CRESCENTCARE START INITIATIVE INTERVENTION

Center for Innovation and Engagement

Background

The Health Resources and Services Administration's (HRSA's) Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of HIV primary medical care, essential support services, and medications for low-income people with HIV. RWHAP funds grants to states, cities, counties, and local community-based organizations to provide care and treatment services to people with HIV to improve health outcomes and reduce HIV transmission.

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Intervention Snapshot

	Priority Population	People with HIV who have been newly diagnosed
	Setting	Federally Qualified Health Centers, Health Clinics, and Community-Based Clinics
	Pilot and Trial Sites	CrescentCare in New Orleans, LA
	Model	The intervention consists of a rapid antiretroviral therapy (ART) initiation model that streamlines clinic enrollment; ensures immediate and sustained access to HIV treatment; expedites benefits enrollment; and facilitates linkage to support services to increase retention in care and viral suppression.
	RWHAP Ending the Epidemic (EHE) Opportunity	People with HIV who are newly diagnosed face challenges with being promptly linked to and retained in HIV care. Intervention outcomes illustrate that 97 percent of CCSI clients were linked within 72 hours of diagnosis, and 99.2 percent of clients who received rapid-ART achieved viral suppression. The median time from diagnosis to viral suppression was 29 days. Further, 92 percent of clients in the CCSI group were retained in care compared to 80 percent who received Health Resources Services Administration (HRSA)'s Ryan White HIV/AIDS Program's Part C Early Intervention Services (EIS) at the CrescentCare clinic (P<.05).
	Intervention Funding	National Institute of General Medical Sciences of the National Institutes of Health, which funds the Louisiana Clinical and Translational Science Center grant, and Ryan White HIV/AIDS Program Part C funds for EIS and other emergency assistance.
	Staffing	Staff positions in the intervention included a Patient Navigator (a staff person available 24 hours a day to link people who have been newly diagnosed with HIV into care), Eligibility Specialist, clinic staff (e.g., Medical Assistants), and referring agencies (e.g., HIV testing sites).
	Infrastructure Needed	A referral system; a streamlined intake process; a data system to capture client-level data; extended hours; same-day provider appointment availability; an expedited benefits enrollment process; and access to 30-day antiretroviral medication packs or ability to facilitate immediate fills with pharmacy services.

Intervention Overview & Replication Tips

Why This Intervention?

The CrescentCare Start Initiative (CCSI) is a rapid-start intervention that involves the prompt initiation of antiretroviral therapy (ART) for people with HIV who were newly diagnosed. This intervention was implemented at CrescentCare, a federally qualified health center (FQHC) in New Orleans, LA, in partnership with the New Orleans Office of Health Policy and funded by the Ryan White HIV/AIDS Program.[1] By starting clients on antiretroviral medication within 72 hours of diagnosis, providing comprehensive care navigation, and expediting clinic intake, the CCSI intervention increased linkage and retention in care for people with HIV. Clients newly diagnosed at existing CrescentCare-run HIV testing sites and sexually transmitted diseases (STD) clinics were linked to care by a navigator available 24 hours a day.[2] The navigator connected the client with a provider, where an initial dose of ARV medication was administered and 30 days of medication was provided.[2] After this visit, clients had HIV labs drawn and were referred for case management, behavioral health, and eligibility specialists where necessary.[2] Clients were then linked to an HIV specialist and retention staff for ongoing care within four weeks.[2] The CCSI intervention used viral suppression, defined as an HIV RNA less than 200 copies/mm^3, and time to suppression, defined as days from diagnosis to viral suppression as indicators of continued engagement in care.[3] Replicators also defined retention as two provider visits separated by 90 days within 12 months.[3]

Rapid antiretroviral therapy initiates antiretroviral medication as soon as possible after an HIV diagnosis, ideally on the day of diagnosis and, if not, on the day of entry to care (rapid ART studies often use a metric of ≤ 7 days from diagnosis).[1] The intervention demonstrated the effectiveness of immediate linkage and rapid ART to improve health outcomes for people with HIV. Of the 130 clients referred to the program between December 2016 and February 2018, 126 (97 percent) were linked within 72 hours of diagnosis.[1] One-hundred and twenty-five clients (99.2

percent) who received rapid ART achieved viral suppression, and the median time from diagnosis to viral suppression was 29 days.[1] Further, 116 clients (92 percent) were retained in care, and 113 clients (90 percent) had a viral load test within the past six months.[1]

Moreover, there were significant differences in retention in care and viral suppression between clients served by the intervention and clients who received Early Intervention Services (EIS) through the Ryan White HIV/AIDS Program.[3] The latter consisted of clients who either had no previous treatment or were out of care, linked to ART between 4 days to 25 years after HIV diagnosis over and received similar services such as same-day linkage and ART.[3] Any client who was referred to ART or contacted the clinic after 72 hours of an HIV diagnosis was placed in the EIS cohort. Once clients in the EIS cohort made the initial contact or accessed care, staff followed the same protocol for rapid ART provision, in which they would be provided with a 30-day pack of antiretroviral medication. 126 clients (92 percent) in the CCSI group were retained in care compared to 55 clients (80 percent) in the EIS group ($P<.05$).[3] Further, 113 clients (90 percent) in the CCSI group were virally suppressed compared to 53 clients (77 percent) in the EIS group.[3] The median CD4 count for clients in the intervention group was higher than that of clients in the EIS group (444 cells/mm^3 and 271 cells/mm^3; $P<.05$).[3] The favorable linkage and retention outcomes demonstrate that starting clients on ARV medication the day of diagnosis before labs are obtained is a safe, well-tolerated, and effective intervention.[3]

The CCSI intervention is intended for use in an FQHC or other clinical setting with the capacity to offer same-day services, extended and weekend hours, wrap-around services, and community-based clinics that can ensure continuous ART coverage.[3]

Intervention at a Glance

This section provides a breakdown of the CCSI intervention conducted at CrescentCare in New Orleans, LA, in collaboration with the New Orleans Department of Health, to help readers assess the steps required for replication. The intervention was funded through a grant by the National Institute of General Medical Sciences of the National Institutes of Health, which funds the Louisiana Clinical and Translational Science Center, and supplemented by RWHAP Part C funding for EIS services as well as other emergency assistance funds.

