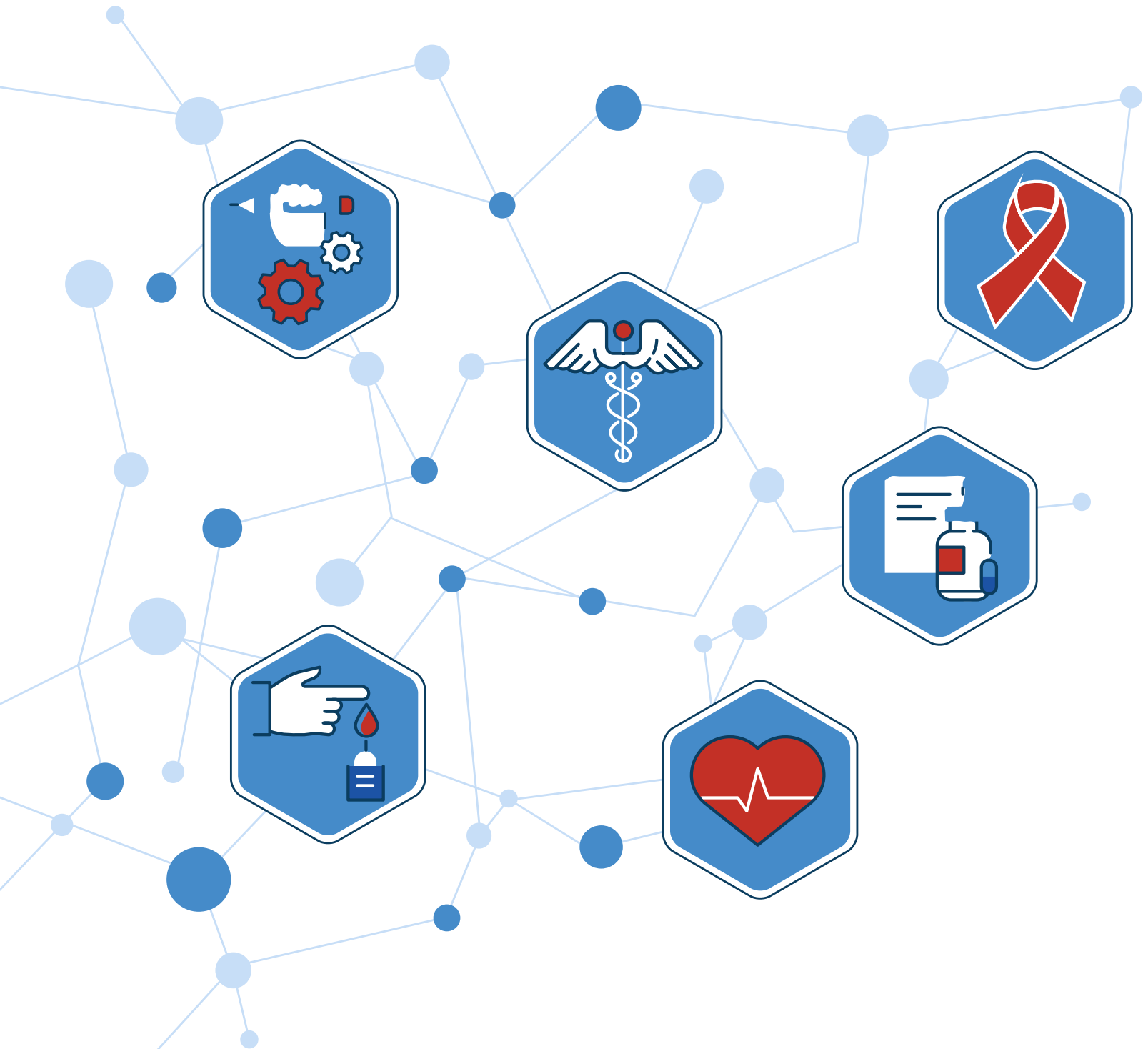


Rapid Antiretroviral Therapy Toolkit



PRIMARY CARE DEVELOPMENT CORPORATION
MY BROTHER'S KEEPER
SAN FRANCISCO COMMUNITY HEALTH CENTERS
DENVER PREVENTION TRAINING CENTER

TABLE OF CONTENTS

Acronym List	2
Introduction to the Toolkit	3
Overview of the Toolkit	3
Initiating ART	6
HIV Navigation Services (HNS)	19
Cost and Program Financing	30
Training and Technical Assistance	34
Conclusions	37
References and Appendices	38

ACRONYM LIST

ADAP	AIDS Drug Assistance Program
AETC	AIDS Education Training Center
ART	Antiretroviral therapy
CBO	Community-based organization
CDC	Centers for Disease Control and Prevention
CDTM	Collaborative drug therapy management
CPA	Collaborative practice agreement
CPN	Capacity Building Assistance Provider Network
DIS	Disease Intervention Specialist
DOT	Directly observed therapy
ED	Emergency department
EHE	Ending the HIV Epidemic in the United States initiative
EHR	Electronic health record
FQHC	Federally Qualified Health Center
HD	Health department
HHS	U.S. Department of Health and Human Services
HNS	HIV navigation services
LTC	Linkage to care
MI	Motivational interviewing
MOU	Memorandum of understanding
NHCLC	National HIV Classroom Learning Center
OSU	Oklahoma State University
PCHCM	Patient-Centered HIV Care Model
PWH	People with HIV
RW	Ryan White HIV/AIDS Program (Funding program)
SBIRT	Screening, Brief Intervention, and Referral to Treatment
TA	Technical assistance
VDH	Virginia Department of Health

Introduction

Over the past two decades, human immunodeficiency virus (HIV) treatment has transformed the HIV prevention landscape and dramatically improved the health, quality of life, and life expectancy of people with HIV (PWH).

The U.S. Department of Health and Human Services (DHHS) [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents](#) recommends antiretroviral therapy (ART) for all PWH regardless of CD4 count, given the effectiveness of HIV treatment in preventing transmission of HIV (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2022). The [National HIV/AIDS Strategy \(2022-2025\)](#) highlights the need to reduce new HIV diagnoses, improve linkage to and retention in care, increase viral suppression, and reduce HIV-related health disparities among key populations. One essential part of the [Ending the HIV Epidemic in the U.S. initiative](#) (EHE) is to offer people immediate access to HIV treatment after diagnosis to decrease the time to viral suppression. Rapid ART is defined as starting ART as soon as possible after HIV diagnosis. According to the [National HIV/AIDS Strategy \(2022-2025\)](#), "programs focusing on the immediate (ideally same day or within 7 days after diagnosis) initiation of ART have demonstrated success and are expanding in communities across the nation." Rapid ART programs benefit from multidisciplinary teams that provide access to clinical care, navigation, pharmacy, and financial services while collaborating with health departments (HDs) and community-based organizations (CBOs).

Overview of the RAPID ART Toolkit

Purpose of This Toolkit

This toolkit describes how to initiate, enhance, or maintain rapid ART in various settings; develop and sustain linkage to care (LTC) activities; and includes resources to develop staff skills in implementing a rapid ART program. This toolkit outlines promising practices for HDs; CBOs; clinical settings, especially those that do not receive Ryan White HIV/AIDS Program funding, such as Federally Qualified Health Centers (FQHCs); and community-based pharmacies. Finance and training resources are also provided to support rapid ART efforts.

The Rapid ART Toolkit was developed in collaboration with CDC and national subject matter experts using published evidence and best practice examples of rapid ART implementation in clinical and non-clinical settings. A comprehensive environmental scan included a literature review and clinical site interviews. The interviews were conducted with nine clinical organizations offering rapid ART services that provide programs to initiate ART quickly to reduce viral burden and decrease transmission. The Rapid ART consortium was consulted and provided a programmatic example relevant to those working in rural and frontier settings. The CBA partners who participated in the toolkit development offered relevant regional and population perspectives that informed the Rapid ART Toolkit development.

Through the Centers for Disease Control and Prevention's (CDC) PS19-1904: Capacity Building Assistance for High Impact HIV Prevention Program Integration, [Primary Care Development Corporation, My Brother's Keeper](#), the [San Francisco Community Health Center](#), and the [Denver Prevention Training Center](#) deliver HIV prevention workforce capacity building to state and local HDs, CBOs, and health care providers. This team, informed by CDC guidance, collaboratively created the toolkit, which offers models, practices, and steps to ensure a culturally responsive approach to reduce disparities in linkage, retention, and re-engagement in care, which in turn supports sustained viral suppression. Furthermore, this toolkit describes benefits and considerations, action planning, relevant resources, and vignettes for skills practice.

How To Use This Toolkit

This toolkit is outlined by specific job title, function, or role within an organization/program and how they fit along the HIV care continuum as it pertains to rapid ART. The user can go directly to the section most relevant to their specific job title, function, or role. Each section also includes bolded blue hyperlinks providing easy access to supplemental materials and key sections of the toolkit. Additionally, as teams and staff utilize guidance and references from the rapid ART toolkit, it may be necessary to tailor activities based on region, setting (urban, rural, frontier), organization type, capacity, and role.

Intended Audience

The intended audience for this toolkit is staff in HDs, CBOs, clinical settings, and community-based pharmacies. Staff holding various roles at an organization, including administrators, patient-facing staff, and those working on finance, billing, and insurance will find the toolkit resources applicable.

- ▶ **Administrators** can gain a high-level perspective of the benefit of rapid ART initiation and organization-wide strategies to enhance rapid LTC and HIV navigation service activities. Key areas for consideration in providing rapid ART services include resource allocation (i.e., planning), organizational readiness, staff capacity (i.e., knowledge, skills, and abilities), training needs, and continuous quality improvement.
- ▶ **Patient-facing staff** can learn how to develop and/or support rapid ART programs through protocols, checklists, and vignettes that demonstrate concepts.
- ▶ **Finance, billing, and insurance staff** can review the Rapid ART program and treatment costs, along with resources for funding.

The boxes below highlight the potential job titles within a variety of organizations offering rapid ART services. This list is not exhaustive and should be considered as a general reference for those utilizing the toolkit.



ADMINISTRATORS

- Program/Branch Directors
- Managers/Supervisors of Implementation Staff
- Project Officers
- Program Administrators
- Owner/Lead Pharmacist
- Clinical Directors



IMPLEMENTING/ CLIENT-FACING STAFF

- Prescribers (i.e., Physician and mid-level)
- Interim Provider
- Case Managers (CM)
- Peer/Patient Navigators
- Pharmacy Technician
- Clinical Pharmacist



FINANCE/BILLING INSURANCE STAFF

- CFO (Chief Financial Officer)
- Medical Billing & Coding Specialist
- Insurance Enrollment Specialist
- Other Administrative Staff
- Legal Administrators-Grants

Toolkit Organization

This toolkit is divided into five sections. Each section has a specific purpose; describes how to implement unique aspects of initiating and implementing ART; and reviews the knowledge, skills, and training required for successful implementation. Additionally, each section identifies which staff from your organization should read the section and how they can best apply the information and resources.

1

Initiating ART

In this section we describe how to initiate ART in clinical, non-clinical, and community pharmacy settings.

2

HIV Navigation Services (HNS)

This section defines LTC and HNS, reviews the roles and responsibilities and skills needed to implement rapid ART programs and describes financial navigation.

3

Cost and Program Financing

This section reviews the financial and insurance considerations for rapid ART programs.

4

Training and Technical Assistance

This section reviews relevant trainings and resources to build and/or enhance your staff's skills to implement rapid ART.

5

Conclusions

This section summarizes the toolkit and provides key resources to support initiating and expanding programs in various settings. This section also provides promising practices, key resources, and lessons learned to support initiating and expanding rapid ART in various settings.

6

References and Appendices

This section contains the references and appendices for this toolkit.

Initiating ART



(See acronym list page 2) This section provides a brief, high-level review of initiating antiretroviral therapy (ART) in clinical, nonclinical, and community-based pharmacy settings.

The Initiating ART section of the toolkit is for the following audiences:

- ▶ Organization audiences: health departments (HDs); community-based organizations (CBOs) and their clinical partners; clinical care settings (e.g., Federally Qualified Health Centers [FQHCs], emergency departments [EDs], and urgent care settings); and community-based pharmacies.
- ▶ Staff audiences: Administrators and implementing/client-facing staff.

General Overview of Initiating ART

Introduction

Rapid ART is defined as initiating ART within 7 days or as soon as possible for those newly diagnosed with HIV. Implementation of rapid ART differs depending on the setting and resources available. Programs will need to identify processes that work best for their populations or setting. In this section of the toolkit, we will introduce two models for ART initiation—immediate start or 7-day start—then detail the steps necessary to identify candidates for rapid ART, initiate ART, and link to HIV continuity of care.

These steps are the same for both models; though the same processes are required in each model, there are several considerations for clinical and non-clinical settings, which will be reviewed in this section. The first consideration is how quickly ART can be provided after a positive HIV test. The key difference in these two models is the type of HIV test available at the time the patient presents for ART initiation. However, the steps by which the patient proceeds from a positive HIV test to initiating ART and finally to being linked to HIV continuity care are the same regardless of whether ART begins immediately or within 7 days. What differs in each model is when and in which order the outlined steps might occur.

Seven-Day Start Model

In this model, ART initiation typically begins a day or more after confirmatory HIV test results are available, preferably within 7 days of the initial HIV [antigen/antibody] test result. ART is not initiated at the point of HIV testing but is achieved through rapid linkage to care, which will be covered in the next section. Programs may choose this model for a variety of reasons including but not limited to:

- ▶ **Availability or co-location of clinical staff**
- ▶ **Turnaround time for baseline laboratory testing**
- ▶ **Experience of the clinician prescribing ART**
- ▶ **Availability of additional resources**
- ▶ **Local HIV prevalence and the populations served**

The benefits of a 7-day start include time for patients to acclimate to their HIV diagnosis and for organizational patient-facing staff to start psychosocial support services (e.g., determining need for addiction counseling services, housing assistance, transportation assistance) and to enroll the patient in insurance and financial assistance programs before the first medical visit. However, one potential downside of the 7-day start is that the patient may be lost to follow-up between testing and initiation of ART.

