



BIG IDEAS

ENDING THE HIV EPIDEMIC —
SUPPORTING ALL PEOPLE LIVING WITH HIV AND REDUCING NEW TRANSMISSIONS

GREATER STATE AND LOCAL LEADERSHIP IS NEEDED TO SCALE-UP RAPID START PROGRAMS

AS WE MAKE PROGRESS AT PREVENTING HIV AND IMPROVING OUTCOMES FOR PEOPLE WITH HIV, research shows that our efforts are hindered by delays in diagnosis and initiating treatment. Rapid Start is the accelerated entry into HIV medical care at the time of diagnosis, as well as swift initiation of antiretroviral therapy (ART) for people with HIV, preferably immediately or within the first seven days of diagnosis. Rapid Start of ART is an essential intervention that is not yet the standard of care throughout the U.S. It can help ensure that people with HIV are quickly linked to care, establish an ongoing and successful relationship with an HIV care provider, and remain in care to achieve viral suppression.¹ Viral suppression is critical to protecting the health of people with HIV, and since U=U (undetectable equals untransmittable),² it also can be motivating for individuals to know that if they are suppressed they cannot transmit HIV to their sexual partners. **Rapid Re-Start is a form of Rapid Start for persons returning to care and ready to re-start ART.** Approximately 42% of people with HIV in the U.S. are not engaged in care.³ The people most likely to not be engaged in care often come from communities that have historically been poorly served by the health care system.

PRIME OPPORTUNITIES TO SUPPORT RAPID START

State and local leaders can take many actions to expand early access to HIV care upon diagnosis:

1. EDUCATE PROVIDERS AND COMMUNITY

Work with AIDS Education and Training Centers (AETCs) and state medical boards to provide training and education.

2. COORDINATE CLINICAL PROVIDERS WITHIN A JURISDICTION

Convene the local providers in a community with the specific purpose of setting expectations for the adoption of Rapid Start and to identify and fill gaps when there are a limited number of services providers to ensure community level access across the system of care.

3. SUPPORT ADMINISTRATIVE READINESS

Develop a Rapid Start implementation plan and set minimum standards.

Limit health plan utilization management.

4. ENSURE IMMEDIATE FINANCIAL ELIGIBILITY

Make policy changes to facilitate immediate coverage of services and, where necessary, fund rapid initiation programs.

5. BOLSTER WORKFORCE CAPACITY

Facilitate the adoption of team-based models of care that extend the capacity of the entire care team to respond to newly diagnosed individuals.

6. RE-ENGAGE PERSONS WHO HAVE STOPPED ENGAGING IN CARE

Ensure that Rapid Start initiatives create new pathways for re-engaging diagnosed persons who have stopped engaging in care.

THE FIRST VISIT: THE RED-CARPET ROLLOUT

It is normal for individuals who have just been diagnosed with HIV to be apprehensive, unsure, and fearful. Welcoming environments must be established, especially because one negative experience in a clinical setting can mean disengagement altogether. To achieve this, some organizations have established rapid entry programs called “Red Carpet Programs.” These programs are meant to roll out the figurative “Red Carpet” and treat people with a great deal of compassion and care. The initial visit will typically last 2-3 hours. After scheduling this visit with a Rapid Start Navigator and arriving to the care facility, the steps that encompass the visit usually include:

- **Meeting the specialized multidisciplinary team designated to the patient’s care.** This often consists of a social worker/navigator, a nurse, and a clinician.
- **With assistance from a social worker or linkage navigator, establishing or optimizing insurance benefits.** This includes medication access as well as any immediate needs for stabilization.
- **Receiving clinical education and emotional support around the diagnosis of HIV (as needed) from a nurse.** An overview of the clinic and HIV care offered is provided by the care team.
- **Establishing an initial care plan based on an assessment conducted by a clinician.** The assessment should gather enough patient history for the clinician to determine whether starting ART is appropriate and if so, what medications to use.
- **Educating about ART.** The benefits of early ART and remaining on treatment to prevent transmission will be emphasized.
- **Providing medication after consent is received, preferably on the same day as the initial visit.** Starter packs should be provided to the patient if a prescription cannot be immediately filled.
- **Linking to care and other services either through in-house or external linkage navigators.**

The most important aspect of the initial visit is ensuring a follow-up care system is in place so that a second (and additional) visit is attended and so adherence to treatment is maintained.

