings with staff, like huddles, to address Q/A in a one-on-one or small group setting.
- Data visualization to communicate to staff the benefits of rapid ART.
- Clinic-level data to show the rapid program's effects on patients and identify areas for improvement.

Training topics can include, for example, efficacy and outcome data; feedback on patient interest and acceptance; the feasibility of starting ART before baseline (or confirmatory) lab results are available; and, an explanation of how adjustments can be made in medications if needed based on genotypic resistance test results.

Staff Training on Rapid ART is available from TAP-in (TAP-in@caiglobal.org) and HRSA's AIDS Education and Training Centers (AETCs) https://aidsetc.org.

Secure Access to Medications

Patients need the option to start ART immediately at the initial HIV care intake visit. Ideally, insurance benefits are active so that medications can be dispensed upon receipt of a prescription (whether through an on-site pharmacy or a commercial pharmacy). However, patients may encounter obstacles (e.g., lack of insurance or absence of a prior eligibility determination). Various options are used by sites to facilitate same-day ART, including:

- Starter packs purchased by the clinic or donated by pharmaceutical companies. Starter packs help clients who are unable to get medications immediately from the pharmacy (e.g., insurance or co-pay problems; requirements for the use of a mail-order pharmacy; practical obstacles to accessing a pharmacy like transportation or limited business hours). Some sites, however, may have policies that prohibit donations from pharmaceutical companies.
- Pharmaceutical patient assistance programs. Some provide 24-hour access to enrollment. These programs include:
  - Gilead Advancing Access
  - Janssen Care Path
  - ViiV Connect
- A streamlined application and eligibility process for AIDS Drug Assistance Program (ADAP) and/or Medicaid.
- Ryan White vouchers, which reflect a site's intent to either cover costs with RWHAP funds pending the determination of patient eligibility for RWHAP or to recoup costs from other sources for RWHAP-ineligible patients.

Notably, Ryan White vouchers are an example of a broader potential challenge: a clinic's inability to secure reimbursement for medication costs that are not covered by the RWHAP or insurance. (See Page 3, HRSA and EHE Guidance on Rapid ART.)

Support Patients at First Appointments and Over Time

Rapid ART is not simply a matter of providing patients with medications. Patients must be provided with extensive support at the initial appointment and over time. Often, programs respond most quickly to patients who can advocate for their own needs. However, rapid ART needs to focus on those patients less likely to show up over time, who may be less vocal in advocating for their own care. This commitment to focusing on patients most at risk of being lost to follow up works best when the number of rapid ART patients is relatively small.

Notable considerations for patient support include:

- For new HIV diagnoses, clinics should be prepared to provide needed emotional support, as the news of having HIV can be overwhelming for patients. One technique is to limit the number of people the patient has to encounter during the initial rapid visit. Tell patients they have a lead contact but explain that a team is there to provide support. Also, have staff who are trained in or have experience dealing with emotional situations. One rapid ART site uses linkage coordinators to help clinicians who may have little to no experience delivering an HIV diagnosis and are more comfortable doing so with assistance.
- Provide the patient with a phone number to contact the clinic. Many patients are likely to look for support and clarifications the day after their initial diagnosis and rapid ART session.
- For patients who have been out of care and are re-engaging, be prepared to explore why they fell out of care and provide additional interventions to keep them engaged in care in the future, like more frequent check-ins (e.g., calls, in-person clinic visits, telehealth sessions).

The First Care Appointment

Once the HIV diagnosis has been established with the patient, varied issues should be covered in the first appointment with a rapid ART patient. The following steps help establish a relationship with the individual:

- Introduce the patient to the care team and tell them what services they will receive and who will provide them.
- After initial introductions, designate a single point of contact for the patient. This will provide a more personalized experience and will help avoid overwhelming the individual.
- Ask the patient if they want friends or family to join them at this or subsequent visits. Friends and family can provide emotional support and help the patient stay engaged in care and adherent to their medications.
- Assess opportunities for HIV-related stigma or trauma in the patient's life. The patient may not be able to disclose their status to anyone or may have to hide medications in their home. Develop a plan that the patient feels comfortable carrying out.
- Establish or optimize insurance benefits and medication access. A benefits counselor or case manager will usually do this.
- Create an initial care plan based on a needs/acuity assessment.
- Provide ART medications, ideally on the same day and administered by a designated clinic staffer.
- For unhoused patients, support medication storage, for example, through in-clinic self-storage lockers, medication necklaces with daily medication pouches, medication ankle wallets; or work with the pharmacy to dispense smaller quantities that the patient can manage (e.g., unhoused clients who may not be able to hold onto a larger supply).
- Offer counseling on topics like coping, communicating with family and friends, and access to future counseling. Help the patient identify someone they can talk with about their HIV. The patient does not need to disclose to anyone if they are not comfortable doing so.
- Provide linkages/referrals to needed services. Stable housing and substance use treatment are most likely to foster patient success in maintaining care engagement. For example, consider office-based buprenorphine induction for patients with substance use, if needed.
- Be sure the patient schedules a follow-up before the first visit ends and knows the plan for their ongoing care. This step helps demonstrate that they are being supported and will have continuing access to care.
- Obtain any necessary specimens for the baseline laboratory tests and make arrangements to discuss the results.