Immediate Start Model

This section focuses on how ART initiation can be achieved at the point of HIV testing or on the same day as HIV testing. Programs could start ART before completion of confirmatory HIV testing. In some cases, this means beginning ART based on a positive lab-based antigen/antibody test, and in other cases, after a positive point-of-care antibody/antigen result. With the immediate start model, clinical care initiation takes place the same day as the initial positive HIV result.

One consideration to starting ART based on the preliminary positive result is that the HIV test could be a false positive, which happens in a small percentage of persons. This requires clinicians to discontinue unnecessary ART as soon as possible if confirmatory test results are negative. Clinicians can mitigate this risk when starting ART by performing two serial/sequential rapid tests on the same day. Two rapid HIV test results increase the likelihood of a true positive and support starting ART immediately. In a population where HIV prevalence is high, the probability of an HIV test being a false positive is less likely than one where HIV prevalence is much lower. As such, the likelihood of needing to stop ART due to false-positive results is lower in high-prevalence HIV settings. It is important to understand the local prevalence and decide whether this rapid ART model suits your setting.

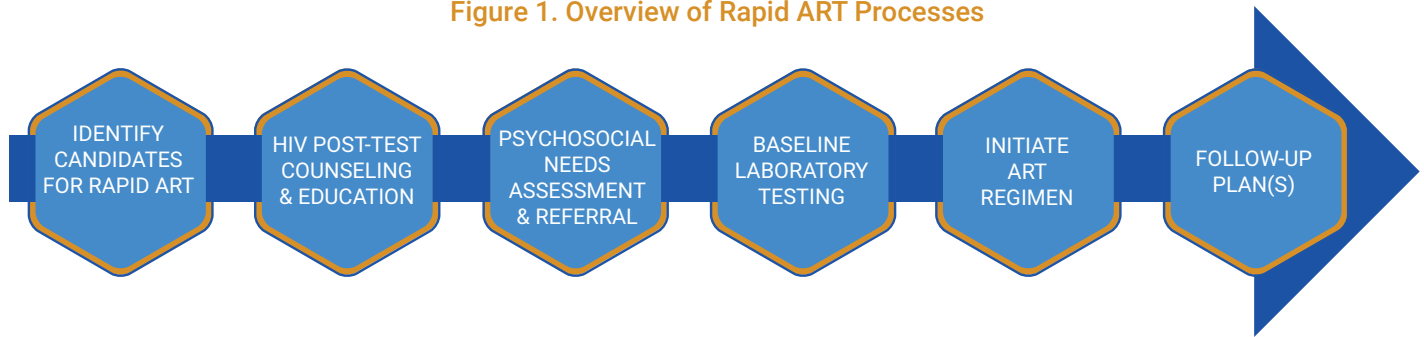
In both the immediate and 7-day start models, the steps from the HIV test result to linkage to HIV care are the same. The difference is the time between identifying appropriate candidates for rapid ART and administering the first dose of ART. Next, we will review the steps required to initiate ART in more detail, regardless of whether the patient is starting immediately or within 7 days.



SERIAL RAPID HIV TESTING ALGORITHM FOR IMMEDIATE START MODELS

If deciding to start ART based on positive point-of-care test results, build an algorithm based on the proposed rapid HIV testing algorithm by (Delaney et al., 2016).

Figure 1. Overview of Rapid ART Processes



Identifying Rapid ART Candidates

Identifying rapid ART candidates for your program is a crucial first step in deciding how to implement rapid ART and may help guide selection of the appropriate ART initiation model (immediate versus 7-day start). Note that selection of an initiation model is dependent on the setting and the availability of clinical and nonclinical personnel needed to execute the tasks outlined above in Figure 1. Appropriate candidates for rapid ART include people with:

- ▶ **A new reactive point-of-care HIV test (consider if testing a population with high prevalence)**
- ▶ **A new diagnosis, including those recently diagnosed with acute HIV**
- ▶ **Willingness to start ART**
- ▶ **Previously diagnosed HIV infection and one of the following:**
 - **No prior ART use.**
 - **Prior ART use without known drug resistance.**
- ▶ **No medical conditions or opportunistic infections that require delayed ART start (see current [DHHS Guidelines](#) for additional details)**

Providing Post-Test HIV Counseling and Education

There is little difference in post-test counseling for rapid ART compared to usual initiation of ART. Members of the multidisciplinary team should assess the patient's readiness to begin and continue ART and identify any barriers that might affect ART compliance. Additional details of the post-test counseling visit including the appropriate psychosocial needs assessment and referral, are available in the linkage to care (LTC) and HIV navigation services (HNS) sections of this toolkit on page 19.

Once it has been established the patient is eligible and ready to begin ART, a baseline clinical evaluation and laboratory tests should be completed per current [DHHS Guidelines](#).

Initiating an ART Regimen

Using the [DHHS Guidelines](#), choose the best regimen based on the patients' current medications, medical co-morbidities, and patient preference. Currently, most medications available for rapid ART are tablet-based regimens. When creating a standardized protocol for rapid ART programs, it is important to consult with infectious disease or other HIV care specialists to discuss which regimens to start. In addition, create consensus among colleagues about which regimens reduce the chance of switching regimens when patient care is transferred from the initial setting to an HIV continuity of care clinic. Telemedicine could also be considered for sites that do not have access to a provider on site to prescribe ART.

Administering the First Dose Onsite

We recommend having ART available onsite and asking patient permission to take the first dose in the clinic under directly observed therapy (DOT). DOT allows patients to start ART the same day they receive the prescription and serves as an opportunity to provide emotional support to patients as needed. Consider making this practice optional rather than a program requirement. Taking ART by DOT start can be supported by a clinician, pharmacist, case manager, navigator, or other staff member with some training on how to provide support. If staffing is limited but time permits, the patient could have someone else in their social support system present when they take their first dose of ART.

Create a clear plan for following up (see Appendix I – Rapid ART Follow-up Plan Checklist) before the patient departs from the intake visit. You may choose to schedule all follow-up visits at this time or plan for the most immediate visit only. It is important to discuss the purpose of these planned follow-up visits with the patient, setting the expectation that their attendance is important while also allowing for some scheduling flexibility to accommodate patient needs. Consider completing visits remotely via telephone or video if needed (see [Telehealth Implementation Playbook](#)).

Twenty-four to Forty-eight Hour Follow-up Visit

Checking in with the patient 24 to 48 hours after their initiating ART can be brief and accomplished remotely via telephone call or video visit. The purpose of this visit is to assess the patient's overall well-being, answer questions, and assess if the patient has any immediate adverse reactions to ART medication(s). The follow-up visit may be completed by any member of the multidisciplinary rapid ART care team. However, we do recommend that the prescribing clinician be available for consultation as needed. In addition, we suggest that this visit include staff to address any outstanding psychosocial issues identified during the first appointment. Finally, this visit is an opportunity to reinforce adherence counseling messages introduced at the post-test counseling visit.

One to Two Week Follow-up Visit

Another follow-up visit should occur within 7 to 14 days after ART initiation. At this visit, we recommend discussing all baseline laboratory results. The goal is to re-assess the patient's medical condition after starting ART. This is an opportunity to assess for early complications of treatment (immune reconstitution syndrome, missed opportunistic infections) or adverse reactions to ART. This is also an opportunity to adjust ART if needed or initiate prophylaxis for opportunistic infections after reviewing baseline laboratory results. Clinicians should complete this visit. Additional members of the multidisciplinary rapid ART team may also be present, depending on the patient's psychosocial needs.

Table 1. Sample Checklists for Follow-up Visits After Initiating ART

24-48 hours Follow-up Visit	1-2 weeks Follow-up Visit
CLINICIAN	
<ul style="list-style-type: none"> ▶ Review lab results and notify patient of results ▶ Touch base with patient regarding new questions about medications ▶ Provide adherence counseling 	<ul style="list-style-type: none"> ▶ Review outstanding lab results and discuss with patient ▶ Discuss and evaluate new medical concerns that have arisen in the interval period ▶ Provide adherence counseling ▶ Discuss any additional follow-up as needed
LINKAGE TO CARE STAFF/PATIENT NAVIGATOR	
<ul style="list-style-type: none"> ▶ Touch base with patient regarding initial visit ▶ Refer for outstanding psychosocial needs, e.g., housing, transportation, health insurance, mental health, or addiction counseling needs ▶ Refer for partner services ▶ Schedule follow-up visits if not already completed 	<ul style="list-style-type: none"> ▶ Re-assess psychosocial needs and provide referrals or follow-up on outstanding referrals as needed ▶ Discuss referral for HIV care ▶ Schedule follow-up visits if not already completed

Telehealth Considerations for Rapid ART Visits

To initiate ART, some of the visits and activities outlined in the previous section could be completed remotely if it is more convenient for the client or program to do so. To support ART initiation via telemedicine, we recommend reviewing the technology available and selecting the telemedicine platform that works best for your organization. Then, identify a staff member who can assist with learning the technology and provide technical support when necessary. Also, consider the differences in required resources between phone and video visits.

When conducting initial phone visits or using video technology, consider:

- ▶ Allotment of time in workflow for an extended phone call.
- ▶ Integration of Health Insurance Portability and Accountability Act (HIPAA) requirements.
- ▶ Paperwork and data collection utilized for case monitoring and follow-up.
- ▶ Patient access to a technology platform.
- ▶ Technology support.
- ▶ Time required for other collaboration and referrals lists.

For a further overview of telemedicine best practices see the: [Telehealth Practitioners Guide for HIV Prevention and Care](#)

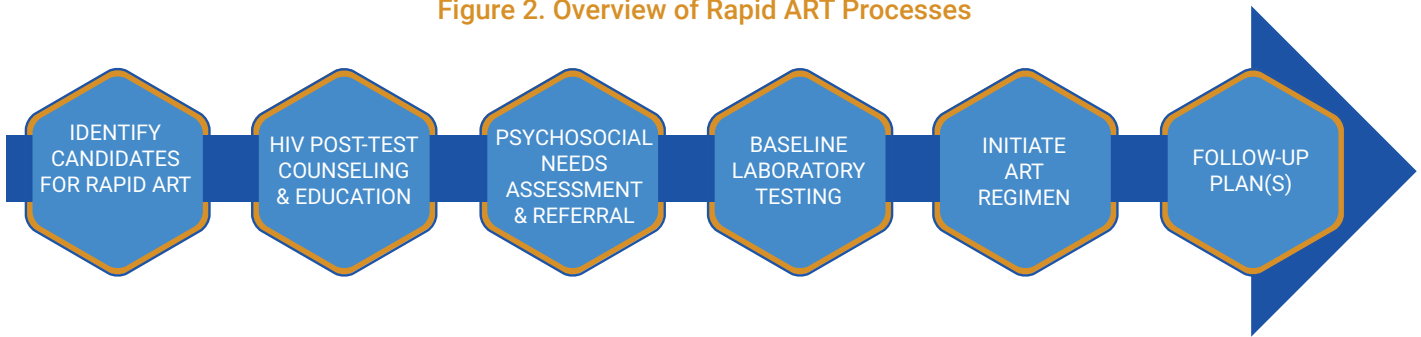
Table 2. Telehealth Considerations

Telehealth	
PHONE VISIT	VIDEO VISIT
<ul style="list-style-type: none"> ▶ Preliminary screenings, lab review, and medication review ▶ The prescription is picked up on site, at a local pharmacy, or mailed to patient's desired location 	<ul style="list-style-type: none"> ▶ If clinical or non-clinical site has access to video technology and a private consultation room, the visit can be conducted remotely ▶ The prescription can be picked up at a local pharmacy or mailed to patient's desired location

Initiating ART in Clinical Settings

This section focuses on clinical settings that are not primarily funded by the Ryan White HIV/AIDS Program (RW) to provide direct health care services for PWH. Examples of these settings include EDs, urgent care clinics, FQHCs, primary care clinics, and sexual health clinics. These are all sites where persons may obtain HIV testing as part of their comprehensive health care services. If the HIV test is reactive, clinicians in these settings can initiate ART before transferring care to a specialty setting, such as an infectious disease clinic or RW-funded clinic. Some primary care clinics or FQHCs have integrated HIV care into their practice and may also serve as the patient's continuity of care site. In either case, whether the patient is being transferred to specialty care or staying at the same site where ART was initiated, the overall process remains the same. However, there are some additional considerations for non-RW-funded clinics noted below in this section of the toolkit.

Figure 2. Overview of Rapid ART Processes



(For more information, see page 8)

Providing Post-Test HIV Counseling and Education

ADDITIONAL RESOURCES

- ▶ **Rapid ART: An Essential Strategy for Ending the HIV Epidemic TargetHIV.** This resource, created on behalf of the Health Resources and Services Administration, outlines how to strengthen or develop a rapid ART program. Additional resources for ending the HIV epidemic are also available at the TargetHIV website link above.
- ▶ **Rapid (Immediate) ART Initiation & Restart: Guide for Clinicians.** AIDS Education & Training Center Guide: This guide is a distillation of best practices for immediate ART initiation and is based on resources from San Francisco's Getting to Zero and San Francisco General Hospital's RAPID program.
- ▶ **Integrating HIV Care, Treatment & Prevention Services into Primary Care – A Toolkit for Health Centers** offers resources, tools, and promising practices that can be adapted by organizations seeking to integrate HIV testing, prevention, and management into primary care settings. The toolkit spotlights examples of primary care-public health partnerships to expand the provision of HIV care and prevention services.

Setting Considerations for Initiating ART

Here are some additional considerations for initiating an ART regimen in specific clinical settings.

- ▶ Urgent care and EDs: As follow-up most likely occurs outside of this setting, clinicians should consider prescribing a limited supply of medication (for example, a 7-day supply) and facilitate timely follow-up in the setting where the patient will receive HIV care. If giving a limited supply, it is imperative that the patient leaves with a clear follow-up plan and scheduled appointments.
- ▶ FQHCs or other primary care settings: After initiating ART, it would be acceptable to prescribe up to a 30-day supply of medication and follow the recommended activities until the 2-week follow-up. If the primary care or FQHC setting does not have HIV care integrated into clinical operations, the patient may be transferred to an HIV continuity of care clinic after the 2-week follow up appointment at the latest.