Sources: Susa Coffey and Oliver Bacon, *Immediate ART Initiation & Restart: Guide for Clinicians*, AIDS Educ. & Training Ctr. (June 2021).

People with HIV who are not engaged in care are more likely to be Black, young, and have unmet needs across several areas (e.g., finances, mental health, and more) than those in-care.⁴

The National HIV/AIDS Strategy⁵ identifies Rapid Start as a key strategy for improving HIV-related outcomes and it is also endorsed by the Department of Health and Human Services’ ART treatment guidelines,⁶ which establish the standard of HIV care in the U.S. Further, the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau through its Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS) Program has supported initiatives that found that **Rapid Start programs were reasonably inexpensive to implement and cost-effective or cost-saving during initial and sustained implementation.**⁷

Greater state and local leadership is critical to adopting Rapid Start as the standard of care. Undoubtedly, critical new federal policy and financial support would enhance state and local efforts (see box on page 6). Nonetheless, there are many opportunities for state and local policymakers to have an impact. Prioritizing the adoption of Rapid Start may present both states and local jurisdictions with a rare opportunity to make tangible progress toward improving HIV outcomes and reducing the spread of HIV in their communities without large new ongoing financial commitments. **Because insurance coverage or support from the RWHAP is generally available to finance ongoing HIV care once an individual has established eligibility, adopting Rapid Start does not require a long-term financial commitment.** Implementing new models of care, however, generally requires education and technical assistance. Ensuring immediate access to care may require having a source of payment for the initial period (i.e. an initial prescription of ART and labs and other services) until insurance or other coverage can be established, but this is a temporary commitment. To realize the potential of Rapid Start programs, jurisdictions should build the systems needed to ensure linkage to HIV care and initiation of ART on the same day or within seven days of diagnosis. To achieve this vision, at least six priority areas call out for state and local leadership:

1. EDUCATING PROVIDERS AND COMMUNITY

Establishing large-scale Rapid Start programs often requires clinical transformation. This requires clinical champions. Therefore, key actions in support of scaling-up Rapid Start are to educate clinics and prescribing providers on the benefits of Rapid Start, show them various models and best practices, as well as to provide technical assistance to adopt this new approach. The history of HIV shows that people with HIV themselves are critical to facilitating change. Thus, people with HIV and coalitions and networks of people with HIV also can build support for Rapid Start

with RWHAP Planning Councils and Consortia, and among other state and local policymakers.

POLICY ACTION: WORK WITH AIDS EDUCATION AND TRAINING CENTERS (AETCs), PRIMARY CARE ASSOCIATIONS AND STATE MEDICAL BOARDS TO PROVIDE TRAINING AND EDUCATION.

State and local health departments have a critical role to play in educating HIV and primary care providers, as well as communities of people with HIV and community-based social services providers about the advantages of and models for Rapid Start programs. This could include sending clinics and health care providers “Dear Colleague” letters that explain the rationale and benefits of Rapid Start and set expectations for adoption of new Rapid Start models of care. Health departments should access the resources of the AETC program,⁸ TargetHIV (a HRSA-supported technical assistance resource that has many resources, including information from the SPNS demonstration on Building Capacity to Implement Rapid ART Start for Improved Care Engagement in (RWHAP) and Dissemination Assistance Providers,^{9,10} and work with state medical boards, state associations of county & city health officials (SACCHOs), and other professional associations to spread awareness of and build support for Rapid Start programs.