One goal of the first appointment is to get the person to return for their second appointment.

Support Retention in Care

Consider the following in supporting patient retention in care:

- Communicate to patients the goal of therapy, which is lifelong HIV care with viral suppression. Additionally, tell patients that effective treatment with viral suppression prevents HIV transmission-- undetectable equals untransmittable (U=U)because individuals with a sustained undetectable viral load will not sexually transmit HIV.
- Schedule future appointments ahead of time, at the first visit.
- Provide rideshare, public transit tokens, or gift cards to attend subsequent visits.
- Consider telehealth visits as an option, or even a preferred method for some future visits.
- Engage a peer navigator, friends, or family to help the patient attend appointments.
- Remind patients to attend follow-up appointments via text messages and phone calls.
- Provide added attention to patients who don't show up (e.g., to determine why they are not coming to appointments and come up with solutions).

Use Data to Support Patients and Track Outcomes

The RWHAP has a robust client-level data system that can readily accommodate data collection on rapid ART. Below are considerations in adding data elements on rapid ART.

Establish Goals and Metrics and Track Data

Goal setting for rapid ART entails looking at the current baseline of patients at your site and determining goals to achieve improvements. Goals and data elements should track:

- Demographics (to help identify variations across patient populations).
- Days from diagnosis to 1st visit, to ART start, and to viral suppression.
- Percentage of patients who accept rapid ART at the time of diagnosis.
- Patient satisfaction or patient experience.
- Percentage of patients who achieve viral suppression.
- Retention rates.

Analysis and Use of Data

Rapid ART data should be used to monitor trends and identify variations across patient populations. Issues, such as disparities in delivery or acceptance of rapid ART, in viral suppression, and loss to follow-up, can be assessed in greater detail to address both individual client needs and programmatic success, and to make adjustments in rapid ART operations.

Data visualization is one of the most effective ways to present data, particularly with a newer rapid ART program where a dynamic presentation of results can bolster clinic provider buy-in on the value of rapid ART.

Observations on Collection and Use of Data

RWHAP agencies are managing rapid ART data in varied ways. Birmingham's 1917 Clinic has developed an engagement in care form for use within their electronic medical records system. The form helps them ensure accuracy and proper documentation. Various EHE jurisdictions are planning to use CAREWare to track rapid ART data. The Baltimore City Health Department envisions more chart review and new processes to review new patients more frequently to prevent people from falling through the cracks. Baltimore also wants to compare patient data from year to year to identify trends, improvements, and challenges, like making comparisons between those lost to follow-up and those starting rapid ART for the first time. The San Francisco Bay area is developing an areawide rapid ART plan and has identified a need for real-time data in some counties in order to understand successes and gaps in rapid ART delivery. They are developing shared rapid data across the region.

Use Quality Improvement to Make Adjustments

Quality management is one of the fundamental elements of the RWHAP in that funded sites utilize quality improvement techniques to set goals, monitor activities, and make needed adjustments. At the 2020 Ryan White Conference, the Family Health Centers at the New York University Langone outlined their quality improvement work, under which they set goals to improve 3-day and 7-day linkage to care results. Their three steps included:

- Generating a daily report of network-wide HIV results. The data were auto-generated by their system. The HIV data quality manager manually reviewed reports. Navigation staff were alerted to positive results for patients not already known to be in HIV care with the site.
- Establishing a rapid-rapid testing protocol to confirm test results with a different rapid test (consistent with CDC guidelines). A reactive result on two tests allows the site immediately and seamlessly to get patients into HIV care. The protocol outlined roles so that staff understood how linkage to care was to be carried out.
- Conducting provider education via individual staff meetings/huddles and a provider brochure. Provider education also stressed the value of involving patient navigators to help providers in delivering HIV test results.