Follow-up Visits

Schedule the next medical visit quickly after the urgent care, ED, or clinic visit. Rapid linkage to continuity care limits the risk of patients being lost to follow-up and having a gap in the continuation of medication after the initial appointment. Any follow-up appointment should be scheduled before the patient leaves the initial visit. The example follow-up visit schedules below are more suited for clinical sites where some continuity care can be provided such as primary care or sexual health clinics.

Twenty-four to Forty-eight Hour Follow-up Visit

The 24 to 48-hour follow-up visit can occur with a member of the rapid ART team or if your program is able to quickly transfer to an HIV continuity of care clinic, this visit may also occur there. When ART is initiated in clinical settings where an infectious disease specialist may be unavailable to provide HIV continuity care, consider transferring the patient to an HIV clinic or infectious disease specialist after this visit. However, availability of appointments at HIV continuity of care clinics is often a limiting factor. Ensure the follow-up visit can be completed within 2 weeks of ART initiation. Given that the purpose of this visit is to assess the patient's overall well-being, answer questions, and assess if the patient has any immediate adverse reactions to the ART medication(s), this visit may be completed by any member of the multidisciplinary rapid ART team.

One to Two Week Follow-up Visit

As noted above, the purpose of this visit is to re-assess for early complications of treatment (immune reconstitution syndrome, missed opportunistic infections) or adverse effects of ART. This is also an opportunity to adjust ART if required or initiate prophylaxis for opportunistic infections after reviewing baseline laboratory results. When ART is initiated in clinical settings where an infectious disease specialist may be unavailable, consider transferring the patient to an HIV clinic or infectious disease specialist prior this visit so that any new concerns that arise may be addressed by a specialist.

If unable to transfer care by this point, the 1 to 2-week follow-up visit should be completed by the rapid ART clinician. After this visit, every effort should be made to connect the patient to HIV continuity of care within 4 weeks of ART initiation. Primary care clinics or FQHCs with HIV care integrated into their clinical operations may continue to follow patients every 3 months after this visit.

CLINICAL CONSULTATION FOR RAPID ART VIA THE UNIVERSITY OF CALIFORNIA SAN FRANCISCO'S WARMLINE

▶ [Peer-to-Peer for Clinicians on HIV/AIDS Management](#)

Initiating ART in Non-Clinical Settings

For this toolkit, a non-clinical site is defined as one outside of a clinic where HIV testing is available, such as mobile testing sites, CBOs, and pharmacies. This section begins at confirmation of HIV diagnosis instead of following the steps outlined in [Figure 1 on Page 8](#), since non-clinical settings provide HIV testing. Furthermore, to successfully initiate ART in non-clinical settings, several partnerships and collaborative agreements are likely needed; partner organizations may include HDs, pharmacies, and clinics. Once these agreements and partnerships have been established, clinical partners may follow the steps outlined in the overview of rapid ART section. This section will instead outline considerations for non-clinical settings establishing rapid ART programs in partnership with a clinical site(s).

Confirmation of HIV Diagnosis

Additional testing to verify previous results may be done onsite or in partnership with a private laboratory, health department, or public health lab. Ideally, confirmatory testing is completed shortly after the preliminary positive result. Once confirmatory testing is completed, the non-clinical site links the patient to a clinic to begin rapid ART.

Establishing Partnership(s) with Clinical Sites

Start by identifying a clinical site where HIV care and management are provided that are culturally responsive to your key populations. If no direct relationship exists, your local HD can help determine an appropriate partnership with a clinical site.

An ideal clinical site for this type of partnership is one where:

- ▶ The first visit to the clinic involves a clinical evaluation and ART is prescribed by a clinician.
- ▶ Flexible scheduling can facilitate easy scheduling of clinical visits with short notice once a candidate is identified for rapid ART.
- ▶ An experienced on-call clinical provider can identify any medical concerns from the initial visit.
- ▶ LTC specialists or navigators are available to assist with getting the patient connected to care.
- ▶ Appointments can be completed virtually with telemedicine. This might be especially helpful for rural or frontier areas where access to HIV care providers may be limited.

Linking to Rapid ART Programs

Once partnerships have been established with relevant clinical, pharmacy, or HD sites, the process from identifying a candidate to start ART to ART initiation can have several iterations depending on the settings and the resources available. Below are some examples of how rapid ART is initiated at different sites.

Rapid ART Vignette

Organization: Oklahoma State University (OSU); RW Clinic embedded within an academic medical institution.
Location: Tulsa, Oklahoma

The OSU program is an example of how collaboration across CBOs, academic medicine practice, RW Clinics, and state HDs can yield innovative results and shared use of resources to provide rapid ART services across a large geographic area, including urban and rural counties. The OSU HIV clinic was first established in 1996 in Tulsa, OK and they started providing services to rural areas using telemedicine in 2014. This HIV clinic is RW Program-funded and offers services to the eastern half of Oklahoma. To stretch their reach, the program collaborates with a community hospital in Poteau, an FQHC in McAlester, and a CBO in Oklahoma City that provides HIV testing services.

OSU has a mobile telemedicine vehicle funded by the university system with expenses shared by multiple departments. The mobile unit is state of the art; it is equipped with an internet connection, an exam room, a computer cart with a monitor, a high-quality camera, and digital software such as electronic health records, digital stethoscope, electrocardiogram, and additional equipment that allows for high-resolution examination of the patient. The mobile unit is staffed by a driver and a nurse. The OSU program is a collaborative practice model that allows remote HIV specialty care provision using specialized telemedicine equipment supported by the local clinic or CBO staff trained in the mobile unit operations. The mobile unit is typically parked outside the designated location. Staff from the clinic or CBO are trained to operate equipment on the mobile unit and assist the patient in getting ready for their telemedicine visit by taking vitals, medical history documentation, and connecting the patient to the specialist in Tulsa using the specialized computer on the mobile unit. This model reduces the need for satellite OSU staff while allowing patients across the state to see a doctor to start rapid ART without traveling hundreds of miles to Tulsa. Partnership with the state HD increased access to ART via expedited AIDS Drug Assistance Program (ADAP) application and approval. This expedited ADAP approval allows patients to get ART at their first visit.

Successes

- ▶ Partnerships established across institutions to share existing resources and expenses; the mobile unit cost alone would be prohibitive for a single clinic, but cost-sharing across departments makes it feasible.
- ▶ Reduction in the administrative burden of ADAP application and approval resulted in expedited access to ART.

Challenges

- ▶ The overall cost of the program: While this was mitigated by sharing resources available in an academic medical center, other programs without well-resourced partners would be challenged to duplicate this program. Also, programs would need to consider the ongoing costs to maintain the mobile unit, the high-tech equipment aboard, and well-trained staff.

Lessons Learned

- ▶ Patients in this program still preferred to meet their HIV care provider in person first to build rapport. The mobile unit was often used for follow-up visits rather than for the initial intake visit. When offered, patients still preferred to drive long distances for the initial intake visit, after which they switched to telemedicine services for subsequent follow-up visits.

This innovative telemedicine program resulted in another opportunity to collaborate with the state HD to create the Test and Treat Program, in which providers offer rapid ART services across the state to clients in their preferred location.

*Approximately 90% of Americans reside within 2 miles of a community pharmacy. Prescriptive authority of pharmacists leads to improved public health access points and outcomes.
—(Qato et al., 2017; Sachdev et al., 2020).*

Initiating ART in Community-based Pharmacy Settings

Community-based pharmacies can include traditional settings, such as neighborhood pharmacies, supermarkets, or general merchandise locations. Other community-based pharmacies are located within larger health systems and clinics (Goode et al., 2019). The community-based pharmacy setting, in collaboration with HDs and CBOs, provides a trusted, easily accessible means for patients to obtain rapid ART services.

Rapid ART initiation can begin in community-based pharmacies where HIV testing may be also being provided depending on the setting.

ART Providers in Community-Based Pharmacies

Pharmacists offer a wide range of generalist or specialist ambulatory care services, including educational consultations, medication management, medication optimization, chronic condition management, patient empowerment, care coordination, health and wellness services, and other services to improve lives of patients in the community. Pharmacists who practice in community-based settings have a track record of improving adherence to prescription medications and, therefore, would make good partners for rapid ART programs (Frederick, 2015).

In collaboration with HDs and clinical prescribers, pharmacists can provide patients with initial ART and provide patient education on regimens. State laws allow pharmacists to prescribe medications, adjust drug therapy, administer vaccines, and perform lab tests under a collaborative practice agreement, though only a select few have expanded authority of pharmacists for certain activities.

Prescribing rapid ART in community-based pharmacy settings can occur in a variety of ways:

- ▶ Pharmacists using telemedicine in collaboration with a clinical provider
- ▶ Pharmacist linking patient to care after a rapid HIV test
- ▶ Partnership with clinical sites and CBOs
- ▶ HD-pharmacy collaboration
- ▶ Pharmacists prescribing via collaborative practice agreement

Collaborative Practice Agreements

A collaborative practice agreement (CPA) allows qualified pharmacists working within the context of a defined protocol to assume professional responsibility for performing patient assessments, counseling, and referrals; ordering laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens. The potential benefit of a CPA in supporting rapid ART services is the expanded reach to implement rapid ART in community-based pharmacies, improving time to viral suppression, and reduce the likelihood of HIV transmission.

Learn more about CPAs with these best practices guide: [Pharmacy Collaborative Practice Agreements](#)

Collaborative Practice Agreement Vignette

Organization: Virginia Department of Health (VDH)
Location: Richmond, Virginia

The Virginia Department of Health (VDH) and Walgreens designed a collaborative effort to offer rapid HIV testing in 2016 at select Walgreens locations that included both rural and urban settings. Rapid HIV testing administered by Walgreens pharmacists were offered daily with no appointment necessary. VDH provided linkage to care services through a 24/7 consultation line operated by state HD staff. Counseling was provided by phone with facilitation of linkage to confirmatory testing, clinical care, and/or other services as needed. This collaboration between a community pharmacy and HD is a model that was effective to provide testing and linkage services across both rural and urban settings in Virginia.

HD & CBO Collaboration with Community-Based Pharmacies

In considering innovations for community-based pharmacies, collaboration with local HDs is a key relationship that provides support, training, linkage to care, and other tools that facilitate rapid ART programming. Likewise, community-based pharmacies' connections to CBOs also facilitate rapid ART initiation.

Considerations for Rapid ART in Community-Based Pharmacy Settings

Table 3 below outlines some general recommendations for community-based pharmacies implementing rapid ART programs. It is essential to review and understand facilitators while identifying and mitigating barriers, as well as organizational capacity needs before offering rapid ART for patients.

Table 3. Facilitators and Barriers for Rapid ART in Community-Based Pharmacies

Facilitators	Barriers
Ease of access, convenience	Legislative barriers unique to each state that impact pharmacist scope of practice
Community pharmacists are trusted stewards of medical and health information	Time required to complete paperwork, participating in training; a workflow that includes time with rapid ART clients and partners
Community pharmacists have extensive training and expertise on biological effects of medication	The scope of practice can limit payment structures, and services provided may be non-billable

Confirming HIV Diagnosis in Community-Based Pharmacies

Community-based pharmacies or other partner sites (clinical sites, CBOs, and HDs) can conduct initial HIV testing. Then, through partnerships with HDs, clinical sites, or standing labs, complete the confirmatory testing. In addition, pharmacies can partner with LTC or HIV navigation support organizations with the time and skills to quickly access initial and confirmatory testing. It is imperative for pharmacy sites to develop these relationships and agreements before beginning the rapid ART program to avoid lapses in services.

For more information on HIV testing in non-clinical settings, see the Centers for Disease Control and Prevention resource:

- ▶ [HIV Testing in Nonclinical Settings](#)
- ▶ [HIV Testing in Retail Pharmacies](#)

Initiating ART Regimens in Community-Based Pharmacy Settings

Pharmacist prescriptive authority in the US occurs on a continuum with four identified models: patient-specific collaborative prescribing through CPAs, population-specific prescribing through CPAs, statewide protocols, and class-specific prescribing.

Initial Visit and Follow-up Plan Considerations

Careful preparation for rapid ART services during the initial visit is essential for both the patient and the community-based pharmacy site. The initial visit is the first opportunity for the pharmacy team to build rapport with the patient, provide rapid ART services, and provide a lasting connection with LTC and other services. In a community-based pharmacy, there are several considerations for the initial visit. The most critical issues are the pharmacy staff involved, workflow, billing, and technology. Initiation via the pharmacy model requires a multidisciplinary collaboration with HDs, clinical prescribers, administrative support, and roles to manage HIV navigation (case manager, LTC, and community organization staff).

We recommend conducting the initial visit in a quiet, private space. Be sure to provide culturally responsive educational materials about being diagnosed with HIV, the importance of early treatment, and clinical and non-clinical support services (mental health, finance, health care) in the community. Finally, consider using telemedicine to complete some of the visits with the pharmacist or the clinician providing ART. Telemedicine considerations for initiating ART are mentioned in the overview section on [page 10](#).

Developing a Follow-up Plan

Based on the prearranged CPA or memorandum of understanding (MOU), arrange coordinated plans for clinical care and pharmacy pick-up to avoid missed dosing or loss to follow-up. In addition, pharmacies can continue adherence counseling and medication monitoring in collaboration with clinical partners.

Linking to Rapid ART Programs

Before beginning the rapid ART program, community-based pharmacies need to develop and agree upon CPAs or MOUs to ensure clarity of roles and responsibilities for the pharmacy and collaborating organizations.

Table 4. Summary of Key Steps for Developing a Community-Based Pharmacy Rapid ART Program

Key Steps for Developing a Community-based Pharmacy Rapid ART Program	
STEP	ACTIVITY
1	Arrange CPA or MOU with HD or clinical site
2	Plan for workflow and billing
3	Create linkage plan with local HD, CBO, and clinical site
4	Plan for HIV diagnosis and confirmation (internal or with testing site)
5	Access training for pharmacist and staff
6	Create space for patient counseling and ART initiation
7	Plan for follow-up and collaboration with clinical provider

Note: Some services, even under a CPA, might not be reimbursable or have additional considerations regarding reimbursement for pharmacists.