2. COORDINATING CLINICAL PROVIDERS WITHIN A JURISDICTION

Rapid Start programs must be able to ensure that prescribing providers and other essential members of the care team including navigators and linkage staff are available for the initial visit. This is especially challenging with small clinics or private practices with one or a small number of prescribing providers. One way to overcome this obstacle is for local or state governments to convene all of the providers within a jurisdiction to identify the range of community resources and facilitate collaborative activities to identify resources for organizations to adopt rapid start. An on-call strategy may help clinics ensure clinical availability for the initial visit. For example, if four clinics in a community want to establish Rapid Start programs, but on their own, they cannot ensure staffing for a broad range of hours, the health department or a network of clinics could establish a local process to ensure availability of rapid start appointment slots across clinics and share this information with relevant organizations, including organizations that provide HIV testing, including hospitals (for instances when people are diagnosed with HIV in the emergency department). Advance agreements could be established to coordinate care

and linkage from HIV testing sites, facilitate data sharing, and preserve a client’s ability to select where and by whom they prefer to seek ongoing HIV care.

POLICY ACTION: CONVENE THE LOCAL PROVIDERS IN A COMMUNITY WITH THE SPECIFIC PURPOSE OF SETTING EXPECTATIONS FOR THE ADOPTION OF RAPID START AND TO IDENTIFY AND FILL GAPS WHEN THERE ARE A LIMITED NUMBER OF SERVICE PROVIDERS TO ENSURE COMMUNITY LEVEL ACCESS ACROSS THE SYSTEM OF CARE.

State and local health departments should use their convening power to create spaces to collectively explore barriers and opportunities, share information about different models for Rapid Start, and provide technical assistance for individual clinics and practices to participate in a Rapid Start network, including supporting the development of memorandums of agreement and data-sharing protocols. Depending on the jurisdiction, health departments could play differing roles ranging from simply providing technical assistance to more actively supporting such a system by, for example, managing calendars of Rapid Start open slots at clinics throughout a jurisdiction.

3. SUPPORTING ADMINISTRATIVE READINESS

In small trials, Rapid Start has proven its value.¹¹ The challenge with getting to scale is that the whole system must work in a coordinated fashion, and it must be ready for a greater volume. A key ingredient to success is ensuring that the clinic or program is capable of expanding its capacity. Part of this readiness includes having an approved standard protocol with minimum standards for Rapid Start for the jurisdiction. If the newly diagnosed person was tested at an organization that provides testing only, this begins with the smooth handoff between that organization and a clinical organization. Minimum standards for Rapid Start also include agreeing on the standard for accepting that the individual has tested positive for HIV (i.e. a best practice is to accept a second positive point-of-care test result for ART initiation even if additional laboratory testing is ordered for follow-up), establishing standardized ART regimens, having standing orders for labs, and defining roles and responsibilities among all members of the care team and identifying handoffs. HRSA’s AIDS Education and Training Center (AETC) Program National Coordinating Resource Center has resources for clinics and clinicians that includes recommended regimens.¹² The AETC Program also supports the National Clinical Consultation Center (i.e. the warm

THE BASIC RAPID START TREATMENT PROTOCOLS

Rapid Start programs depend on protocols that determine the flow of decisions and actions taken when an individual presents for services. Too frequently, however, each individual clinic makes its own decisions. Not only can this confuse providers and patients, but it can also reduce capacity to effectively deliver services. Although we do not endorse any specific protocol, standardization across clinics and jurisdictions may be beneficial. The following are key elements from New York State's AIDS Institute's Rapid Start protocols, which appear largely consistent with common practices across the field:

To determine whether to initiate Rapid ART, confirm the individual has:

- A new reactive point-of-care HIV test result, confirmed HIV diagnosis, suspected acute HIV infection (HIV antibody negative and HIV RNA positive), or known HIV, and
- No prior antiretroviral therapy or limited prior use of antiretroviral medications, and
- No medical conditions or opportunistic infections that require deferral of ART initiation, including suspected cryptococcal or tuberculous meningitis and cytomegalovirus retinitis.