Challenges

Rapid ART is a relatively new approach and can be resource-intensive in terms of securing sufficient time to support patients, as many have multiple challenges in engaging and remaining in care. Below are some of the challenges rapid ART sites have identified:

- Patients entering rapid ART from referral sources may not initiate ART as rapidly as patients tested in-house. This is simply because the added step of a referral and an off-site visit can lead to some loss to follow-up (e.g., when a patient lacks transportation to a site).
- Some sites are unable to have ready access to medications for uninsured and underinsured patients. This includes clinics without a pharmacy and sites that cannot utilize starter packs due to policy prohibitions.
- Buy-in from providers can be difficult to obtain when staff are asked to prioritize and accommodate rapid ART patients, which can and does happen without warning.
- Clinics may lack sufficient time to spend with patients at the time of diagnosis and subsequent visits.
- Some patients have multiple challenges that can delay initial engagement in HIV care and increase later loss to care. By definition, more staff time and services will be necessary to provide needed support.
- Laboratory costs may be difficult to cover for uninsured/underinsured patients. The major laboratory companies may negotiate lower prices for tests not paid through insurance or even offer free laboratory services as part of a clinic contract. A clinic may be able to use 340b and/or EHE funding, general clinic funds, or community fundraising to cover these costs.

Appendices

Guidelines and Guides

HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV – Initiation of Antiretroviral Therapy

AETC NCRC- Immediate ART Initiation: Guide for Clinicians (2/14/19, updated 2020).

Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults, 2020. Recommendations of the International Antiviral Society–USA Panel.

Protocols

Getting to Zero. San Francisco Consortium. Resources for providers and consumers on rapid ART, PrEP, and testing/treatment/care.
Includes Immediate ART initiation upon HIV diagnosis (provider detailing brochure), San Francisco Department of Public Health, 6/2019.

Louisiana Rapid Start Protocol.

Immediate Initiation of HIV Treatment. NYC Health.

Descriptions of Rapid ART Programs

At the 2020 National Ryan White Conference, multiple workshops and poster sessions were held on rapid ART. Sessions described their protocols, staff training, quality improvement, provider education, and other features. They are posted on TargetHIV.org.

Rapid ART Plans

State of Florida Integrated HIV Prevention and Care Plan 2017–2021. Florida's Plan to Eliminate HIV Transmission and Reduce HIV-Related Deaths includes four key components, including implementing the test and treat model to provide medications as soon as possible after an HIV diagnosis....

New York State, Rapid Initiation of (HIV) Antiretroviral Treatment (RIA), Revised 2019.

California, Laying a Foundation for Getting to Zero: California's Integrated HIV Surveillance, Prevention and Care Plan, California Department of Public Health, 2016.

HRSA HIV/AIDS Bureau and Rapid ART

PCN 13-02- Clarifications on Ryan White Program Client Eligibility Determinations and Recertifications Requirements (Revised 5/1/2019).

HRSA HIV/AIDS Bureau, Rapid ART Eligibility, and Determinations. Letter from the Associate Administrator, HRSA HIV/AIDS Bureau, May 2, 2019. And "Rapid ART Eligibility and Determinations." Letter from the Associate Administrator, HRSA HIV/AIDS Bureau, May 2, 2019.

HRSA's Ryan White HIV/AIDS Program, Engaging People with HIV in Care and Rapid Antiretroviral Therapy Programs to Help End the HIV Epidemic CAREAction Newsletter, September 2019

Advancing Innovation to End the HIV Epidemic: 2019 RWHAP Highlights, HRSA.

Select Journal Articles

Coffey S, Bacchetti P, Sachdev D, Bacon O, et al. RAPID ART: High virologic suppression rates with immediate ART initiation in a vulnerable urban clinic population. AIDS 2019 33(5):825-832.

Colasanti J, Sumitani J, Mehta CC, et al. Implementation of a Rapid Entry Program Decreases Time to Viral Suppression Among Vulnerable Persons Living With HIV in the Southern United States, Open Forum Infectious Diseases, 2018.

Halperin J, Butler I, Conner K, et al. Linkage and Antiretroviral Therapy Within 72 Hours at a Federally Qualified Health Center in New Orleans. AIDS Patient Care STDS. 2018 Feb 1; 32(2): 39–41.

Reports

O'Neill Institute. Leveraging the Ryan White Program to Make Rapid Start Of HIV Therapy Standard Practice.