Final Thoughts

Rapid ART programs in clinical, non-clinical, and community-based pharmacy settings rely on a multidisciplinary team working together to ensure patients' progress through each step, from identifying appropriate candidates to initiating the appropriate ART regimen and establishing the follow-up plan. Initiating ART in clinical sites includes a few key steps:

- ▶ Identifying appropriate candidates for ART based on the clinical characteristics of the patient.
- ▶ Providing post-test HIV counseling and education.
- ▶ Identifying psychosocial needs of the patient and making the appropriate referrals for services, such as housing, substance abuse counseling and treatment, and insurance enrollment

In clinical settings, ART should be initiated after a baseline laboratory and clinical evaluation; this evaluation and the choice of an appropriate treatment regimen should be based on the current clinical guidelines. In addition, making a clear follow-up plan with the patient and the multidisciplinary team involved in the patient's care is important to ensure the patient progresses from initiation to continuity care.

In non-clinical settings, successfully initiating ART relies on strong partnerships with clinicians, pharmacies, HDs, and clinical sites where a PWH can be quickly connected to an established rapid ART program. This will require care coordination across multiple organizations with warm handoffs and a clear delineation of roles for each role and organization involved.

As we consider the current state of provider availability for rapid ART, community-based pharmacy settings are a key underutilized resource supporting the EHE initiative. They can enhance provider availability to treat HIV infection rapidly and effectively achieve sustained viral suppression. Research shows when pharmacists and primary medical care providers share patient information and collaboratively address ART-related challenges, HIV outcomes—including viral suppression and retention in care—improve.

HIV Navigation Services (HNS)



(See acronym list page 2) This toolkit section is for client-facing staff providing HIV navigation services (HNS), including linkage to care (LTC) for rapid ART, and those overseeing rapid ART programs and frontline linkage staff.

This toolkit is also relevant for program administrators within state and local health departments (HDs), community-based organizations (CBOs), AIDS Service Organizations (ASOs), and community-based pharmacies.

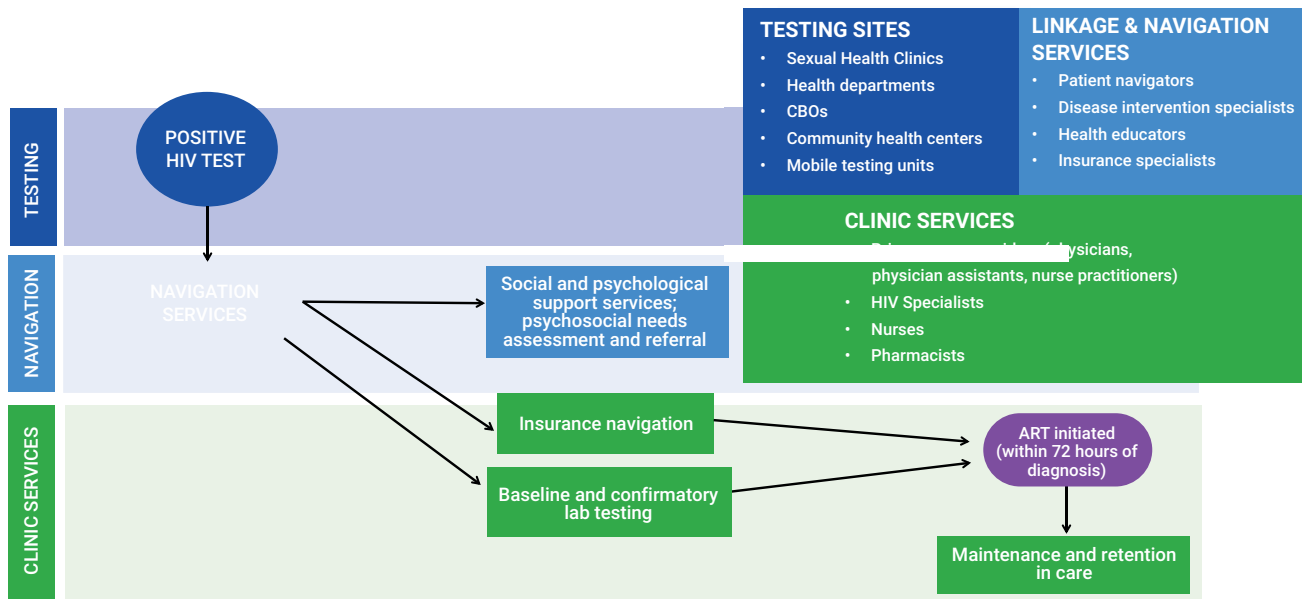
HNS and LTC may be carried out by staff with varying roles and skill levels within a particular setting. Therefore, this section will be necessary for all multidisciplinary team members, as roles often overlap in resource variable settings.

LTC and HNS functions may fall under these titles:

- ▶ Linkage to care coordinators
- ▶ Patient/client navigators
- ▶ Social workers
- ▶ Disease intervention specialists (DIS)
- ▶ Case managers
- ▶ Health educators
- ▶ Insurance specialists
- ▶ CBO staff
- ▶ Health care organizations implementing HIV programs and services

This section will review the essential role of HNS in rapid ART services. It will also describe methods and strategies to adapt existing HIV navigation models to support rapid ART. This section of the toolkit includes a review of staffing needs and considerations for resource-limited settings, suggested protocols, and real-world examples of how to provide services in resource variable settings. This section also reviews key terminology associated with HNS and how roles under this umbrella overlap and complement one another. Program staff providing HNS will often have the most contact with patients starting rapid ART. This relationship can have a significant and lasting impact on ongoing engagement in care and viral suppression. The graphic on the following page is an overview of the early and continuous intersection of HNS for rapid ART. Regardless of delivery model used for rapid ART, robust HNS services are foundational to facilitating access to care, services and financial resources.

Figure 3. The Role of HNS in Rapid ART



Starting with Cultural Humility

Centers for Disease Control and Prevention (CDC)-funded programs using this toolkit and providing HNS will work with people and cultures that may fall outside their understanding of culture; therefore, any efforts to provide these services must start from a place of cultural humility (Boston University Center for Innovation in Social Work & Health, 2019). Applying the following principles to HNS will build trust, which is critical to helping PWH make decisions about starting HIV treatment right away.

- ▶ Suspend judgments
- ▶ Offer empathy
- ▶ Celebrate diversity
- ▶ Systematically check your assumptions
- ▶ Become comfortable with ambiguity

Cultural humility is "a lifelong process of self-reflection and self-critique whereby the individual not only learns about another's culture, but one starts with an examination of her/his own beliefs and cultural identities." (Sufrin, 2019)
 –Cultural Humility, National Institutes of Health

Recognizing the Role of Trauma and Trauma-Informed Care

TRAUMA-INFORMED CARE

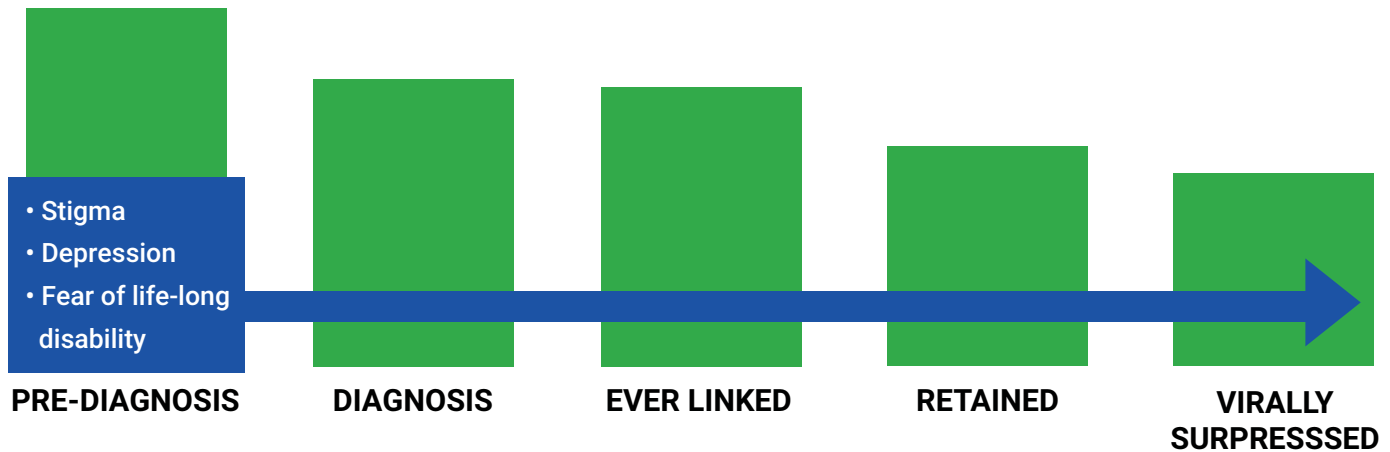
Trauma-Informed care is an approach to administering services in care and prevention that acknowledges that traumas may have occurred or may be active in patients' lives, and that those traumas can manifest physically, mentally, or behaviorally. See the [Trauma-Informed Approaches Toolkit](#) (National Alliance of State & Territorial AIDS Directors, 2020).

In addition to approaching HNS and rapid ART from a place of cultural humility, it is essential to recognize that many PWH have had traumatic experiences. Diagnosis and the process of linking to and engaging in care can also be traumatic events. Therefore, it is critical to provide “low-threshold services” and “beyond the office” support when helping people with a history of trauma link to care (National Alliance of State & Territorial AIDS Directors, 2020).

According to the Substance Abuse and Mental Health Services Administration, 70% of PWH have experienced trauma, and PWH are twenty times more likely to have experienced trauma than the general population.
 – Substance Abuse and Mental Health Services Administration 2020

Traumatic experiences impact the HIV care continuum and influence whether a person contracts HIV, is diagnosed, starts treatment, stays in care, and maintains viral suppression. The graphic below highlights the importance of addressing trauma at every stage of the continuum.

Figure 4. Trauma and the HIV Continuum



Traumas related to HIV diagnosis

- HIV care (invasive procedures, staff)
- Systemic abuse and/or insensitivity
- Cost of care & benefits navigation
- Obstacles to care
- Hypervigilance of labs, diet, appointments, & medication
- Medications for life – sometimes many pills
- Anniversary dates

**Figure reproduced from the Trauma-Informed Approaches Toolkit (National Alliance of State & Territorial AIDS Directors, 2020)*

HIV Navigation Services

Understanding how trauma and culture impact decisions about starting HIV treatment is fundamental to providing comprehensive and supportive HNS. This section of the toolkit provides an overview of HNS including roles and activities that fall under this umbrella and how they can support linkage, engagement, and retention in care to achieve and maintain viral suppression (Mizuno et al., 2018).

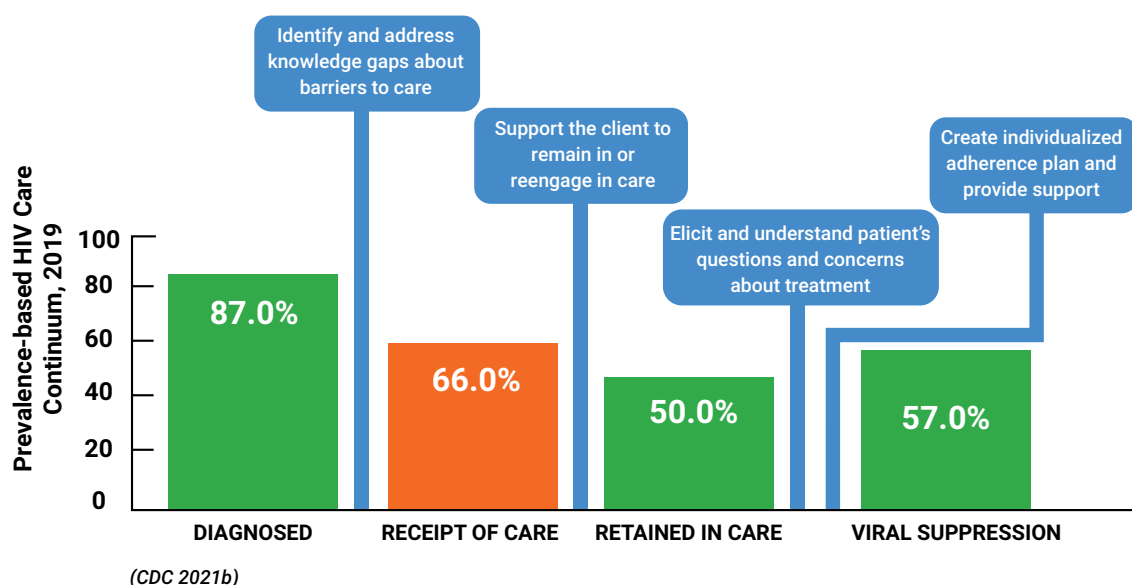
Navigators provide one-on-one “hands on” guidance and support to individuals in HIV care and treatment and coordinate services between community and clinical settings (Dombrowski, 2020). Patient navigation, as part of HNS, supports rapid start ART by ensuring that patients have timely, consistent, and sustainable support to address treatment. Additionally, HNS staff are often well-positioned to provide LTC for rapid ART in resource-limited settings.

The graphic on the next page highlights how those providing HNS help PWH achieve and maintain viral suppression across the care continuum.

HISTORICAL CONTEXT

Patient navigation is a support service specifically designed to help individuals find their way through complex and often fragmented medical or health-relevant systems initially developed to address disparities in cancer mortality (Koenig et al., 2021).

Figure 5. HIV Prevention in Care Objectives



Rapid ART Linkage to Care (LTC)

LTC is a critical HNS activity in rapid ART. For this reason, this section will focus on this activity as it relates to rapid ART and provide a suggested LTC protocol for rapid ART programs. LTC is broadly defined as a process to link persons with newly diagnosed HIV to HIV medical care and ART initiation as soon as possible (Dombrowski, 2020).

In the absence of dedicated LTC staff, this role may be filled by those providing HIV services, including patient navigators, social workers, community health workers, case managers, or peer support specialists.

Ryan White early intervention services are another resource if such services are available in the region where LTC services are being provided.