Clinicians should perform baseline laboratory testing for all patients who are initiating ART immediately; ART can begin while awaiting the results. Baseline laboratory testing includes:

- HIV-1/2 antigen/antibody immunoassay
- HIV quantitative viral load test
- Baseline HIV genotypic resistance profile
- Baseline CD4 cell count
- Testing for hepatitis A, B, and C viruses
- Comprehensive metabolic panel (creatinine clearance, hepatic profile)
- Pregnancy test for individuals of childbearing potential
- Urinalysis
- Syphilis, gonorrhea, and chlamydia screening as per CDC's Sexually Transmitted Infections Treatment Guidelines and Screening Recommendations, 2021

Sources: See *Clinical Guidelines Program: Rapid ART Initiation*, New York State Department of Health AIDS Institute (Jan. 2020), bit.ly/43hYtca.

line) that providers can consult for clinical guidance.¹³ Additionally, TargetHIV has additional resources including a compendium of best practices and emerging models for Rapid Start.¹⁴ A number of local jurisdictions also have produced their own resources.¹⁵

POLICY ACTION: DEVELOP A RAPID START IMPLEMENTATION PLAN AND SET MINIMUM STANDARDS.

State and local leaders should commit to supporting Rapid Start and developing a time-phased implementation plan. For states without Rapid Start guidelines, this process should begin with developing a standard protocol for all providers in the jurisdiction. TargetHIV has developed numerous resources that can offer a useful guide to implementing Rapid Start. One resource, *Rapid ART: An Essential Strategy for Ending the HIV Epidemic*,¹⁶ offers the following as key steps during site-level implementation:

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

POLICY ACTION: LIMIT HEALTH PLAN UTILIZATION MANAGEMENT.

Health insurance is primarily regulated at the state level with the governor, in most cases, appointing the insurance commissioner. Whether through executive action or through legislation, states could establish rules to require Medicaid plans and commercially insured health plans to provide ART without prior authorization or other forms of utilization management for an initial (i.e. 30-day) period so that this does not delay initiation of ART. This should permit ART initiation without documentation of confirmatory tests and other record-keeping requirements, as long as the clinic asserts that it has followed a standard Rapid Start protocol approved by the state using an ART regimen approved for Rapid Start by HHS guidelines.¹⁷

4. ENSURING IMMEDIATE FINANCIAL ELIGIBILITY

One of the major challenges with Rapid Start is the potential financial risk for clinics and providers involved in providing medications for individuals for whom a source of coverage has not been established. Most people with HIV, however, have lower incomes and are often income-eligible for Medicaid and almost certainly eligible for assistance from the RWHAP. Due to existing rules for establishing financial eligibility and complying with the payer-of-last resort requirement in the RWHAP and complex Medicaid eligibility processes, administrative delays in establishing eligibility can preclude clinics from adopting Rapid Start.

POLICY ACTION: MAKE POLICY CHANGES TO FACILITATE IMMEDIATE COVERAGE OF SERVICES AND WHERE NECESSARY FUND RAPID INITIATION PROGRAMS.

There are many overlapping opportunities for state and local action:

RYAN WHITE HIV/AIDS PROGRAM (RWHAP): Governors should develop formal guidance to ensure that the scaling up of Rapid Start programs is considered and prioritized in their comprehensive plan (a federal requirement when they receive funding from RWHAP Part B) and the Statewide Coordinated Statement of Need (SCSN).¹⁸ These plans should emphasize consistent access to Rapid Start throughout the state, recognizing differing resources and challenges in rural versus urban areas. Additionally, they should ensure full compliance with HRSA Policy Clarification Notice (PCN) 21-02 by conducting a programmatic review of their AIDS Drug Assistance Programs (ADAPs) to identify steps to simplify and speed-up eligibility, including through presumptive eligibility or rapid eligibility determinations.¹⁹ Some states have developed models that allow for eligibility to be determined electronically during the initial visit and Washington state was able to reduce the time from application to ADAP approval from two weeks to about 48 hours.²⁰

Mayors, Chief Elected Officials, or jurisdictional leaders in RWHAP Part A jurisdictions can establish Rapid Start initiatives and bring together all providers in the jurisdiction to develop a coordinated and collaborative approach to overcoming barriers to Rapid Start. Part A of the RWHAP funds 24 eligible metropolitan areas (EMAs) with a high burden of HIV (and 28 transitional grant areas [TGAs] with fewer cases than EMAs, but a disproportionate burden of HIV). EMAs are required to operate planning councils that represent the diversity of the local epidemic and at least 33% of its members must be people with HIV receiving Part A services who are unaffiliated with

a sub-recipient (i.e. they cannot be employees of an organization that receives funding from Part A).