 Step 1	**Engage Stakeholders:** Coordinate meetings with clients, RWHAP Part A planning councils, key public health leaders, testing and rapid ART sites, clinic leadership, and staff to discuss psycho-social and structural barriers to care and create common goals to link people with HIV into care.
 Step 2	**Assess Resources:** Ensure that your organization has the resources to provide ART through various existing funding streams (e.g., organization funding sources, AIDS Drug Assistance Programs, Medicaid).
 Step 3	**Hire and Train Staff:** Designate a Patient Navigator and an Eligibility Specialist. Provide comprehensive training. Incorporate a rapid start initiation model into the organizational workflow. Facilitate recurring meetings to gather feedback on the intervention and ensure the intervention is being implemented with fidelity and benefitting clients.
 Step 4	**Enhance Infrastructure:** Determine a process to gather client consent. Collaborate with staff to ensure the clinical space is set up to best meet client needs. Assess whether pharmacy services can be provided in-house.
 Step 5	**Link Clients to Medical Care:** Upon referral, connect clients to patient or linkage coordinators and providers within 72 hours of an HIV diagnosis. Provide HIV medical education to clients. Gather contact information and consent.
 Step 6	**Deliver Medical Care:** Conduct a whole health assessment (e.g., perform vitals and brief assessment). Facilitate early and sustained access to antiretroviral medication by providing an initial dose and 30-day supply . Discuss risks associated with the medication.

 Step 7	**Assess Labs after ART Initiation:** Draw a comprehensive HIV lab panel. Document and inform clients of any contraindications found (e.g., liver function).
 Step 8	**Link Clients to Benefits and Social Services:** Expedite insurance or payer source enrollment. Assess interconnected and intersectional client needs. Help clients stay engaged in care by linking them to support services that address retention and adherence barriers.
 Step 9	**Follow-up and Retain Clients in Care:** Provide ongoing client navigation, HIV education, and coordination with retention teams.

Cost Analysis

The CCSI intervention was sustained by a National Institute of General Medical Sciences of the National Institutes of Health, which funds the Louisiana Clinical and Translational Science Center grant. The funding opportunity announcement number for this project was U54-GM104940.[4] The intervention was also supplemented by a HRSA Ryan White HIV/AIDS Program grant RWHAP. The federal program supports direct care and treatment services, and Part C provides health care and support services in outpatient settings for people with HIV. HRSA's RWHAP Fact Sheet provides more context on the different parts. Additionally, the RWHAP's Policy Clarification Notice 16-02 outlines details on allowable costs.

A more detailed cost analysis of the CCSI intervention was not available when this guide was developed. However, you can use the CIE Cost Analysis Calculator to create an estimate of the cost of implementing the intervention at your organization. (See Additional Resources Box).

Resources Assessment Checklist

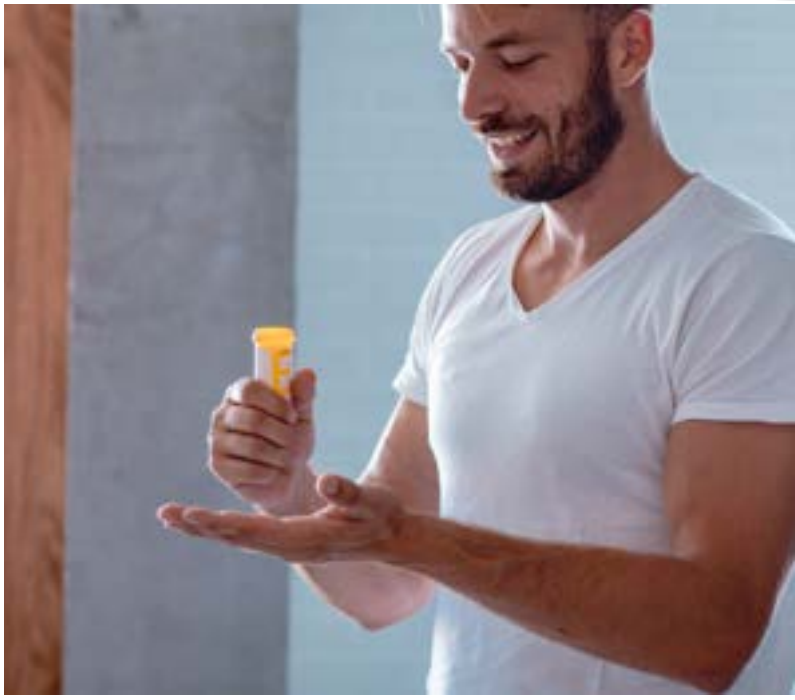
Before implementing the CCSI intervention, your organization should go through the following Resource Assessment (or Readiness) Checklist to assess the organization's capability to do this work. If you do not have these components in place, you are encouraged to develop the capacity to conduct this intervention successfully. Questions to consider include the following:

- ❑ Has your organization secured buy-in from people with HIV, clinic leadership and staff, testing or other wellness sites, and other key public health leaders?
- ❑ Do staff understand HIV trends and interconnected social determinants of health that impact health outcomes in your community?
- ❑ Are staff willing to work with replicators on planning and implementing the intervention?
- ❑ Does your organization have patient or linkage navigators who can link clients to care and providers who deliver specialized HIV services?
- ❑ Does your organization have flexible scheduling options (e.g., weekend and evening hours)?
- ❑ Does your organization have the resources to have a dedicated, full-time navigator?
- ❑ Does your organization have a standard operating procedure (SOP) or medical checklist to ensure non-HIV care specialists can deliver a consistent model of care?
- ❑ Does your organization have the capacity to provide antiretroviral medication within 72 hours of an HIV diagnosis and beyond initiation (e.g., provide a 30-day pack and refills, serve clients outside of traditional operating hours)?
- ❑ Can your organization establish a pathway for guaranteed access to ART through health care coverage or RWHAP services?
- ❑ Can your organizational processes facilitate access to medical and support services (e.g., behavioral and mental health services, housing, transportation, and legal support)?
- ❑ Does your organization have staff who can dedicate time and effort to ensuring clients are re-engaged in care (e.g., providing ongoing HIV education following up with clients after visits)?

Setting the Stage

According to the U.S. Centers for Disease Control and Prevention (CDC), there are an estimated 1.2 million people with HIV in the United States.[4] The CrescentCare Start Initiative was implemented in 2016 and intervention developers evaluated data gathered through 2018. Approximately 75.7 percent of people with HIV received HIV medical care, 57.9 percent were retained in care, and 64.7 percent were virally suppressed.[5] People with HIV who receive ongoing, regularly scheduled care are more likely to have significantly lower viral loads, higher CD4 cell counts, reduced morbidity and mortality, and improved overall health than those who missed even one medical visit over a two-year period.[6] Receipt of medical care is defined as a client taking one or more tests [CD4 or viral load] in the measurement year. Although significant strides have been made to ensure that people with HIV effectively progress through the HIV care continuum, these figures demonstrate that retention remains a critical issue. Improving client engagement and re-engagement in care is a national priority with tailored retention measures established by the National HIV/AIDS Strategy (see Additional Resources Box), HRSA, and the Ending the HIV Epidemic in the U.S. (EHE) initiative, among others.