Because rapid ART shortens the timeline to treatment, the role of LTC is magnified and may include addressing several steps in the linkage process in one visit. Therefore, the person providing LTC services in this setting should be the primary contact for patients. At a minimum, programs should have someone who can offer the LTC services described below at the time of rapid ART (Pilcher et al., 2017; Halperin et al., 2018); these services will be discussed in greater detail later in this section.

CDC RESOURCE

Steps to Care is an evidence-based linkage to, retention in, and reengagement in HIV care strategy. [STEPS to Care Toolkit: Dashboard](#)

STAFFING

Staffing resources will vary depending on clinic settings, budgets, and personnel. In the absence of a dedicated LTC and HNS staff, program administrators should look at similar or overlapping roles within an organization and possible partnerships.

HNS and LTC Services

- ▶ Post-test counseling, education, and support
- ▶ Navigating confirmatory testing needs and referrals
- ▶ Assessing barriers to taking daily medication and engaging in care
- ▶ Assessing and addressing medical and medication coverage needs
- ▶ Making referrals to ancillary services
- ▶ Accompanying patients to testing, treatment, and intake appts
- ▶ Providing early intervention for missed visits

LTC Referral Process

Successful LTC in a rapid ART program will require collaboration between clinical and non-clinical staff and may, in some cases, require cooperation between organizations and systems to ensure that individuals newly diagnosed with HIV can fully benefit from rapid ART.

People with newly diagnosed HIV will require direct referral to LTC staff and a clinical provider to prescribe ART. Programs that have clinical care and clinicians onsite will need to consider provider availability and establish dedicated protocols for rapid ART. Programs that do not reliably have an onsite provider will need to identify clinical partners committed to providing rapid ART and develop a referral process with input and memorandums of understanding from all parties. All programs should aim to create a “low threshold” for engagement by limiting the number of handoffs and prioritizing warm handoffs whenever possible, offering flexible appointment times or walk-ins and documented protocols.

Considerations include:

- ▶ Determine how patients are referred, what is included in the referral, and who processes referrals
- ▶ Create well-defined workflows for clinical and non-clinical roles
- ▶ Standardize communication between multidisciplinary teams involved in rapid ART
- ▶ Plan for adapting roles and filling gaps in the absence of staff (discussed in HNS section)

Not all testing locations have the resources to start PWH on ART medication. Here are some examples of rapid ART sites that collaborate with other partner organizations, HDs, and testing locations to initiate ART for newly diagnosed individuals. See [Appendices III and IV](#) for sample referral forms.

HNS Vignettes

Organization Name: Howard Brown Health; Federally Qualified Health Center

Location: Chicago, IL

Team: Linkage to Care, Medical Provider, Pharmacy

Howard Brown collaborates with community testing sites, the HD, and primary providers in the city of Chicago. Referring sites can contact the LTC team directly to schedule an appointment for additional testing and rapid ART. Someone is available to schedule appointments and answer questions until 7:00 pm. During the referral process, the LTC staff will assist with scheduling a clinical visit for the patient. The clinical visit consists of additional testing and a meeting with a medical provider to start ART. Once the referral has been completed, Howard Brown staff will follow the patient. Staff at Howard Brown will ensure that patients receive connections to partner services for testing, behavioral health services, insurance navigation, and community resources.

Each person on the multidisciplinary team has a distinct role in the rapid ART process. The LTC staff helps the patient with available services and schedules visits with various care team members. Moreover, LTC staff ensure that the patient knows the reason for the visit and who they will be meeting. This goal is to ensure that the patient is not overwhelmed at any given time. Howard Brown staff will have the patient meet with one or two individuals per visit unless the patient agrees to meet with more at a given time. The patient can also use LTC staff as advocates to limit the number of contacts with staff. This can include the patient providing information for LTC staff to pass along to other multidisciplinary team members to work on different aspects of the patient's care behind the scenes on the patient's behalf. For example, LTC staff may provide information to the insurance navigator to assist with medication and medical coverage.

Organization Name: Denver Health and Hospital Authority**Location: Denver, CO****Team: Linkage to Care, Medical Provider, Pharmacy**

The Denver Sexual Health Clinic receives referrals to their rapid ART program, known as FAST (Fast Anti-retroviral Start), from community testing sites, syringe access programs, and state and local HDs. The team works with referring partners to connect patients newly diagnosed with HIV to care and treatment as soon as possible. Referring sites can call LTC staff directly through a central call number. LTC staff will schedule the patient for confirmatory lab work and a FAST visit. LTC staff serve as the access point for rapid ART services. The staff assists with viral load and CD4 count testing, scheduling a provider visit, and connecting to other supportive services. The patient will work with the same LTC staff from referral to the program to a continuity care clinic. LTC staff work with the patient and clinic team to address barriers to engagement in care, including insurance navigation, behavioral health referrals, and other community support services. LTC staff rely on established relationships with community partners providing HNS to ensure ongoing support for patients after starting ART. Once the patient begins working with LTC, they can use them as advocates for their care and a resource for HIV information. Having one point of contact for referring entities and the patient limits confusion regarding next steps and allows the patient to feel in control and not overwhelmed.

LTC Visit Protocol

Staff assigned to provide LTC should meet with a newly diagnosed client on the same day of a positive HIV result. In addition to standard LTC practices, staff will determine whether a client is eligible for and would be ready to participate in rapid ART. The steps below are a guide and may be more fully discussed or deferred based upon individual patients. Below you will find a suggested rapid ART LTC protocol for someone newly diagnosed with HIV and for those patients re-engaging in care. Users of this toolkit should adjust the number of interactions and activities listed under each based on client progress and needs and whether they are newly diagnosed or re-entering care. It should also be noted that the steps below refer to non-clinical activities and assessments specific to HNS staff working on LTC for rapid ART programs. The table below provides an example of LTC activities and visits associated with immediate and 7-day rapid ART models; however, activities and timelines will vary depending on the client and context of the program.

LTC Visit Activities	IMMEDIATE START			SEVEN- DAY START		
	LTC Visit #1	LTC Visit #2	LTC Visit #3	LTC Visit #1	LTC Visit #2	LTC Visit #3
Notes	Start ART During This Visit	Can be Virtual	Can be Virtual	Can be Virtual	Start ART During This Visit	Can be Virtual
Provide post-test counseling and basic ART education	✓			✓		
Obtain confirmatory lab	✓			✓		
Review confirmatory lab		✓			✓	
Assess rapid ART eligibility	✓			✓		
Assess rapid ART readiness	✓			✓		
Schedule ART intake visit	N/A			✓		
Assess barriers to care		✓			✓	✓
Develop sustainable long-term care plan		✓	✓		✓	✓
Conduct insurance assessment	✓				✓	✓
Follow-up LTC activities		✓	✓			✓

LTC Visit # 1

LTC staff should meet in person with the PWH at the time of diagnosis whenever possible. Staff will need to have a confidential space and an open timeline for this visit. In addition, staff should start building a trusting relationship with the client by introducing themselves, assuring the client that the staff member will be their primary point of contact. What follows below are suggested steps that fall under the first LTC visit with a new client. There is a proposed order to the steps in this visit. However, the order may shift depending on the client's priorities during the visit.

Post-Test Counseling – Provide post-test counseling per standard practice

✓	Start by asking the patient, “What are you most concerned about right now?” <ul style="list-style-type: none">• Asking this will help to guide your counseling and education
✓	Destigmatize and normalize results
✓	Provide a roadmap for the next steps in the visit
✓	Discuss rapid ART, letting the patient know that they may be eligible to start treatment that day or at the time of confirmatory lab work

Basic ART Education – For people to make informed decisions about starting HIV treatment, any rapid ART program should include ART education during LTC and medical visits. The LTC visit will primarily focus on the importance of daily medication adherence, achieving and maintaining an undetectable viral load, strategies to overcome barriers to taking medication, and thoughts, feelings, and emotions associated with starting treatment.

Suggested ART Messages

- ▶ To control the virus and keep you as healthy as possible, take your HIV medications daily. Find a time that fits your daily routine to help avoid missed doses.
- ▶ Pill dispensers and setting alarms can help keep track of medications.
- ▶ A person with HIV who takes medicine as prescribed, and maintains viral suppression/undetectable, can stay healthy and will not transmit HIV to their sex partners. [HIV Treatment as Prevention](#)

Obtain Confirmatory Labs – Briefly explain the meaning, purpose, and timing of confirmatory lab tests and results; specific labs vary depending on local jurisdiction requirements and lab availability ([see the Initiating ART section above for more details](#)).

✓	Review necessary lab work and timeline for results
✓	If labs cannot be drawn in the room, plan to walk the patient to the lab whenever possible
✓	Schedule a date and time to review lab work with the patient
✓	Confirm contact information and date and time of next appointment (this may happen at the end of the visit)

Rapid ART eligibility assessment – LTC and clinical providers will use eligibility criteria discussed in earlier sections of this toolkit to determine eligibility for rapid ART. Other inclusion and exclusion criteria considerations might include residency outside of the clinical or program service area, access to medical coverage, comorbidities, and HIV treatment history.

Rapid ART readiness assessment – *Only perform this assessment if the person meets inclusion criteria for rapid ART.* A readiness assessment can help identify potential barriers to medication adherence and engagement in ongoing HIV care. This will also allow you to identify the level of support a client might need before initiating ART. Some assessments use open-ended questions, while others use efficacy scales to help patients self-identify strengths and weaknesses around ART adherence (Balfour et al., 2007). This assessment falls into HNS and LTC workflows as a psychosocial readiness assessment. See the textbox for sample questions.

Readiness Assessment Sample Questions

- ▶ **If your other HIV tests are positive, how would you feel about starting medication for HIV as soon as possible?**
- ▶ **Will you be able to take medications daily?**
- ▶ **What would prevent you from starting medications to treat HIV in the next week?**

Scheduling rapid ART intake appointment – If a client meets eligibility criteria and is agreeable to rapid ART, LTC staff should follow the steps below.

- ▶ **Provide a Roadmap:** Let the client know what to expect at the rapid ART intake appointment, including:
 - Appointment length—how long the client should expect the appointment to last
 - What will happen in the visit (i.e., meet the provider, review lab work, additional HIV education, medication counseling, additional lab work, time for questions)
 - Who the client will meet with—this includes the provider and any other staff expected to be part of the visit
 - What will happen after the visit—meeting with LTC, how and where to pick up medication, any additional information or referrals needed
- ▶ **Same-day rapid ART:** If rapid ART is happening at the time of diagnosis, LTC staff will provide a warm handoff to the provider. LTC staff will meet with the client after this visit to schedule a follow-up visit 2 weeks from the start of rapid ART.
- ▶ **Scheduling rapid ART:** If the clinic protocol is to wait for confirmatory lab work, LTC staff will work with the clinical provider and client to schedule a rapid ART appointment as soon as possible. All parties should agree to the date and time of the appointment. LTC staff should review what to expect at the rapid ART visit, including the expected length of the visit (usually 2 to 2.5 hours).
- ▶ **Assess barriers:** When scheduling, LTC staff should help patients self-identify barriers that may prevent them from making it to scheduled rapid ART appointments. LTC staff should work with the client and provider to address and overcome barriers; this might include arranging transportation, making reminder calls, and identifying alternative appointment times or locations.
- ▶ **Reminders:** Provide the client with the time, date, and location of the appointment, send reminders to the client, and meet the client and be the “familiar face” at the rapid ART appointment.
- ▶ **Establishing a sustainable long-term care plan** – Rapid ART is beneficial in helping patients achieve viral suppression and maintain their health by providing linkage to a continuity care clinic for ongoing care. Ideally, linkage to a long term care provider happens within the first 30 days. Insurance is often an immediate barrier to care that should be tackled head-on. Below is guidance for addressing coverage barriers. See Table 5 for specific financial assistance program information.

- ▶ **Insurance assessment:** You may choose to start an insurance discussion with the following script: “My goal is to help you receive excellent HIV care so that you can stay healthy. Many newly diagnosed people worry about treatment costs; there are programs available to help with costs, and I can help you navigate them. To do that, I need to ask some questions about your health insurance status. I know health insurance can be tricky—I am here to help.”
 - **Insurance enrollment:** If applicable, contact enrollment or an insurance navigator to get an appointment the same day as or before the rapid ART intake appointment so that the client can be evaluated for and enrolled in Medicaid or other medical coverage.
- ▶ **AIDS Drug Assistance Program (ADAP):** Start ADAP enrollment if available and appropriate—complete the application with the client, review how to gather necessary supporting documentation, along with the process steps for applying.
- ▶ **Financial assistance programs:** Initiate pharmaceutical medication assistance program enrollment if other coverage is not available or cannot be obtained in a timely manner. See [Appendix V](#) (Financial Navigation) for a detailed table of additional payor sources.

LTC Visit # 2

This visit protocol assumes that the client is starting ART at the second LTC visit. However, some programs may start rapid ART at the time of diagnosis and first LTC visit. As mentioned above, steps and timelines should be adjusted to meet the needs of patients and programs starting rapid ART. This visit happens 30–40 minutes before medical intake for rapid ART and should include the following steps.

✓	LTC will meet with the patient in the clinic 30-40 minutes prior to the scheduled appointment with the provider
✓	Disclosure of confirmatory test result
✓	Address any additional questions that have arisen in the interim
✓	Confirm patient is still interested in starting ART at this visit
✓	Review what to expect during 2-3 hour intake visit
✓	Discuss options for long term follow-up care
✓	Obtain signed Release of Information Form if the patient is being referred to an outside clinic for ongoing care
✓	Walk with the patient to registration, vitals, and labs prior to proceeding to the exam room for the clinical portion of the intake visit

Follow up LTC Activities LTC Visit # 3 (and additional visits as needed)

This visit may be in person or virtual (phone call), depending on the client's preference and LTC staff judgment. This is where all ongoing support needs will be addressed, including linking patients to continuity care and referrals to ancillary services and HNS. What follows is a suggested checklist to ensure that a client's LTC needs have been addressed and they are able to link to continuity care.