Planning councils review the services needs of the community and set priorities for the kinds and amounts of services to be supported with Part A funding. Whereas the governmental recipient administers the grant and awards funding, it must fund activities consistent with the planning council priorities. Mayors or the Chief Elected Official in a jurisdiction could work with the planning council to prioritize Rapid Start as an intervention and prioritize Rapid Start as part of their required Clinical Quality Management (CQM) activities.²¹ One approach to be considered would be to create a triage (on-call) network with local clinical providers to ensure access to an immediate entry to care visit if newly diagnosed individuals (or those re-engaging in care) present for care at a clinic that cannot provide Rapid Start services on the same day.

STATE MEDICAID AGENCY: Governors should direct their Medicaid programs to request a Section 1115 waiver to establish presumptive eligibility for people with HIV. Medicaid is a primary provider of HIV and other health care services to people living with HIV. The Centers for Medicare and Medicaid (CMS) has several pathways that allow for states to claim Medicaid presumptive eligibility for individuals that are eligible for the program based on preliminary information.²² This means that they can provide immediate Medicaid coverage and be assured of being paid for services for an initial period before eligibility is fully confirmed. Current pathways through a State Plan Amendment (SPA), which is the normal procedure for states to make changes to their Medicaid program, would not work for the narrow adoption of presumptive eligibility for newly diagnosed people with HIV. Thus, states should request a section 1115 waiver (that must be approved by the CMS) to provide for presumptive eligibility for newly diagnosed people with HIV.

ESTABLISH PARTNERSHIPS TO ADOPT RAPID START: Unlike other efforts to expand access to HIV care, Rapid Start does not require new financing for clinical care costs. Rather, barriers to Rapid Start often include an insufficient number of providers, lack of established protocols by the state, no financing for an initial supply of ART (sometimes called starter packs) and inadequate coordination among various providers. Governors, legislatures, mayors, city councils, county executives, and county commissions can establish and fund Rapid Start implementation to overcome these barriers. Ending the HIV Epidemic (EHE) is a new initiative that is bringing new resources to heavily impacted jurisdictions. These funds may be available to support immediate initiation of ART. Additionally, 340B income may offer another way to finance such efforts. Further, in addition to dedicating public funds, jurisdictions can seek public-private partnerships to support these efforts.

FEDERAL LEADERSHIP CAN SUPPORT STATE AND LOCAL EFFORTS

While Federal HIV programs already have taken action to support Rapid Start, key policy changes can greatly enhance current efforts:

HRSA'S HIV/AIDS BUREAU

IMMEDIATE ACCESS TO RYAN WHITE HIV/AIDS PROGRAM (RWHAP) SERVICES ON DIAGNOSIS:

Longstanding HRSA policy interpreting the Ryan White CARE Act statute has been seen as a barrier to AIDS Drug Assistance Program (ADAP) and RWHAP funds being used for Rapid Start until an individual has been fully determined to be eligible. The statute requires proof of HIV status, proof of financial eligibility (as defined by the state), and proof of residency. Due to the documentation needed to establish financial eligibility and the payer of last resort requirement that does not allow RWHAP funds to be used for items or services for which another form of coverage is available, this delay can make Rapid Start unavailable to some individuals.

HRSA issued Policy Clarification Notice (PCN) 21-02 that expects RWHAP recipients to establish protocols that facilitate the rapid delivery of services including the provision of ART for those newly diagnosed or re-engaged in care. It further states that “if services are initiated prior to eligibility being established, RWHAP recipients and subrecipients must conduct a formal eligibility determination within a reasonable timeframe and reconcile (i.e., properly account for) any RWHAP funds to ensure that they are only used for allowable costs for eligible individuals.”