CrescentCare is a community health center located in New Orleans, Louisiana, which aims to provide quality, person-centered healthcare, and support services.[7] The southern region of the U.S. has been disproportionately impacted by the HIV epidemic, and innovative models of care are integral to prevention and care efforts. In 2018, 51 percent (N=19,396) of new HIV diagnoses were in the South.[8] Among people diagnosed with HIV in the South during the same period, 52 percent were Black or African American.[4] In 2018, there were 980 new HIV diagnoses in Louisiana, of which 28 percent (N=279) occurred in New Orleans and 22 percent (N=216) in Baton Rouge. New Orleans also ranked sixth (24.6 per 100,000, N=313) in HIV diagnosis rates among the large metropolitan areas in the nation during this period. Seventy-four percent (N=233) of people newly diagnosed were assigned male at birth,



23 percent (N=71) were assigned female at birth, and 3.2 percent (N=10) were transgender women.

Further, 67 percent (N=211) were Black or African American. Among this population, 24 percent (N=77) were between the ages 13 to 24 years and 37 percent (N=116) were between the ages 25 to 34 years.[9] Among people newly diagnosed, 78.9 percent were linked to care.[10] Among all people with HIV in LA in 2018, 78 percent received care, 67 percent were virally suppressed.[10] These statistics highlight HIV health inequities and the need to invest in, develop, and sustain programs that remove barriers to HIV care. Rapid ART is an example of an approach that can work to address these issues.

While there have been concerns about rapid ART, including ART toxicities and lack of a medication payer source, studies have shown that rapid ART can significantly improve the health outcomes of people with HIV, reduce transmission rates, improve linkage to care, and reduce time to viral suppression.[1] Moreover, studies have consistently shown the impact of rapid ART on long-term viral suppression among those who initiate rapid ART across RWHAP clinics, Federally Qualified Health Centers (FQHC), and health departments.[1]

The CrescentCare Start Initiative (CCSI) intervention ensures that everyone is offered rapid ART from the onset, thereby reducing potential prescribing biases and barriers to care, including for clients who have been historically marginalized.[1] This is evidenced by the demographic breakdown of clients enrolled in the CCSI intervention from December 2016 through February 2018.[3] Among the intervention population, 74.6 percent (N=94) were cisgender men, 64.3 percent (N=81) were Black or African American, 57.9 percent (N=73) were gay, bisexual or other men who have sex with men, and 27.8 percent (N=35) were under 25 years.[3] The CCSI intervention directly serves clients who have historically been impacted by the HIV epidemic, which is integral to implementing any rapid ART intervention and the acceleration of equitable efforts to end the HIV epidemic.

Description of the Intervention Model

The CCSI intervention aims to link people to antiretroviral therapy within 72 hours of an HIV diagnosis as a way of improving viral suppression rates and overall health outcomes. The intervention aims to successfully engage and retain people with HIV who were newly diagnosed in HIV medical care.

The keys to success for this intervention are to establish working relationships with clients, staff, and clinic sites and ensure early and sustained access to ART. This work can be done by connecting clients with accessible patient or linkage coordinators, prioritizing same-day clinic visits, and providing insurance navigation and support with other needs. Upon successful engagement in care, staff can support clients to remain in care by providing close follow-up, patient navigation as needed, and ongoing HIV education. The implementation of a rapid ART program involves intentional planning, coordination, teamwork, and funding.[1] The following information has been adapted from the Standard Operating Procedure (SOP) manual (See Additional Resources Box). The CCSI intervention is implemented in six steps:

1. Determine Organizational Resources and Engage Stakeholders

a. *Engage Stakeholders:* Facilitate conversations with leadership, clinicians, phlebotomists, and non-clinical staff (e.g., front desk and janitorial staff). Discuss the benefits of a rapid ART initiation model and address key concerns, including providing rapid ARV medications before labs. Present the model to HIV, sexually transmitted diseases, and sexually transmitted infections (STD/STI) testing sites, sexual wellness centers, and other relevant programs associated with the health center.

- Prepare relevant literature and information about the benefits of a rapid ART intervention. For many clinicians, prescribing ARV before intake laboratory results requires a significant shift in practice and may take time to adopt.1 Providing information upfront can help assuage any concerns that they may have.
- When discussing the need for the intervention, discuss psycho-social-structural barriers to care at the implementation site. Review current processes for linking people with HIV who have been newly diagnosed and how the intervention can address gaps and reduce time to viral suppression (e.g., determine the average amount of time it takes for clients to get on ARV medication from the moment they meet with a case manager).
- Leverage RWHAP Part A planning councils and center the perspectives of people with HIV and other key public health leaders. The intervention must also meet the needs of the client population and address key structural barriers to HIV care and retention. Identify champions at the organization who can connect with a wide range of stakeholders (e.g., have conversations with staff on how this will change their current workflow). Implementing a rapid ART initiation model will require a cultural shift as it will impact staff's responsibilities—discussing barriers and solutions upfront can help mitigate potential issues in the future.

b. *Assess Funding Sources:* Discuss existing and potential funding streams that can support a rapid ART intervention, such as leveraging RWHAP funds and enrolling clients in Medicaid or drug assistance programs. Client needs will vary depending on whether they are uninsured, underinsured, or privately insured, so it is important to have these conversations with the Finance team to determine consistent and sustainable funding streams and prevent ART disruptions for clients.
   - In the original intervention, every uninsured client or those with a high deductible received a 30-day ARV pack through RWHAP programming funds.[1] Clients who were insured by Medicaid were processed immediately. Replicators have shared that it may be challenging to cover the cost of starter packs in states without Medicaid expansion. However, some mechanisms can be leveraged to develop initial supplies of ARV, such as RWHAP "stopgap" medication funding and pharmaceutical patient assistance programs.[1] Programs can provide immediate access to medications for all recommended first-line ARV regimens until medication payer sources are firmly in place.[1]

c. *Identify and Train Key Staff:* Intervention success is dependent on a full-time Patient Navigator (PN) and an Eligibility Specialist (ES). Provide comprehensive training to the Patient Navigator and other providers to integrate pertinent client information into electronic medical records and provide clients with relevant information regarding their diagnosis and the ARV initiation processes. The ES will facilitate access to healthcare coverage enrollment and other support services. Additionally, identify a set of clinical providers (e.g., primary care providers and HIV specialists) and patient or linkage coordinators who will work with CCSI clients.
   - Facilitate recurring meetings to gather intervention feedback and ensure the intervention is being implemented with fidelity.
   - While the PN will support clients initially, clients should be connected to linkage and retention teams for ongoing care management.

d. *Explore and Enhance Existing Infrastructure:* Various systems need to be in place to implement the intervention, including a referral mechanism, an informed consent process, and

a data system. The implementation site should also determine how the physical space will facilitate linkage to care and rapid ART (e.g., availability of clinical space to assess clients, the flexibility of clinic hours).