- ▶ Follow up with the client about their emotional state after starting medication and provide client-centered counseling.
- ▶ Evaluate the client for additional resources needed, including but not limited to:

- Housing needs
 - Mental health needs
 - Eligibility for any additional medical or medication assistance needs
 - Gather necessary supporting documents for ADAP
 - Substance use counseling/treatment
 - Peer groups for support—Community-based or in an HIV continuity clinic
- ▶ If not completed in visit 1, explain the DIS role and facilitate linkage to DIS and partner services.
 - ▶ Review continuity care options and help the client schedule an appointment for ongoing care.
 - Call the clinic with the client and request an appointment.
 - Discuss support needs (i.e., transportation, reminders, social work, mental health, and substance use disorder resources).

Ongoing LTC Assessment

- ▶ LTC staff should also plan to meet with the client to address any existing barriers to linkage to continuity care if the client is having trouble engaging in care.
- ▶ Notify the provider if additional visits will be necessary and facilitate scheduling.
- ▶ Make referrals to other support services as needed; this may include coordination with other HNS roles that support navigation like DIS, case management, etc., discussed below.

See [Appendix I](#) for a sample LTC client follow-up plan.

Outreach and Re-engagement into Care

In addition to LTC processes and referrals, any program starting rapid ART should have a plan for missed appointments and drop-offs in communication with patients. One way to support retention and minimize the need for re-engagement is to offer flexible appointment times and drop-in appointments where possible. Flexible scheduling may help patients who have difficulty scheduling in advance or keeping appointment times due to competing commitments or other challenges. In addition, teams should discuss the factors that most impact retention in care for their communities and seek input from key stakeholders. Identifying common challenges will help programs develop a thoughtful re-engagement plan.

Outreach Steps

- ▶ Create an outreach plan with rapid ART patients (How would you like to be contacted? Is there another way I can reach you?).
- ▶ Reach out to patients immediately or as soon as possible after missed appointments and referrals.
- ▶ Work with public health and community partners to develop a plan to track and locate rapid ART patients if outreach attempts are unsuccessful.
- ▶ Work with a provider to determine a plan for medication management where engagement in care concerns exist.

HNS Roles that Can Support Rapid ART Linkage and Engagement

We've discussed how HNS providers work with patients, multidisciplinary teams, and organizations to support LTC; next, we'll look at roles that are well-positioned to support rapid ART programs with linkage and ongoing HNS.

Case Management Services

HIV case management, if available, is a way to provide holistic and ongoing support to individuals benefitting from rapid ART. Case managers often work one-on-one with patients to provide long-term support and develop individualized care plans focusing on psychological and clinical care.

- ▶ Onsite case management services – Depending on staffing resources, this person may also be filling other roles, including LTC or patient navigation. Again, teams will need to think through referrals and handoffs to work with different internal team members as they move from rapid ART to engagement and retention in care.
- ▶ Offsite case management – When referring to case managers outside of the rapid ART setting, it will be important to develop strong relationships and clear communication channels with referral agencies. Make sure that community partners providing case management support are aware of the rapid ART program. Develop and document the referral process and workflow so that all team members and community partners are on the same page and can fully support retention in care.

WHAT IF THERE IS NO HIV CASE MANAGEMENT AVAILABLE?

Look for agencies and CBOs that can help fill the gap. This may include local Health and Human Services offices and agencies providing case management for common co-morbidities (e.g., substance use disorders, people experiencing homelessness, harm reduction, and mental health support).

Disease Intervention Specialist/Partner Services

Rapid ART programs should have an established relationship and referral process with local HDs, DIS, and others providing partner services for persons newly diagnosed with HIV. CDC strongly recommends that partner services be initiated within 30 days of diagnosis. As such, DIS are in a unique position to refer those that may have been exposed to HIV for rapid ART programs and provider services. DIS are well positioned to provide short-term LTC support for rapid ART patients (CDC, 2021c).

Peer Navigation

Peer navigators trained to provide HNS can be an incredible resource for both patients and organizations. Peer navigators who are PWH can be especially helpful for rapid ART as they have experience taking daily medication, processing diagnosis, and overcoming barriers to care (CDC, 2021d).

Organizations using peers should remember that they may require additional training resources and supervision. Peers should also be compensated for their time and expertise. Existing peer support services may be adapted to support rapid ART in short-term LTC or ongoing HNS support when available.

Final Thoughts

Any program implementing rapid start ART must have a well thought-out plan for HNS, specifically LTC. Key takeaways for this section include:

- ▶ HNS for rapid start ART should be culturally humble and trauma-informed.
- ▶ HNS staff providing LTC services should follow a protocol that addresses specific challenges of rapid start ART.
- ▶ HNS and LTC activities and duties can be shared or referred out in resource-limited environments; when planning, consider what will be needed immediately and what can be referred out for ongoing client support.
- ▶ HNS staff will need to work with patients to address barriers to engagement and retention in care to ensure that patients who start rapid ART achieve viral suppression and are not lost to care.

Cost and Program Financing



(See acronym list page 2)

This section provides an overview of cost and program funding for rapid ART.

This information is designed for individuals who are responsible for the cost and program financing of rapid ART programs.

Introduction

Financing rapid ART programs can be challenging. Creating a sustainable rapid ART program involves the development of community partnerships and the identification of funding sources. Building a sustainable financial model for a rapid ART program requires knowledge of jurisdictional and organizational funding sources. Diverse funding sources are needed to cover medications, staffing, equipment, and other resources needed to maintain services. Understanding and leveraging jurisdictional resources can help when funding opportunities do not cover the entire cost of implementing rapid ART.

Resources that programs can use to establish and maintain rapid ART programs are included in this section. Cost and program financing can be overwhelming; this section is not an exhaustive list of resources, steps, or actions required to cover the cost of your organization's rapid ART program. This section is focused on identifying jurisdictional resources and potential partner organizations and providing examples of how to fund and sustain a rapid ART program.

Rapid ART: Jurisdiction Financing

Health Department (HD) Role in Rapid ART

(HDs) CAN PROVIDE CRITICAL LEADERSHIP BY:

- ▶ Increasing local and regional awareness on the benefits of rapid ART, and how HD support can enhance efficiency of services.
- ▶ Prioritizing competitive funding for rapid ART. The Health Resources & Services Administration supports the use of ADAP funds to promote rapid ART. HDs can assist organizations interested in implementing such programs through ADAP supplemental grant programs.
- ▶ Supporting monitoring and evaluation. HDs can help local programs track effectiveness and program successes that can potentially lead to securing additional funding streams for rapid ART programs. For example, HDs can assist with measuring process steps and time to initiation/suppression as a measure of program success.
- ▶ Providing guidance to existing organizations in the jurisdiction that are funded to provide HIV care services. HDs can share available resources and facilitate partnerships for rapid ART programs.

HDs CAN EXPEDITE ADAP ELIGIBILITY AND PROCURE STARTER PACKS OF ART BY...

- ▶ Streamlining AIDS Drug Assistance Program (ADAP) eligibility. To reduce the administrative burden on rapid ART programs, ease the cost burden, and assist in building program sustainability, state HDs should consider any of the following strategies in coordination with the RW Planning Council:
 - Allowing provisional same-day eligibility determinations
 - Permitting retroactive coverage for services provided prior to ADAP enrollment
 - Streamlining the ADAP recertification process to minimize gaps in coverage
 - Facilitating purchase of ART starter packs. The availability of starter packs allows rapid ART programs to provide medication to patients while more permanent funding and linkage to care is substantiated.

Collaborative Funding Strategy Vignette

Organization: Oklahoma State University (OSU), Ryan White HIV-AIDS Program Clinic embedded within an academic medical institution.

Location: Tulsa, Oklahoma

The OSU program is an example of how collaboration and relationships with HDs can yield innovative ideas to create and fund rapid ART programs. The OSU HIV clinic is Ryan White HIV/AIDS Program–funded and offers services to the eastern half of Oklahoma. To stretch their reach, the program collaborates with a community hospital in Poteau, a FQHC in McAlester, a CBO in Oklahoma City (providing testing services), and the Oklahoma State Department of Health. OSU has a mobile telemedicine vehicle funded by the university system with expenses shared by multiple departments. This collaboration is an example of leveraging resources and programs to offer rapid ART access to communities across the state of Oklahoma.

According to Dr. Madhuri J. Lad (Assistant Medical Director–Oklahoma State University Internal Medicine Specialty Services), “It felt like our hands were tied in considering how we could provide rapid ART to our rural communities. It turned out, as we began to engage with our state HD, that not only were they willing, but they had ideas to enhance patient access to care and services.”

Partnership with the state HD increased access to ART via expedited ADAP application and approval. This expedited ADAP approval allows patients to get ART at their first visit.

Key financial programmatic benefits are listed below:

- ▶ ART samples are provided for up to 30 days from OSU or Oklahoma State Department of Health.
- ▶ The state HD increased access to ADAP for same-day approval.
- ▶ The state wrote a grant and was funded for nurse practitioners to start testing and treating around the region.
- ▶ The state HD funded laboratory testing and initial medication packs.
- ▶ Telemedicine was also utilized to reach clients in rural communities and initiate rapid ART. Telehealth visits are billable through insurance.
- ▶ Medical residents were used to reduce the cost of clinicians; partnership with a university was an effective strategy.

Ultimately, the state was prompted to complete these efforts by Dr. Lad’s advocacy for the importance of rapid ART access and programming. Building and developing relationships with HDs, community organizations, and clinical care sites can be innovative strategies to provide financial support for rapid ART programs.

Successes

- ▶ The development of partnerships across institutions to share existing resources and expenses; the mobile unit cost alone would be prohibitive for one clinic, but cost-sharing across departments made it feasible.
- ▶ Reductions in the administrative burden of ADAP application and approval resulted in expedited access to ART.

Challenges

- ▶ The overall cost of the program: While costs were mitigated by sharing the resources available in an academic medical center, other programs without well-resourced partners would be challenged to duplicate this program. Also, programs would need to consider the ongoing costs to maintaining the mobile unit, the high-tech equipment aboard, and well-trained staff.

Rapid ART: Organizational Financing

In addition to seeking new funding streams or partnerships for resource sharing, rapid ART programs usually require coordination of new and existing resources. When it comes to financing rapid ART programs, there is no “one size fits all” approach. Developing a funding strategy requires knowledge of the variety of insurance programs and contracts in the state and local area; billing and coding practices; local, state, and federal funding opportunities; status of Medicaid expansion in the state; co-pay payment programs; and relationships with pharmacies, community-based organizations (CBOs), and state and local HDs. The development of community partnerships, especially between HDs, CBOs, clinical sites, pharmacies, and other social service programs are vital for the development of community-wide systems that can expedite early access to ART. A key step prior to building a rapid ART program might include an environmental scan or inventory of the organizations in your area also providing HIV care. Once these organizations have been identified, a next step should include identifying opportunities to partner or share resources to bolster your rapid ART program.

Although HDs are an important source of funding for HIV services, in general, there is no specific funding stream for rapid ART programs. Funding is dependent on availability, local HIV incidence, and established public health priorities. To determine what funding is available from state and local HDs, it is essential to become familiar with key contacts at these agencies. In cases where direct funding is unavailable, there may be opportunities for staff to request other resources. For example, an organization could ask the HD to provide HIV medication in 30-day starter kits or provide provisional ADAP approval to allow for rapid ART in patients newly diagnosed with HIV. For more information to support funding rapid ART programs, see [Appendix VI](#)—How to Maintain Funding from Local and State Health Departments.

Options for Funding a Rapid ART Program (for CBOs, Community-based Pharmacies, and Clinical Sites)

Grant Funding

There are many opportunities for agencies to fill funding gaps through prevention grants. Including rapid ART services within a prevention grant application can help with funding gaps. There are potential opportunities for programs to expand supplemental funding or apply for grants that provide prevention and primary care services. In addition, CBOs can enhance partnerships with HDs and other CBOs and faith-based organizations to facilitate referrals for individuals in need of HIV prevention services. To find specific opportunities for HIV-related services, please visit www.grants.gov, where all federal grants are announced; the site also allows interested parties to apply directly for grants and provides access to a variety of grant writing tools. (Additional information on federal opportunities is also available in [Appendix IV](#) – Financial Navigation Resource Table.)

Many pharmaceutical companies provide grants to organizations to promote community action, to conduct research, or to fund implementation projects. Navigating partnerships with pharmaceutical companies can be challenging, depending on your organization’s policies; however, public-private partnerships can provide avenues for funding rapid ART programs. Funding opportunities are typically posted on various pharmaceutical manufacturers’ websites. See [Appendix VI](#)—How to Maintain Funding from Local and State Health Departments.

Considerations to Decrease Program Costs

Rapid ART programs can decrease overhead costs through appropriate planning and working collaboratively within the organization. Various grants have limitations on the allocated amount for indirect or overhead costs. Organizations should monitor the different streams of funding to ensure overhead costs do not exceed budgets. Organizations should also identify direct costs of the rapid ART program and consider when there might be opportunities to share costs across different programs. For example, when hiring a full-time patient navigator to assist with rapid ART linkage to care, costs could be shared with a program in your department that needs a navigator for other services. This allows the rapid ART program to pay for a fraction of the patient navigator's time while another program pays for another fraction. For those unfamiliar with building budgets for grants and allocating costs, a more detailed overview of grant costs and budget allocation, a helpful guide titled [Cost Allocations for Nonprofits](#) is available here.

Medication and staffing costs are often the most significant costs of rapid ART programs. The 340B program discussed below is an example of how programs can decrease program costs by paying less for ART and represents a key strategy in building sustainability in rapid ART programs. For more information on reducing cost, see [Appendix V—How to Reduce Financial Barriers for Rapid ART programs](#).

340B Drug Discount Program (for HDs, CBOs, Community-Based Pharmacies, and FQHCs)

What is 340B?

The 340B Drug Discount Program was created in 1992 by the federal government and requires drug manufacturers to provide significant discounts for outpatient drugs to eligible health care organizations that serve low-income and uninsured patients, also known as “covered entities.”

In addition to providing discounts and increasing access to medication for patients, 340B helps safety-net providers generate savings that they can use to support their clinical programs and expand additional services into the community in which they are located.