HRSA should consider additional actions to provide a roadmap for states or to offer technical assistance for ensuring immediate access to services. Since the statute permits states to establish financial eligibility requirements, HRSA could consider a policy clarification that indicates that state eligibility standards can permit a two-stage financial eligibility process. Provisional financial eligibility (i.e. 30 days) could be based on self-attestation of income and a second stage based on written or electronic income verification. States would be deemed to comply with payer of last resort if they establish a pay-and-chase model to bill for covered services.

GUIDANCE ON ADAP ELIGIBILITY SIMPLIFICATION:

HRSA can provide guidance and technical assistance on adopting electronic eligibility determinations during the initial visit and sharing best practices from states that have reduced the time needed to establish eligibility.

DEVELOPMENT OF CORE METRICS AND REPORTING STANDARDS:

Clinics and providers are burdened by tracking and reporting on too many metrics, yet Rapid Start requires consistent data to monitor progress. HRSA could establish reporting standards for core metrics to track time to first clinical visit and time to ART initiation.

SUPPLEMENTAL FUNDING FOR THE AETC PROGRAM:

The RWHAP has been relatively flat-funded for many years and increases have been associated with financing direct medical costs. The Administration should request, and Congress should provide, supplemental funding to extend the capacity of AETCs to support Rapid Start adoption.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

WAIVER GUIDANCE TO OFFER PRESUMPTIVE ELIGIBILITY FOR NEWLY DIAGNOSED INDIVIDUALS:

State Medicaid programs can always request Section 1115 waiver approval, but federal approval is uncertain and can be time consuming. **CMS can greatly strengthen state interest in presumptive eligibility for newly diagnosed people with HIV by creating waiver guidance and developing a waiver template for new Rapid Start Presumptive Eligibility Waivers.** This would signal CMS support for such an approach, would clarify what states need to show to receive approval, and would lead to standardization of policies across states.

STATE MEDICAID DIRECTOR LETTER (SMD):

CMS has periodically issued SMD letters to State Medicaid programs to update them on advances in HIV clinical care to ensure that Medicaid programs align with current standards of care. The last HIV-related SMD was issued in 2016. CMS should issue a new SMD that provides guidance on the benefits of Rapid Start and links to HRSA and other resources for adopting these programs, as well as providing other critical updates, highlighting the National HIV/AIDS Strategy and addressing new and forthcoming longer-acting products for HIV treatment and prevention, guidance and expectations of scaling-up access to PrEP with data on current disparities in use, and the latest data on self-testing for HIV.

5. BOLSTERING WORKFORCE CAPACITY

One challenge with adopting Rapid Start programs is that the capacity of HIV clinics and organizations is already greatly strained, and this model could increase and further exacerbate existing staffing demands at clinical sites. New models of care, however, offer the potential to enable the adoption of Rapid Start programs in ways that also could lessen the stresses experienced by many individuals involved in providing HIV care. A recent survey conducted by the Centers for Disease Control and Prevention (CDC) that collected responses from over one thousand HIV services provider facilities across the country found that just over half of those facilities (52%) could offer a first appointment within five days of an initial request for care, but only 20% could offer a visit on the same day or within one day of a request being made.²³ In the same study, the number one barrier was not having enough qualified individuals available to see and treat those seeking care.²⁴

POLICY ACTION: FACILITATE THE ADOPTION OF TEAM-BASED MODELS OF CARE THAT EXTEND THE CAPACITY OF THE ENTIRE CARE TEAM TO RESPOND TO NEWLY DIAGNOSED INDIVIDUALS.

Health departments can facilitate the adoption of team-based care models in clinics by providing training and technical assistance. These models can enhance the capacity of other members of the team and reduce the time burden needed by the clinician and can facilitate the use of physician assistants, nurses, and other non-physicians as the clinical provider. Teams can include many types of individuals and expertise including nurses, social workers, patient navigators, and people with HIV who serve as peer navigators. Teams can share responsibility for basic education and health and HIV literacy, facilitate linkage to social services, and establish insurance benefits. Some clinics are also utilizing other service methods to facilitate Rapid Start that may include mobile units, and non-traditional clinical sites to enhance the reach and capacity of Rapid Start programs.