- *Develop a Referral System:* Establish an appropriate referral method that fits organizational processes and can streamline referrals and services from external partners. CCSI intervention referrals came from various places, including the CrescentCare Sexual Health Center and Healthcare for the Homeless. Identify who will be the main points of contact at the implementation site and referring organizations.
- *Determine an Appropriate Process to Obtain Client Consent:* The PN can meet clients in an office space to have them fill out consent forms and avoid the waiting room.
- *Secure a Physical Space for Appointments:* Collaborate with staff to ensure the clinical space is set up to best meet clients' needs. Discuss whether patient rooms will be available during the weekends and how this will impact staff workflow, such as janitorial staff and others preparing the rooms for client visits.
- *Leverage Data Systems:* A data system, such as an Electronic Health Record (EHR) or Electronic Medical Record (EMR) system, is necessary to capture relevant client information and follow them through their course of care. After obtaining informed consent, the PN should enter all pertinent client information into the EMR or EHR. Identify additional information that should be captured (e.g., sexual orientation and gender identity, confirm insurance). Ensure the PN has access to all data systems to reduce the number of interactions clients will have with other staff during their visit.
- *Assess Pharmacy Services:* Determine whether pharmacy services can be provided in-house. Clients should be able to gain access to 30-day prescription refills in addition to their first dose of ARV medication.
- *Develop a Standard Operating Procedure (SOP) Manual:* This resource should outline all steps that PN, clinical and non-clinical providers, and ES should follow to link and retain clients in care. Gather input from key staff and ensure the process is also aligned with standard clinic protocols. Disseminate the manual across the agency. The manual should be a supplementary resource for provider training efforts and be reviewed and updated consistently (e.g., yearly).

2. Link Client to Medical Care

Once the implementation site receives referrals, the first component of the CCSI visit is linkage to medical care by the Patient Navigator or in-clinic for a medical visit. The intake process for the CCSI intervention should be streamlined for a focused HIV visit with a provider with prescribing privileges. This visit may take approximately 30-minutes.

a. *Communicate with the Referral Source:* Respond to referrals received from the main point of contact (e.g., the counselor from a testing site). A PN should be available 24 hours a day to coordinate linkages for people with new HIV diagnoses.

b. *Schedule an Appointment:* If the client is in the EHR or EMD system, the PN can schedule appointments with a clinical provider for labs and an Eligibility Counselor (EC). Optimize provider availability where possible. Otherwise, follow organizational protocols to register clients into the clinic. If provider appointments are limited, consult with providers about flexibility in scheduling or other options. The client may get a lab panel or see an Eligibility Specialist while waiting on the clinical provider to become available.

    - If the client is on-site upon HIV diagnosis, the PN can facilitate the intake process at that time. The PN can escort the client through registration, consent to treatment protocols, and gather medical insurance information. The PN can also stay with the client until they are linked to a clinical provider. It is important for clients to be informed about their diagnosis. The PN can utilize this time with the client to deliver

"HIV 101" medical education, which clinical providers can elaborate on during the visit.

- If the client receives their diagnosis while at a clinic visit, the PN might not need to be involved. In this case, the PN can be informed about the client, but they are not expected to attend the visit unless requested. The clinical provider seeing the client will facilitate access to rapid ART and schedule a same-day appointment with an Eligibility Specialist.

3. Deliver Medical Care

Visits with a physician or a nurse are an integral part of the CCSI intervention. This visit may take approximately 30-minutes.

a. *Complete Intake:* A nurse or other clinical staff person (e.g., Medical Assistant) should perform a limited intake with the client before their medical visit. During the intake, take vitals, perform a brief assessment, and confirm an HIV diagnosis. If you are unable to confirm the diagnosis, the PN or nurse can reach out to the referral source or perform a rapid HIV test. Document the results of the most recent HIV test in the EMR or EHR. If staff cannot confirm previous HIV test results and would like to capture this in the EMR or EHR, the nurse, medical assistant, or clinical provider can list "Unknown" for the Previous HIV Test. Primary care providers can commit to seeing clients for the initial visit, and an HIV specialist can be assigned to clients for ongoing management. In certain settings, the primary care provider can also serve as the HIV specialist depending on the organizational structure.

b. *Meet with Client:* After a brief intake, the client can meet with the clinical provider to link them to rapid ART. During the visit, assess ARV readiness and conduct a brief mental health assessment or check-in. Ensure HIV medical education is readily available to the client and dedicate time to providing this information (especially if they did not meet with a PN before the visit).

   - Correspond with a behavioral health specialist, social worker, or another provider if needed. A case manager or social worker can meet with the client before completing the visit to address their psychological needs.

c. *Obtain Consent for Treatment:* If not previously obtained, get consent for treatment from the client. Discuss the low but possible risks associated with ARV medication. Further, share that they will be initiating ARV before genotype and safety-lab results.

   - The medications referenced by CCSI intervention developers have been found to be safe and effective. However, if a client has severe pre-existing kidney disease, alternate choices for HIV treatment may be indicated by the provider. Additionally, the provider should choose a different regimen if a client is pregnant based on established guidelines. This can be confirmed after labs are performed.
   - It is important to note that clients have full autonomy and agency. Thus, the client can decline therapy through shared decision-making at any point.

d. *Prescribe Medication:* Provide clients with a 30-day supply of medication or starter pack. Providers should confirm that ARV medication will be stocked on the clinic floor. Bottles should have pre-made labels affixed to them, allowing providers to write the name and date during the visit. Provide the client with the first dose during the visit and document the dispersal of medications in the log.