TIP

Additional information and guidelines on how to enroll in the 340B program is available at: [340B Drug Pricing Program | Official web site of the U.S. Health Resources & Services Administration \(hrsa.gov\)](#)

Final Thoughts

There is no “one size fits all” approach to funding and sustaining rapid ART programs. Some key strategies include applying for existing grants from federal agencies or state/local HDs; forming partnerships and sharing resources with CBOs, health care entities, and other organizations providing HIV care; and lastly, if direct funding is unavailable, considering other ways state HDs can support rapid ART programs.

Training and Technical Assistance



(See acronym list page 2)

This section is for program administrators and patient-facing staff and provides a high-level overview of general training recommendations for staff implementing rapid ART programs.

General Trainings to Enhance Rapid ART Implementation

The training considerations for rapid ART programs are designed for HIV workforce staff seeking to maximize the skills and knowledge required to effectively implement rapid ART services in diverse communities.

Training gives program administrators and patient-facing staff the direction, confidence, and skills to carry out assigned tasks.

We recommend program administrators and patient-facing staff have training in the following areas (see next page).

TRAINING TOPIC	DESCRIPTION
Mental Health First Aid	Mental Health First Aid teaches participants to identify, understand, and respond to signs of mental illnesses and substance use disorders. The course also provides participants with the skills needed to reach out to and provide initial help and support to someone who may be developing a mental health or substance use problem or experiencing a crisis.
HIV Testing and Counseling	HIV Testing and Counseling teaches participants how to: <ul style="list-style-type: none"> • Conduct HIV pretest and posttest counseling • Deliver test results using culturally responsive techniques • Develop effective risk reduction options based on test results • Conduct appropriate linkage to care activities
Motivational Interviewing (MI)	MI is a style of communication that is situated between good listening and giving information and advice. MI empowers people to change by drawing out their own meanings, concerns of importance, and capacity for change. Moreover, MI facilitates the natural process of change and honors a patient's autonomy. MI courses often provide training on the vital topic of trauma-informed care and its importance in counseling.
Adherence Counseling	Adherence counseling helps patients develop an understanding of their treatment and its challenges. Adherence counseling also prepares patients to initiate treatment. Additionally, adherence counseling provides ongoing support for patients to adhere to treatment over the long term. Finally, adherence counseling assists clients in developing good treatment-taking behavior.
Case Management (CM)	CM is a strategy where participants assist patients with developing medical goals and enrolling in appropriate wrap-around services.
HIV Navigation Services (HNS)	HNS improves navigation skills for those delivering services to PWH and individuals at elevated risk for HIV acquisition. HNS provides navigators with supplementary information about navigation skills, how navigation fits in the overall field of HIV prevention, structural components of a navigation program, rapport building, cultural humility, and professional conduct. For more information on HNS see Section 2 on page 19 .
SKILLS	
Rapport Building	Rapport building is the process of creating rapport and building trusting relationships between two or more people.

National HIV Classroom Learning Center (NHCLC)

NHCLC provides trainings that support the implementation of rapid ART. The courses are critical for program administrators and patient-facing staff. For more information about the training available through the NHCLC, visit [Training Resources](#).

AIDS Education Training Center (AETC) Trainings

The AETC Program is the training arm of the Ryan White HIV/AIDS Program. The AETC Program is a national network of leading HIV experts who provide locally based, tailored education, clinical consultation, and technical assistance (TA) to health care professionals and health care organizations to integrate high-quality, comprehensive care for those living with or affected by HIV. For more information about the training available through the AETCs, visit <https://aidsetc.org>.

Capacity Building Assistance Provider Network (CPN)

Program administrators and patient-facing staff can access no-cost TA for their rapid ART program. CPN provides no-cost TA and information dissemination to HDs, CBOs, and health care organizations. For more information and to access TA visit [Capacity Building Assistance](#).

Final Thoughts

Several training and TA resources are available for program administrators or patient-facing staff seeking to provide holistic HIV care services, including rapid ART. Training and TA are essential for successful programs and service delivery. Additionally, patient-facing staff benefit from ongoing training and TA in an effort to build capacity to provide culturally responsive treatment and care.

Conclusions

This toolkit is a culmination of processes, practices, and recommendations for rapid ART. Rapid ART programs and service providers can play a crucial role in HIV treatment and prevention by reducing the time to viral suppression for PWH and limiting the risk of transmission. However, coordination, buy-in, and training across multiple entities is needed to successfully initiate and offer rapid ART services.

Initiating rapid ART requires collaboration between programs offering HIV testing, clinical sites, health departments (HDs), and other community-based programs. Whether partners are utilizing the rapid ART immediate start or 7-day model, planning and coordination before working with newly diagnosed patients will result in fewer barriers to beginning treatment. Testing sites and clinical programs prepared to facilitate access to care and services will provide patients with the tools needed to begin ART as quickly as possible, limiting time for disease progression and mitigating concerns about transmission to partners. A multidisciplinary team can address barriers to care and assess physical, social, and psychological needs while enhancing patient engagement. Clinical providers should be knowledgeable about appropriate ART treatment regimens and work with HDs, community-based organizations (CBOs), and other specialty providers who can support seamless access across systems. Staff in administrative roles in HDs, clinical sites, and CBOs can provide process support and offer guidance for developing memorandums of understanding and other legal working agreements.

Utilizing existing HIV navigation services (HNS) and linkage to care (LTC) services can be a key to ART initiation and retention in care. Service providers practicing trauma-informed practices and cultural humility principles are paramount for ART uptake by PWH. HNSs provide guidance to patients in accessing clinical care, insurance, and other services.

Addressing the cost of rapid ART-related clinical, behavioral, and wrap-around services requires utilizing resources from federal, state, insurance, and community organizations. Each rapid ART program will need to assess what is available and may need to access new financial programs, such as patient assistance programs, that will assist in paying for medication costs.

Training for all staff involved with rapid ART that includes cultural humility, trauma-informed care, HIV treatment, and testing along with case management will provide the skills needed to offer inclusive, respectful programming for PWH. In addition, the rapid ART Toolkit offers several national training resources to support new and ongoing rapid ART programs.

Finally, considering innovative rapid ART services such as community-based pharmacies, telehealth, and mobile services that can reach patients where the distance to care can be a barrier is essential for urban, rural, frontier, and other resource-limited communities. The resources and best practices presented within this rapid ART Toolkit can support new and existing programs to provide patients with rapid access to life-saving HIV treatment.

References and Appendices

Balfour, L., Tasca, G. A., Kowal, J., Corace, K., Cooper, C. L., Angel, J. B., . . . Cameron, D. W. (2007). Development and Validation of the HIV Medication Readiness Scale. *Assessment*, *14*(4), 408–416. <https://doi.org/10.1177/1073191107304295>

Boston University Center for Innovation in Social Work & Health. (2019). A Training Curriculum for Using Community Health Workers to Improve Linkage and Retention in HIV Care. <http://ciswh.org/chw-curriculum>

Centers for Disease Control and Prevention. (2021a). Pharmacy: Collaborative Practice Agreements to Enable Collaborative Drug Therapy Management. <https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-cdtm.htm>

Centers for Disease Control and Prevention. (2021b). Monitoring Elected National HIV Prevention and Care Objectives by Using HIV Surveillance Data – United States and 6 Dependent Areas, 2019: HIV Surveillance Supplemental Report 2021; 26 (No. 2). Atlanta, GA: Author. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-26-no-2/index.html>

Centers for Disease Control and Prevention. (2021c). Partner Services. Atlanta, GA: Author. <https://www.cdc.gov/hiv/effective-interventions/diagnose/partner-services/>

Centers for Disease Control and Prevention. (2021d). Effective Interventions: Treat. Atlanta, GA: Author. <https://www.cdc.gov>. <https://www.cdc.gov/hiv/effective-interventions/treat/peer-support/index.htm-l?Sort=Priority%3A%3Aasc&Intervention%20Name=Peer%20Support>

Dombrowski, J. (2020). Linkage to HIV Care [Screening and Diagnosis Learning Module 5]. Seattle, WA: National HIV Curriculum. <https://www.hiv.uw.edu/pdf/screening-diagnosis/linkage-care/core-concept/all>

Frederick, J. (2015, March 13). By the Numbers: How Community Pharmacists Measure Up. Drug Store News. <https://drug-storenews.com/pharmacy/numbers-how-community-pharmacists-measure>

Goode, J. V., Owen, J., Page, A., & Gatewood, S. (2019). Community-Based Pharmacy Practice Innovation and the Role of the Community-Based Pharmacist Practitioner in the United States. *Pharmacy* (Basel, Switzerland), *7*(3), 106. <https://doi.org/10.3390/pharmacy7030106>

Halperin, J., Butler, I., Conner, K., Myers, L., Holm, P., Bartram, L., & Van Sickels, N. (2018). Linkage and Antiretroviral Therapy Within 72 Hours at a Federally Qualified Health Center in New Orleans. *AIDS Patient Care and STDs*, *32*(2), 39–41. <https://doi.org/10.1089/apc.2017.0309>

Koenig, L. J., Higa, D. H., Leighton, C. A., Roland, K. B., DeLuca, J. B., & Mizuno, Y. (2021). Toward An Enhanced Understanding of HIV Patient Navigation as a Health Care Intervention: An Analysis of Navigation in Practice. *AIDS and Behavior*, 25, 4044–4054. <https://doi.org/10.1007/s10461-021-03244-6>

Mizuno, Y., Higa, D. H., Leighton, C. A., Roland, K. B., Deluca, J. B., & Koenig, L. J. (2018). Is HIV Patient Navigation Associated with HIV Care Continuum outcomes? *AIDS (London, England)*, 32(17), 2557–2571. <https://doi.org/10.1097/QAD.0000000000001987>

National Alliance of State & Territorial AIDS Directors. (2020). Trauma-Informed Approaches Toolkit. Washington, DC: Author. <https://nastad.org/resources/trauma-informed-approaches-toolkit>

Qato, D. M., Zenk, S., Wilder, J., Harrington, R., Gaskin, D., & Alexander, G. C. (2017). The Availability of Pharmacies in the United States: 2007–2015. *PLoS ONE*, 12(8), e0183172.

Panel on Antiretroviral Guidelines for Adults and Adolescents. (2022). Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV: Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportu-nistic-infection/>

Pilcher, C. D., Ospina-Norvell, C., Dasgupta, A., Jones, D., Hartogensis, W., Torres, S., Calderon, F., . . . & Hatano, H. (2017). The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting. *Journal of Acquired Immune Deficiency Syndromes*, 74(1), 44–51. <https://doi.org/10.1097/QAI.0000000000001134>

Sachdev, G., Kliethermes, M. A., Vernon, V., Leal, S., & Crabtree, G. (2020). Current Status of Prescriptive Authority by Pharmacists in the United States. *Journal of the American College of Clinical Pharmacy*, 3(4), 807-817.

Substance Abuse and Mental Health Services Administration and Health Resources and Services Administration (2016). The Case for Behavioral Health Screening in HIV Care Settings. HHS Publication No. SMA-16-4999.

Sufrin, J. (2019, November 5). 3 Things to Know: Cultural Humility. Austin, TX: Hogg Foundation. <https://hogg.utexas.edu/3-things-to-know-cultural-humility>

Appendix I: Sample Client Follow-up Plan

Rapid ART: LTC Client Follow-up Plan

This document was created by HIV navigation services staff in the Denver Sexual Health Clinic to guide non-clinical LTC activities for clients starting rapid ART. This document is a sample plan that should be adapted to specific program contexts with a client-centered lens.

During rapid ART visit – The following should be covered at the time of initiation visit.

- ▶ Contact information: How do you prefer to be contacted?
 - Preferred contact – (telephone, email, text/SMS, client portal, other)
 - Contact information – (phone #, mailing address, email, emergency contact)
 - Emergency contact – review what information can be shared with the emergency contact and have the client sign a release of information.
- ▶ Schedule 2-week follow-up appointment: Schedule the date and time that works best for the client to have medical and LTC follow-up appointment. Review the date and time with client and agree on the best way to send the client a reminder for the appointment.
- ▶ Check-in within 24 to 48 hours: How are you feeling since starting treatment? Have you had any trouble remembering to take your medication? What thoughts and feelings are coming up since starting treatment?

Two-week and ongoing follow up – The following should be covered at the 2-week visit and carryover LTC visits.

- ▶ Check-in: How are you feeling since starting treatment? Have you had any problems taking medication every day? What is working well? What has been difficult?
- ▶ Insurance/Financial Assessment (this may have been addressed in the ART initiation visit and will likely be ongoing until the client is linked to continuity care): Do you have insurance or medical coverage? Determine what coverage or financial assistance is needed to facilitate linkage to continuity care after rapid ART.
 - Employment/Income Status – How do you support yourself? What is your current monthly income? Is your income from employment or another source? Does current income support basic needs?
 - Insured – review coverage and determine if client is eligible for financial assistance programs.
 - ▶ AIDS Drug Assistance Program (ADAP) – If eligible for additional support through ADAP, complete application and collect supporting documents.
 - ▶ Manufacturer support – If over income for ADAP, help the patient enroll in Client Assistance or co-pay programs
 - Uninsured—Based on income, determine eligibility for insurance.
 - ▶ Medicaid
 - ▶ Marketplace
 - ▶ Discount Programs
 - Gather necessary supporting documents for financial assistance.
- ▶ Additional Resource Needs: Complete referrals and discuss information to be shared with outside organizations. Have the client sign a release of information where needed.
 - Housing—Do you have stable housing? Do you rent or own? Are you worried about losing housing?
 - Transportation—What is your primary mode of transportation? Do you need additional support?
 - Mental Health—Complete SBIRT and Mental Health Screenings; ask about history of mental or behavioral health issues.
 - Eligibility for any additional medical or medication assistance needs
 - Substance abuse counseling/treatment
 - Peer Groups—Community-based or in HIV continuity clinic

- ▶ Disease Intervention Specialist (DIS)—If not discussed during rapid ART initial visit, explain the DIS role and facilitate linkage to DIS and partner services.
- ▶ Review Continuity Care Plan: Discuss continuity care provider and clinic options. If there are multiple options, help the client decide which clinic is the best fit based on location, services provided, and client preference.
- ▶ Scheduling with Continuity Clinic: Assist client with scheduling follow-up appointment.
 - Call clinic with client and request appointment.
 - Perform a warm hand-off to continuity clinic staff. Does the client know how to contact the clinic and who to call if they need additional support?
 - Discuss support needs with clinic staff (i.e., transportation, reminders, social work, mental health, and substance use disorder resources).
- ▶ Final Check-in: Tell me about your appointment. Does the clinic/provider feel like a good fit for you? What questions do you have? Do you know who to contact if you need additional help or resources in the future?
 - Linked to Care—if the client feels good about the continuity clinic and does not have additional support needs, LTC services end.
 - Additional needs—if the client is not happy with their continuity care clinic or has additional ongoing needs, continue working through this checklist until client has what they need to connect to continuity care.