6. RE-ENGAGING PERSONS WHO HAVE STOPPED ENGAGING IN CARE

The message that is commonly conveyed to people with HIV who initiate ART is that this is a lifelong commitment that requires near perfect adherence. When perfect adherence is not attained, we tend to ascribe blame to the individual. It is important to acknowledge that demanding perfect adherence to almost any medication or behavior is unrealistic.

Adherence is a universal challenge. Therefore, to comprehensively support good care outcomes for people with HIV and foster a high quality of life, programs must convey a different message; gaps in care are not the result of personal failure and providers should assume that there will be interruptions in care. The health system, therefore, must watch for, seek to prevent, and develop supports to facilitate rapid re-entry into HIV care and ART. Further, our programs must recognize and respond to the fact that some populations may have greater barriers to ongoing care that includes past negative history with the health system and other aspects of a person's life. It is incumbent on the health system and HIV programs to build multiple opportunities and pathways to keep individuals engaged in care through housing assistance programs and other supportive services, as well as re-engage them in HIV care and re-start ART should they stop engaging in care.

POLICY ACTION: ENSURE THAT RAPID START INITIATIVES CREATE NEW PATHWAYS FOR RE-ENGAGING DIAGNOSED PERSONS WHO HAVE STOPPED ENGAGING IN CARE.

Adopting Rapid Restart programs for persons with a prior HIV diagnosis is a critical companion to Rapid Start for newly diagnosed individuals. An ART restart visit is similar to an initial ART visit, but there are critical differences. The individual consults with their care team and the clinician then selects an individualized regimen to follow. Initiating treatment for individuals who have previously been on ART raises unique considerations, but restarting ART typically can be initiated at the first clinic reengagement visit if (1) ART and HIV resistance history is known or can be predicted based on prior ART use, and (2) an appropriate ART regimen can be devised even without information from current resistance test results. There are also unique and innovative techniques that can be employed to achieve more successful rates of maintained reengagement. Telehealth can be utilized to conduct Rapid Restart visits, which can be beneficial for those that find it more difficult to attend in-person visits or can benefit from this flexibility for any other reason. Other tools that can be utilized to further Rapid Restart include allowing drop-in/same-day visitation options, extending medication refill timeframes, offering home delivery options, and working with linkage to care and peer navigators to build relationships with individuals to continuously ensure that patients feel properly supported.

THE TIME IS NOW

The establishment and scaling up of Rapid Start and Rapid Restart programs are important innovations that can improve clinical outcomes and quality of life. To date, however, they have generally been implemented at the clinic or hospital level, and they have not been offered at scale to all newly diagnosed people or persons re-engaging in HIV care. Governors, mayors, state legislators and local elected officials, with greater support from the federal government and philanthropy and private sectors partners, have critical roles to play to make Rapid Start a standard of care.