- In the original intervention, providers were encouraged to use tenofovir alafenamide/emtricitabine (TAF/FTC) + dolutegravir as the initial regimen due to the regimen's effectiveness, tolerability, empiric coverage of hepatitis, and approved use in clients with a creatine clearance greater than or equal to 30 mL/min.
- The recommended rapid ARV regimen for most clients are three combinations with tenofovir (TAF or TDF) plus emtricitabine (or lamivudine) plus an integrase inhibitor (bictegravir, dolutegravir, or boosted darunavir).[1]
- In some programs, immediate access to ARV medication is provided through 5-7-day medication starter packs to build a bridge until a payer source kicks in for a full supply of medications.[1]
- The process for prescribing medication to clients insured by Medicaid may differ based on the requirements needed to expedite ART for people who have been newly diagnosed. Establish the protocols that need to be followed to fill the prescription. This may require the nurse, physician, PN, or another staff person to alert the pharmacy of a newly diagnosed client insured by Medicaid. The main referring point of contact may need to complete and send a new enrollment sheet with demographics and insurance information on behalf of the client to the pharmacy. Upon receiving this information, the pharmacy should fill the new prescription immediately and aim to have it ready for the client within 15 minutes. The pharmacy should contact the provider or other staff person once the Rx is ready for pick-up. If you establish a similar protocol, designate a staff person to retrieve and sign the prescription on behalf of the client. If the client must pick up the medication, the PN can accompany them and facilitate this process.

e. *Complete Discharge:* After the client meets with the provider, the nurse or Medical Assistant can discharge the client. Schedule a follow-up appointment for the client with the HIV provider within four weeks and ensure future visits are longer in duration. During the discharge process, notify the Eligibility Specialist that the client has completed the appointment. After the visit, follow-up with the necessary staff person at the clinic (e.g., Medication Coordinator) to ensure a timely resupply of medication. This process may vary by implementation site. The PN can assist with all appointments through the second provider visit.

4. Perform Labs

This visit may take approximately 15-minutes.

a. *Get a Comprehensive HIV Lab Panel:* The phlebotomist should draw an HIV lab panel for new clients and include any other tests as needed (e.g., pregnancy tests and sexually transmitted disease screenings). Designate a provider who can review lab results after the visit. The provider should assess whether the client can stay on ARV based on the results (e.g., ensure the client's glomerular filtration rate is >30mL/min, which is the cut-off for

Descovy use). Labs should be received within 48 hours for review. Ensure an HIV specialist is available to review all client encounters regularly.

- If any laboratory contraindications to the ARV medication are found, clients should be called immediately, and this information should be documented in the EHR or EMR.
- Clients might not always have continuous access to phone services. If laboratory abnormalities are found, ensure clinical providers, case managers, and the Patient Navigator can contact them promptly to return to the clinic. Consider sending a generic text message to the client asking them to call or come into the clinic.

5. Link Client to Benefits and Social Services

This visit may take approximately 30-minutes, depending on client needs.

a. *Connect Client with an Eligibility Specialist (ES):* The visit with the ES can come immediately before or following the medical visit. If the client is unable to meet with the ES, prioritize a follow-up visit within seven days.

b. *Conduct Eligibility Visit:* The ES should perform a brief check-in with the client. For example, perform third-party payer screening and initiate the appropriate applications for Medicaid, marketplace, or HIV drug assistance programs. The ES or another staff person should also complete a RWHAP client eligibility documentation, which helps determine client eligibility for RWHAP services. This must be completed within 30 days of the provider visit and uploaded into the client's EMR.

c. *Connect Client with Social Service Staff:* The nurse, medical assistant or provider should schedule an intake visit with the Social Service team if no same-day appointments are available. This visit will be helpful for clients who could benefit from other support services (e.g., housing, SNAP). It is imperative to assess, and address interconnected and intersectional social determinants of health that can hinder access to and retention in care. Some organizations may not have a social service team and thus, staff should connect clients to the appropriate staff person or other agencies.

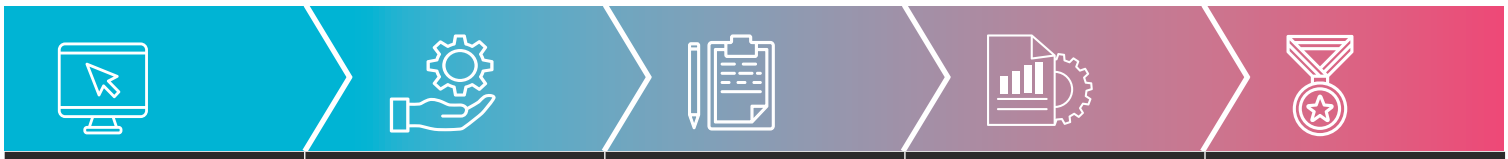
6. Follow-up with Client

a. *Check-in with Client After the Visit:* The PN should reach out to the client to assess how they are doing and answer any questions. Refer the client to the appropriate staff depending on the needs they express (e.g., to a clinical provider for medical concerns). Remind the client about their follow-up appointment and determine if they require any support to get there (e.g., transportation). If any changes are needed for the follow-up appointment, document and share them with the clinical provider. Coordinate with retention teams as needed to ensure that the client receives ongoing HIV education and patient navigation.

- The PN can remain with the client through care enrollment, medication pick-up (if applicable), and initial follow-up. Ensure that all enrollment paperwork is complete and the client has all the resources they need as they move forward.

Logic Model

Logic models are effective tools to assist in planning, implementing, and managing an intervention. Below is a logic model highlighting the resources, activities, outputs, outcomes, and impact of the CrescentCare Start Initiative (CCSI) intervention referenced throughout this guide.