Appendix II : Sample Non-Clinical Referral Form

HIV Linkage to Care (LTC) Referral Form created by HIV navigation services staff in the Denver Sexual Health Clinic. This is a sample non-clinical referral form that can be adapted based on rapid ART program needs and referral criteria

HIV Linkage to Care Referral Form

Linkage to Care is a specialized case management program for patients living with HIV. The purpose of LTC is short-term, individualized support, assessment, and referral for patients from diagnosis to integration into specialized HIV care.

Patients with a reactive HIV antibody/antigen result in an outpatient clinic, urgent care or emergency room **should be referred directly to Linkage to Care by calling 555-555-5555**, during business hours M-F 8am-5pm. For after-hours, please leave a confidential voice message or email completed referral form. A LTC counselor will follow-up the next business day.

New Diagnosis Out of Care

Client Name _____ DOB _____

Address _____ Homeless _____

Phone _____ Preferred language _____ MRN (Denver Health) _____

Any additional contact information _____

linkage to care referral date _____ HIV Test Date _____ results confirmed No Yes

CD4 results obtained? No Yes viral load result obtained? No Yes

1. Are there any concerns about privacy or discretion that the LTC staff should be aware of? No Yes, describe

2. What are the best days/times to contact the patient? _____

3. Was anyone else present or involved in the disclosure process (e.g., family member, partner, friend)?

4. Was the patient informed about LTC process and that LTC staff will contact them? No Yes

Referring Provider: Provider Name _____ Facility Name: _____

Address _____ Email _____ Phone Fax _____

Please email this form and test results to SOMEONE@ABCD.ORG

LINKAGE TO CARE SERVICES • 222 NO STREET • DENVER, CO 00000
P: 555-555-5555 • F: 555-555-5555 • EMAIL: ADDRESS@ABCD.ORG

Appendix III: HIV LTC Referral

HIV Linkage to Care (LTC) Electronic Health Record (EHR) Referral was created by HIV navigation services staff and providers in Denver Health and Denver Sexual Health Clinic to create a more streamlined process for rapid referrals within the system. This is a sample of an EHR referral process that can be adapted depending on rapid ART program needs and contexts.

HIV Linkage to Care Standard Work – EPIC Referrals

Situation: HIV LTC can receive active referrals through EPIC for linkage clients, persons with HIV.

Referral: REF519 - AMB REFERRAL TO HIV LINKAGE TO CARE

- ▶ Referrals are found:
 - EPIC Inbasket
 - My Messages
 - Referral Triage

Routing: Inbasket pool to all linkage to care recipients.

Overview: Outpatients needing HIV LTC services can be referred to Linkage pool via EPIC referral.

Process: LTC on-call person will check EPIC inbasket pool for any new referrals at the beginning of each shift. Pool will be checked twice daily, once in the morning and once in the afternoon.

Sorting: Each referral will be viewed as assessed for appropriateness to receive linkage services.

Accepted referral criteria: Denver Health outpatient; living with HIV; currently out of care (either HIV specialty or primary care); any insurance status, any residency.

- ▶ Outpatients in need of package of linkage services, i.e., assistance...
 - Any person newly identified living with HIV **OR**
 - Person known to be living with HIV who has any of the following needs:
 - Navigating care location options
 - Assessment of complex social issues
 - Need for HIV basic education
 - Needs assistance scheduling an appointment at other Denver Health clinics
- ▶ If the client only needs assistance getting scheduled and has no additional needs, document in EPIC as “Linkage to Care Other.”
- ▶ This person needs only a chart note indicating what was done and “no additional needs at this time.”
 - Do not complete a flow sheet.

Rejected referral criteria: Patients who don't meet the above criteria.

- ▶ If the referral is not for linkage services, but more likely directed to an infectious disease consult service or other clinical care need, choose “Reject” and send a comment back to the referring party with alternate contact info, if available. Additionally, send an EPIC “staff message” to appropriate clinic contact to alert them of the patient need.
- ▶ For other misguided referrals, e.g., pediatrics, simply process the referral as “Reject.”

Accept and reject process steps

Accept:

- From Inbasket, My Messages, Referral Triage, select row of referral then select "Accept" found on left side in header.
 - Type comment in comment field if needed.
 - If more info to share with referring provider, enter notes into "Comments" section.
 - Click bottom right of box "ok" to complete
- Once the referral has been accepted, the on-call staff member can open an encounter in medical record and select "Done" on Referral Triage list, removing patient referral from the active list. Opening an encounter assures patient info is received and that others can see that a Linkage person is involved.

Reject:

- All similar to above.
- From Inbasket, My Messages, Referral Triage, select row of referral then select "Reject" found on left side in header.
- Dialogue box opens. Under "Reject Reason" choose "Incorrect Specialty/Clinic."
- Type comment in comment field about reason for rejecting.
- Click bottom right of box "ok" to complete
- Once referral has been rejected, select "Done" upper left of Referral Triage list, removing patient referral from active list.

Appendix IV Financial Navigation Resource Table

The table below was created by the Denver Sexual Health Clinic HIV navigation services team as a resource for quickly identifying patient assistance programs and funding available to support PWH and starting rapid ART. It should be noted that this table does not include specific state and local financial programs that might be available. Programs using this toolkit should adapt this document to reflect the specific financial navigation resources available for their community and program.

<p>Federal/State</p>	<p>Ryan White Part B: AIDS Drug Assistance Program – Eligibility can vary by state, and medications covered by the ADAP formulary can vary by state. ADAP will only cover HIV treatment and not medical services related to HIV care.</p> <p>Medicaid – A federally and state-funded program that provides medical and pharmaceutical coverage for individuals who have limited income. Individuals can enroll year-round if they qualify. In Medicaid expansion states, the pool of people who qualify for Medicaid has broadened. State participation can be checked here.</p> <p>Medicare—Medicare is health insurance for people aged 65 or older, people under 65 with certain disabilities, and people of all ages with end-stage renal disease. Medicare coverage for eligible individuals includes outpatient care, prescription drugs, and inpatient hospital care. To learn more about Medicare coverage and choices, visit Medicare.gov.</p> <p>American Indian and Alaska Native Programs—The Indian Health Service provides health care services—including HIV services—for members and descendants of federally recognized American Indian and Alaska Native Tribes. For more information, go to https://www.ihs.gov.</p> <p>Veterans Programs—The Veterans Health Administration (VHA) within the Department of Veterans Affairs is the largest single provider of medical care to PWH in the United States, supporting more than 24,000 Veterans living with HIV. If you are eligible, you may be able to receive HIV care through VHA. VHA offers an online benefits website where Veterans, Service Members, and their families can learn about their health care benefits.</p>
<p>Pharmaceutical Companies</p>	<p>AbbVie Patient Assistance Foundation P.O. Box 270, Somerville, NJ 08876 Phone: 800-222-6885 Fax: 866-483-1305</p> <p>Boehringer Ingelheim Cares Foundation Inc. Patient Assistance Program c/o Express Scripts SDS, Inc. P.O. Box 66745, St. Louis, MO 63166 Phone: 800-556-8317 Fax: 866-851-2827</p> <p>Bristol-Myers Squibb: Assist Program P.O. Box 221430, Charlotte, NC 28222-1430 Phone: 888-281-8981 Fax: 888-281-8985</p> <p>Gilead Advancing Access: Reimbursement Solutions for Patients in Need P.O. Box 13185, La Jolla, CA 92039 Phone: 800-226-2056 Fax: 800-216-6857</p>

<p>Pharmaceutical Companies, con't.</p>	<p>Johnson & Johnson Patient Assistance Foundation, Inc. P.O. Box 42796, Cincinnati, OH 45242 Phone: 800-652-6227 Fax: 888-526-5168</p> <p>Merck Patient Assistance P.O. Box 690, Horsham, PA 19044-9926 Phone: 800-727-5400 Fax: 915-849-1037</p> <p>THERA Patient Support P.O. Box 390, Somerville, NJ 08876 Phone: 833-238-4372 Fax: 855-836-3069</p> <p>ViiV Healthcare Patient Assistance Program P.O. Box 220100, Charlotte, NC 28222-0100 Phone: 1-844-588-3288 (toll-free number) Fax: 1-844-208-7676 Website: http://www.viivconnect.com</p>
<p>Private</p>	<p>Individual Health Insurance Marketplace – Also known as health exchanges. These markets allow for people who are uninsured to gain access to purchase insurance. If a person is within certain income guidelines, they can receive a subsidy to offset their monthly premium. PWH can access assistance with paying for premiums, pharmacy benefits, deductibles, and co-pay assistance through the U.S. Health Resources & Services Administration’s Health Insurance Premium and Cost Sharing Assistance. Eligibility and enrollment periods can vary by state. To see if you can enroll in a health insurance plan or change plans, visit healthcare.gov or find local help.</p>

Appendix V—How to Reduce Financial Barriers

Early initiation of HIV medication can help patients achieve viral suppression. Rapid ART programs should examine financial barriers that can be associated with engagement and retention in care. Alleviating as many financial barriers as possible can assist in keeping patients in care. While this is not an extensive list, below are some commonly reported barriers to accessing care.

► **Limited financial resources**

- Clients are often focused on their basic needs, which can impair their ability to see their HIV status as a priority. Clients may focus more on accessing their basic needs instead of engaging in care. Staff should screen for social determinants of health which may adversely affect outcomes, and link clients as appropriate.

► **Lack of insurance coverage**

- While the Affordable Care Act has improved insurance access for millions of Americans, there are still a great number of people who perceive that they are unable to access health insurance. Insurance and benefits navigators are essential in helping patients access health insurance coverage. Many organizations can assist with the cost of HIV medications, housing, and other support services. However, clients may not have this knowledge, and therefore it is essential to give an overview of financial assistance available to patients when initiating rapid ART.

► **Lack of transportation**

- While rapid ART can reduce the number of appointments needed at the health center when initiating ART, there is still follow-up needed to stay retained in care. Lack of transportation can be a significant factor for clients' engagement and retention in care. The lack of transportation can also affect the client's ability to connect to employment opportunities and other health resources. An additional issue to consider is when clients decide to rely on family or friends for transportation. This can some times lead to unwanted disclosure and safety issues. Organizations should consider offering transportation and or telehealth options to patients when applicable and available.

► **Lack of housing and technology**

- Clients who are unemployed or earning low wages may experience issues with housing and access to technology, which can affect their engagement and retention in care. If clients are living in shared housing, they may experience unwanted disclosure, lost or stolen medications, safety issues, and inability to focus on their health. Clients utilizing mail order services to obtain medication may have problems receiving the medication due to lack of a stable address or privacy. When clients are in shared housing situations, organizations can consider accepting and storing medication mail orders on the client's behalf.
- Clients who do not have access to cell phones, computers, and internet may experience difficulties communicating with health care providers. This can cause patients to miss follow-up appointments and other opportunities to engage in care such as telehealth. Assisting patients with accessing government-issued cellphones and discounted internet plans can be considered if possible.

► **High cost of prescription medicines**

- The high cost of prescription medications can pose great barriers when engaging and retaining patients in care. Prescription nonadherence can lead to medication resistance and ultimately make it more difficult for patients to achieve viral suppression.

It is essential for medical providers and patients to incorporate financial considerations when initiating rapid ART.

Barriers to Grant Funding (Funding for Organization vs. Funding for Patient Services)

HIV service organizations face various types of barriers to funding. Many agencies are funded to treat and deliver services to the HIV population specifically. However, the organization may receive restricted funding for organizational needs versus specific services focused on the HIV population. When funds are restricted to specific services the agency must ensure the deliverables are met and services are rendered accordingly.

For example, funding for specific patient services often includes patient navigation, peer services, linkage to care, care coordination, and case management for patients with HIV; an organization's staff might then face challenges of recruiting new patients with HIV into the funded program due to lack of housing and medical adherence. Secondly, agencies may have patients who are HIV negative that need the services the program offers; however, they cannot provide the services due to the restricted funding.

<https://www.health.ny.gov/diseases/aids/providers/standards/casemanagement/docs/casemanagementstandards.pdf>

Appendix VI: How to Maintain Funding from Local and State Health Departments (HDs)

For organizations to maintain grant funding from local and state HDs, there are several pointers/tips to remember. One of the many challenges within organizations is the task management of overseeing the grants. As reports and financial data are passed between organizations, the program stakeholders must ensure that all requirements are met. The grantee/organization will have two primary types of reporting to the funding agency on a regular basis: financial and programmatic. The funder-required reports provide information about the overall financial status and program performance of the grant project. Here are a few tips to remember to assist with maintaining local and state HD funding:

- ▶ **Assign staff member to be a champion/supervisor overseeing the grant** – There should be a designated person speaking to the funder regarding programmatic and financial reporting. Too many people communicating with the funder can cause confusion and inconsistent reporting.
- ▶ **Tracking time and effort** – There should be firm policies in place around monitoring time and effort daily/weekly. It is also recommended that the funder approve the system being used to track time and effort.
- ▶ **Reports** – Plan to submit reports before the scheduled due date.
- ▶ **Vouchering** – There should be ongoing oversight of the grant budget to assure that there is no under- or overspending on the contract.
- ▶ **Compliance issues** – It is very important to ask the funder specific questions related to potential compliance issues or concerns. For example, some contracts require certain compliance training and documentation from the organization before any funding can be drawn down against the grant.
- ▶ **Staffing, filling positions** – Current staff and open positions should be monitored monthly. Best practice would be to have a monthly variance report meeting with the finance and programmatic staff. The staff will review necessary positions and plan for hiring. Implementing monthly meetings reduces confusion and allows more accurate, real-time allocation of funding.