Resources	Activities	Outputs	Outcomes	Impact
• RWHAP (e.g., AIDS Drug Assistance Program) funds or another funding source that supports rapid ART activities • Relationships and collaborations with referring agencies and departments such as testing sites, sexual wellness centers, and community-based organizations • Patient Navigator, Eligibility Specialist, Social Services staff, clinical providers (e.g., primary care and HIV specialists), and accessible patient or linkage coordinators • Data system (e.g., EHR) • Pharmacy services, and early and sustained access to ARV medication • Expedited healthcare coverage or payer source • Infrastructure that facilitates implementation (e.g., flexible clinic hours, clinical space for intakes)	• Engage stakeholders and obtain community input • Identify and train key staff • Conduct intake for the CCSI intervention, get consent and deliver ART education • Schedule an appointment with a clinical provider and assess ARV readiness (aim for same-day clinician visits) • Administer the first dose of ARV and provide a 30-day supply (prescribe medication as needed) • Schedule a follow-up appointment four weeks after the initial appointment • Perform and assess laboratory tests • Connect client with Eligibility Specialist and social services teams • Determine and address interconnected client needs	• A collaborative and streamlined process for engaging and treating people with HIV • Establishing rapid antiretroviral therapy as an initiation model. • A network of providers and organizations committed to serving clients who have been newly diagnosed	Among people with HIV: • Access to ARV medication within 72 hours of an HIV diagnosis • Linkage to services that meet health and social needs • Decreased time to HIV care engagement • Increased rates of long-term viral suppression • Improvement in HIV and overall health outcomes Within the organization implementing the intervention: • Increase in referrals • Enhanced infrastructure to link and retain people with HIV • Demonstrated investment in the client population and HIV relinkage efforts • Strengthened relationships with health department(s) and community stakeholders	• Reduction in HIV morbidity and mortality • Reduction in HIV transmission • Reduction in time between diagnosis and viral suppression • Advancement of health equity for people with HIV

Your Planned Work

Your Intended Results

Staffing Requirements & Considerations

Staff Capacity

The following staff implemented the CCSI intervention at CrescentCare:

- *Patient Navigator (PN).* The PN is available 24 hours a day to link people who have been newly diagnosed with HIV into care. Their responsibilities include:
  - Responding to referrals from testing sites and other departments or organizations
  - Facilitating intake and enrollment of clients into the CCSI intervention
  - Delivering HIV medical education and gathering client consent
  - Scheduling provider appointments and linking them to other services
  - Documenting client information into the EMR or EHR
  - Accompanying clients to obtain their prescriptions if needed
  - Following up with clients after their initial appointment and noting any needs before their next visit
  - Linking clients to benefits and social services if an Eligibility Specialist is unavailable
  - Connecting clients to retention teams for ongoing HIV case management
  - Participating in ongoing training
- *Eligibility Specialist (ES).* The ES supports clients with benefits enrollment and refers them to other teams (e.g., Social Services team) for other support services. Their responsibilities include:
  - Meeting with clients and conducting a brief check-in
  - Conducting third-party payer screenings and initiating appropriate applications (e.g., Medicaid, Marketplace)
  - Assessing RWHAP eligibility and processing enrollment forms
  - Scheduling social service appointments as needed to address other needs
- *Nurse or Medical Assistant.* Their responsibilities include:
  - Performing limited vitals before the visit with a medical provider who will prescribe ARV medication
  - Confirming HIV diagnosis
  - Discharging clients and scheduling follow-up appointments
- *Primary Care Providers or HIV Specialists.* Their responsibilities include:
  - Performing a health assessment (including behavioral and mental health assessment)
  - Assessing ARV medication readiness and sharing medical information
  - Ordering lab work such as comprehensive HIV panel and reviewing results
  - Following up with clients about any contraindications and proposing alternative courses of care
  - Administering the first dose of ARV medication during the visit
  - Corresponding with pharmacy services and expediting fill of 30-day supply of ARV medication
  - Referring clients to other providers such as social workers or behavioral health specialists if needed
  - Documenting information in the EMR or EHR

Staff Characteristics

Core competencies of all staff should include:

- A personable and affirming demeanor and flexibility in identifying individual client needs
- Knowledgeable about HIV and rapid ART interventions
- Willingness to adapt approaches to service delivery
- Ability to collaborate with multiple stakeholders
- Experience with client navigation and benefits enrollment
- Previous work at a community-based health clinic
- Familiarity with the clinic and its dynamics
- Fluency in other languages based on local needs
- Commitment to delivering culturally responsive care
- Demonstrated ability to work with diverse client populations impacted by HIV
- A client-centered and trauma-informed orientation

Replication Tips for Intervention Procedures and Client Engagement

Successful replication of the CCSI intervention involves building and sustaining relationships between testing and rapid ART intervention sites, ensuring accessible linkage staff, and enhancing clinic infrastructure to facilitate early and sustained access to ART for people with newly diagnosed HIV.

- *Invest in the Referral Network:* Rapid ART interventions serve as an integral tool to link and retain people with HIV in care. The referral network is a crucial component of this model, so it is imperative to establish and strengthen relationships with stakeholders before implementing the intervention. During these conversations, clinics can consider doing the following:
  - Establish common goals that will advance the work of all stakeholders. For example, a testing site may consider this an opportunity to ensure that their clients will be linked to HIV care and not be lost to follow-up. The clinic may utilize this model to increase the number of referrals they receive from partners. Organizations can work in tandem and leverage the CCSI intervention to enhance these care efforts.
  - Determine a streamlined process for referring people who have been newly diagnosed with HIV to the clinic. The CCSI intervention is designed to become a part of an organization's workflow. Organizations should evaluate their current processes for referring and linking clients and tailor the intervention accordingly.
  - Maintain open lines of communication and meaningfully gather feedback from stakeholders.
- *Empower Clinic Staff.* The success of the intervention is also contingent on the accessibility of patient or linkage coordinators, Eligibility Specialists, and providers. These key staff are responsible for linking clients into HIV care and facilitating access to ARV medication within 72 hours of an HIV diagnosis. This requires them to be flexible (e.g., coordinating same-day clinician visits, promptly responding to referrals, reviewing lab results once they are available), patient, and willing to address any client barriers as they arise. Clinics should dedicate time to acknowledge staff achievements and prioritize staff needs to prevent burnout.
- *Prioritize Shared Decision-Making Between Client and Provider.* Clients have full agency and autonomy over their HIV care. Racism, stigma, the legacy of medical mistreatment and discrimination against Black, indigenous, and other people of color in the United States has led to mistrust and distrust of healthcare systems. Thus, providers should work to disrupt power dynamics inherent within clinical

settings by delivering affirming care and prioritizing client needs and concerns during clinical decision-making processes.

- *Address Interconnected and Intersectional Social Determinants of Health.* Access to rapid ART interventions is an issue of equity. There have been structural and systematic inequities that have contributed to the disproportionate impact of the HIV epidemic on certain populations. In addition to linking clients to care and facilitating access to ART, clinics should also identify and address the interconnected and intersectional social determinants of health that may prevent clients from engaging and staying in care. These barriers may include lack of health insurance coverage, limited access to reliable transportation, lack of culturally responsive and trans-affirming care, housing instability, mass incarceration, unemployment, poverty, and other health conditions (e.g., diabetes, behavioral and mental health challenges). HIV is one part of a person's life, and clinics should determine strategies and approaches to connect clients with holistic services and resources needed to thrive and stay in care.

Securing Buy-In

The CCSI intervention requires that clinics engage a wide range of stakeholders, including people with HIV, referring sites, and clinic staff. Rapid ART interventions are beginning to be widely implemented across RWHAP clinics, as studies have shown that these models can significantly improve ART uptake and viral suppression rates. However, it is important to incorporate the perspectives of people with HIV, clinic staff engaged in service delivery, leadership, and referring sites to maximize intervention outcomes. While the intervention effectively links and retains people with HIV who have been newly diagnosed in care, stakeholders may have questions and feedback about the model (e.g., logistics around administering ART prior to lab results) and funding, among other topics. To facilitate these conversations and secure buy-in for implementation, organizations should gather information and address stakeholders' questions about rapid ART models. This can be done through surveys, focus groups, or key informant interviews. Additional recommendations on securing buy-in include:

- **People with HIV.** Organizations can engage people with HIV who utilize the services at the clinic, including current or former clients and community advisory councils. Replicators can inquire about the client population's receptiveness to starting ARV medication within 72 hours of an HIV diagnosis. Additionally, the organization can use this as an opportunity to curate direction on additions or adaptations needed to facilitate meaningful engagement and retention in care (e.g., transportation services).

- **Clinic Staff and Leadership.** Clinic leadership, staff, and providers are integral to the CCSI intervention. To gather buy-in, organizations can explain how the intervention will improve the clinic workflow (e.g., the Patient Navigator will be the main point of contact for referrals, and the intake process will be streamlined).

Share how rapid ART interventions can enhance linkage and retention efforts by highlighting outcomes in the existing literature, including the safety and effectiveness of administering ARV medications before lab results. Organizations can further note how these activities can advance EHE goals at the clinic. Present data on service delivery gaps at the clinic (e.g., low referral rates) and how the intervention provides solutions to meet these gaps. Clinic leadership should also discuss or propose funding streams to support the CCSI intervention with minimal disruptions to existing services (e.g., share opportunities to cover these services with RWHAP funding).

- **External and Referring Sites.** The success of the CCSI intervention is contingent on referrals from other sites and departments. Thus, the perspectives of referring sites should be considered before and during implementation. Meet with partner sites and share how the CCSI intervention can enhance their service delivery models (e.g., the intervention provides clients with a resource for immediate linkage to HIV services). Further, organizations can gather their input to inform a personable, streamlined, and effective referral process.

  Organizations should develop a process for gathering feedback and addressing questions from these different stakeholder groups. This will generate the buy-in and support needed to implement the intervention with fidelity, achieve organizational and client goals, and obtain optimal HIV care outcomes.

Overcoming Implementation Challenges

The CCSI intervention is multifaceted, and its implementation can be complex. Anticipated challenges, as well as possible solutions, are noted below.

- **Limited Organizational Infrastructure:** Discuss opportunities to extend hours in a way that complements the organization's workflow (e.g., including weekends). Designate the Patient or Linkage Navigator as the main point of contact for the intervention and ensure provider availability (e.g., same-day appointments).
- **Disruptions in ARV Coverage:** Leverage the Eligibility Specialist to ensure clients have initial access to a 30-day dose pack and continuous access to ARV. Present a pathway for guaranteed access to ART through healthcare coverage enrollment or RWHAP services (e.g., ADAP).
- **Barriers to Care:** To address interconnected social determinants of health that can result in barriers to care, organizations should connect clients with Social Service teams and partner agencies.
- **Lack of Referrals:** Solidify an effective referral process with other teams and organizations. Conduct ongoing check-ins with referring sites to facilitate the process if necessary.
- **Provider Commitment:** Ensure providers (primary care physicians, HIV specialists, nurses, and medical assistants) are support of the intervention.
- **Limited Resources:** Invest in patient navigation and immediate access to and cost coverage for the first 30 days of medication.
- **Staff Burnout:** Find ways to increase staff morale and highlight their work to connect people with HIV to care. Conduct consistent check-ins with staff to address barriers in real-time and prevent burnout.
- **Undefined Staff Roles:** Utilize a Standard Operating Procedure (SOP) manual. Be clear on roles and responsibilities and how these can sometimes overlap. For example, note who communicates with the referring sites and which provider(s) will review the lab results and correspond with clients.
- **Long-Term Goals:** While access to rapid ART is one of the key components of the intervention, it is beneficial to focus on sustained engagement in care to achieve optimal HIV care outcomes. The Patient or Linkage Navigator, Eligibility Specialist, and social service teams can work with other clinic staff to collect information about and address barriers to sustained engagement in care.

Promoting Sustainability

To successfully sustain this intervention, project outcomes must be consistently monitored and evaluated. The CCSI intervention offers many evaluation opportunities to ensure that people with HIV who have been newly diagnosed access the resources they need to start rapid ART and achieve optimal health outcomes. To do this, complete ongoing process and outcome evaluations that include documentation of the following:

- Number of clients who are being referred to the clinic
- Number of clients who receive a medical visit and obtain access to ARV within 72 hours of diagnosis
- Number of clients who return for follow-up within four weeks
- Client demographics (e.g., race, gender, sexual orientation, insurance status) to ensure priority populations are being engaged and retained
- Retention indicators
- Qualitative feedback from clients about barriers to HIV care and overall experiences with the intervention

This information can help inform improvements needed for successful intervention replication, and data can also be leveraged during stakeholder meetings (e.g., with federal partners, clinic leadership). An organization can also gather feedback from referring sites, the Patient or Linkage Navigator, and clinic staff. By creating consistent, intentional, and responsive feedback loops, organizations can ensure that outreach efforts are effective while concerns are prioritized and addressed as they arise. Evaluation approaches can help explore innovative and data-informed strategies to tailor the intervention, increase its impact, demonstrate how the intervention is working, and emphasize to stakeholders the importance of integrating a rapid ART intervention.

SWOT Analysis

SWOT is an acronym for Strengths, Weaknesses, Opportunities, and Threats. A SWOT analysis is a structured planning method that can assess the viability of a project or intervention. By conducting a SWOT analysis before implementing an intervention, organizations can proactively identify challenges before they occur and think through how to best leverage their organizational strengths and opportunities to improve future performance. A SWOT analysis of the CCSI intervention at CrescentCare identified the following:

STRENGTHS

The intervention increases linkage and retention outcomes for clients who have been newly diagnosed with HIV by:

- Streamlining the referral and intake process for clients who have been newly diagnosed
- Providing a full-time Patient or Linkage Navigator 24 hours a day to respond to referrals
- Offering same-day appointment accessibility
- Ensuring clients have immediate and sustained access to ARV (within 72 hours of a diagnosis)
- Procedure and medical checklist
- Addressing interconnected social and health needs that hinder access to HIV care
- Establishing strong relationships between clinic staff, leadership, and referring sites; and
- Leveraging RWHAP funding resources to support a novel intervention

WEAKNESSES

Agencies will find it challenging to implement the CCSI intervention without:

- A Patient or Linkage Navigator, an Eligibility Specialist, providers, clinic staff (e.g., medical assistants), and referring sites
- A comprehensive and easy-to-navigate referral system
- Ability to promptly schedule an appointment for a client once they receive an HIV diagnosis
- Access to 30-day dose pack of tenofovir alafenamide/ emtricitabine and dolutegravir (TAF/FTC and DTG) in-clinic
- Client follow-up with a provider within four weeks of diagnosis
- Relationships and ongoing communication with referring sites and other teams (e.g., pharmacy services, phlebotomists)
- Provider commitment to this model of care
- Secured funding streams support linkage activities and ensure rapid ART coverage

OPPORTUNITIES

The CCSI intervention offers opportunities to:

- Increase ARV medication uptake among people with HIV who have been newly diagnosed
- Leverage referring sites or a broader healthcare network to increase intervention enrollment
- Tailor the intervention to meet the unique health needs of priority populations
- Streamline linkage and retention services using one linkage specialist who is connected to the broader clinical team

THREATS

Threats to the success of the CCSI intervention include:

- Hesitancy from providers and others around providing ARV before labs are obtained
- Difficulty securing funding to sustain services (potentially leading to disruptions in ART coverage)
- Limited organizational infrastructure (e.g., lack staff capacity, restrictions in scheduling or offering extended hours)
- Inability to address barriers to care due to interconnected social determinants of health
- Lack of a centralized system that fosters engagement between different organizations
- Reallocation of funding to meet other pressing and emerging needs

Conclusion

To curtail the HIV epidemic and improve health outcomes for people with HIV who have been newly diagnosed, the CrescentCare clinic implemented the CCSI intervention, allowing the clinic and referring sites to work collaboratively and intentionally to address linkage and retention gaps. The CCSI intervention allows clinics to establish and leverage a referral system, triage clients within 72 hours of an HIV diagnosis through the support of a Patient or Linkage Navigator and clinic staff, provide immediate and sustained access to ART; expedite healthcare coverage and benefits enrollment, and provide access to support services to address interconnected social determinants of health.

For many organizations, prescribing ARV before intake laboratory results requires a significant shift in practice and thus necessitates careful adaptation.[1] However, rapid ART initiation models are needed to ensure people with HIV who have been newly diagnosed have access to the resources and treatment they need to achieve viral suppression. Further, these models have demonstrated that starting clients on the day of diagnosis or linkage, before labs are obtained, is a safe, well-tolerated, and effective intervention.[3] Federally Qualified Health Centers and other community-based clinics are uniquely positioned to implement rapid ART interventions. This model can increase referrals, high rates of linkage to care, earlier viral suppression, and sustained impact over time.

Among the 77 clients newly diagnosed with HIV and referred to CCSI between December 5, 2016 and August 6, 2017, 92 percent (N=71) were linked, saw a clinical provider, and started ART within 72 hours of diagnosis.[2] Four of the six clients not linked within 72 hours of diagnosis were linked to care within 30 days of diagnosis.[2] When CCSI was compared to a cohort of 29 clients diagnosed and linked utilizing EIS services between December 2015 and August 2016, the meantime to linkage in the historical cohort was 30 days (95% CI: 25.1-43.6 days) compared to 1.3 days (95% CI: 1.09–1.51 days) in CCSI ($p<0.0001$).[2] The median time to viral suppression (<200 copies/mm^3) in the historical cohort was 68 days (95% CI: 60–92 days) compared to 30 days (95% CI: 27–34 days) in CCSI ($p<0.0001$).[2] These data demonstrate the effectiveness of rapid ART models and the potential in helping to advance health equity for people with HIV at RWHAP clinics, FQHCs, health departments, and beyond.

Additional Resources

The National HIV/AIDS Strategy (2022–2025)
https://www.whitehouse.gov/wp-content/uploads/2021/11/National-HIV-AIDS-Strategy.pdf

CrescentCare Start Initiative Standard Operating Procedure Manual
https://ciehealth.org/wp-content/uploads/2021/01/CCSI_SOP_Final_4-2018.pdf

CrescentCare Southeast Education and Training Center—Webinar
https://ciehealth.org/wp-content/uploads/2021/01/CrescentCare-Southeast-AIDS-Education-and-Training-Center-Webinar.pdf

CrescentCare—2018 National Ryan White Conference on HIV Care & Treatment Presentation
http://ciehealth.org/wp-content/uploads/2021/01/CrescentCare-2018-Ryan-White-Conference-Presentation.pptx

CrescentCare Start Initiative an Intervention to End the Epidemic Presentation
https://s3.amazonaws.com/media.guidebook.com/upload/146358/2F4wP69gRh0uXulyHcFRzLZTfRxekKChq4Zx.pdf

CrescentCare Start Initiative–2020 Conference on Retroviruses and Opportunistic Infections—Poster and Webcast
https://www.croiconference.org/abstract/rapid-start-leads-to-sustained-viral-suppression-in-young-people-in-the-south/

CIE Cost Analysis Calculator
www.CIEhealth.org/innovations

Rapid Start Leads to Sustained Viral Suppression in Young People in the South—CROI Poster
www.CIEhealth.org/intervention/crescentcare#resources (Click on Resources)

Endnotes

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[3] Halperin, J., Conner, K., Butler, I., Zeng, P., Myers, L., Clark, R., & Van Sickels, N. (2019). A Care Continuum of Immediate ART for Newly Diagnosed Patients and Patients Presenting Later to Care at a Federally Qualified Health Center in New Orleans. *Open forum infectious diseases, 6*(4), ofz161. https://doi.org/10.1093/ofid/ofz161

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[8] Centers for Disease Control and Prevention. (2018). *HIV surveillance in urban and nonurban areas through 2018* (slides). https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-surveillance-urban-nonurban-2018.pdf

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