ENDNOTES

- 1 Michienzi SM, Barrios M, Badowski ME. Evidence regarding rapid initiation of antiretroviral therapy in patients living with HIV. *CURRENT INFECTIOUS DISEASE REPORTS*. 2021 May;23:1-9.
- 2 HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention, Nat'l Institute of Allergy and Infectious Diseases (2019), <https://www.niaid.nih.gov/diseases-conditions/treatment-prevention>
- 3 Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data United States and 6 Dependent Areas, 2019, *CTRS. FOR DISEASE CONTROL & PREVENTION* (2021).
- 4 Lindsey Dawson and Jennifer Kates, *What Do We Know about People with HIV Who Are Not Engaged in Regular HIV Care?*, Kaiser Family Found. (June 22, 2023).
- 5 WHITE HOUSE OFFICE OF NATIONAL AIDS POLICY, *National HIV/AIDS Strategy 2022-2025*, 39 (2021), <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>
- 6 *Guidelines for the Use Antiretroviral Agents in Adults and Adolescents with HIV*, DEP'T OF HEALTH OF HUMAN SERV., 1, 64 (Mar. 23, 2023), <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>.
- 7 Shade SB et al. *Presentation: Costs and cost-effectiveness of immediate initiation of antiretroviral therapy upon diagnosis of HIV (Rapid Start) in the United States* [OALBEO603]. Presented at IAS 2023, Brisbane Australia (23-26 July).
- 8 AIDS Education Training Center, <https://aidsetc.org/> (last visited Oct. 1, 2023).
- 9 Target HIV, Building Capacity to Implement Rapid ART Start for Improved Care Engagement in Ryan White HIV/AIDS Program, <https://targethiv.org/ta-org/building-rapid-start#disrep> (last visited Oct. 1, 2023).
- 10 Target HIV, About the Rapid ART DAP Project, <https://targethiv.org/rapid-art-dap/about> (last visited October 1, 2023).
- 11 Sarah Michienzi, et al., *Evidence Regarding Rapid Initiation of Antiretroviral Therapy in Patients Living with HIV*. 23 *Curr Infect Dis Rep*. 5 (2021).
- 12 AIDS Education and Training Center Program National Coordinating Resource Center, *Rapid (Immediate) ART Initiation & Restart: Guide for Clinicians*, <https://aidsetc.org/resource/rapid-immediate-art-initiation-restart-guide-clinicians> (last visited Oct. 1, 2023).
- 13 National Clinician Consultation Center, California COVID-19 Therapeutics Provider Warmline is available for healthcare professionals in California-based long-term care and skilled nursing facilities until June 30th, 2024, <https://nccc.ucsf.edu> (last visited October 1, 2023).
- 14 Ciatelli Associates, Inc., *Compendium of Best Practices in Provision of Rapid Start Services for People with HIV*, https://targethiv.org/sites/default/files/media/documents/2023-03/Rapid-DAP_Best_Practices_for_Rapid_ART.pdf (last accessed Oct. 1, 2023).
- 15 For example, San Francisco has made their protocols and other resources available to the public at <https://gettingtozerosf.org/sf-rapid-program-resources/>.
- 16 Technical Assistance Provider Innovation Network, *Rapid ART: An Essential Strategy for Ending the HIV Epidemic*, <https://targethiv.org/library/rapid-art-essential-strategy-ending-hiv-epidemic>, last visited Oct. 1, 2023).
- 17 Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed (Mar. 23, 2023) [Table 6, page G-5]
- 18 See Section 2617(b)(5-7) of the Public Health Service Act. The RWHAP requires states to develop a comprehensive plan for the use of its Ryan White Part B resources that, among other requirements, establishes priorities for funding allocation, includes a strategy that identifies individuals who know their HIV status, but are not receiving HIV care services; includes a strategy for coordinating the provision of such services with HIV prevention and substance use disorder treatment and prevention services, describes how allocation and utilization of funds are consistent with the SCSN. The SCSN requires the public health agency administering the grant to periodically convene a meeting of individuals with HIV/AIDS, members of federally recognized Indian tribes, representatives of recipients under each Part of the Ryan White Program, providers, and public agency representatives for the purpose of developing a SCSN and assure that the public health agency engages in a public advisory planning process, including public hearings, that includes these and other members of the public.
- 19 HIV/AIDS BUREAU, HEALTH RESOURCES AND SERVICES ADMINISTRATION, CLINICAL QUALITY MANAGEMENT POLICY CLARIFICATION NOTICE #21-02
- 20 Ciatelli Associates, Inc., *supra* note 12
- 21 HIV/AIDS BUREAU, HEALTH RESOURCES AND SERVICES ADMINISTRATION, CLINICAL QUALITY MANAGEMENT POLICY CLARIFICATION NOTICE #15-02
- 22 42 CFR §§ 435.1100- 435.1110 Subpart L
- 23 *Scaling up Rapid ART at HIV Care Facilities: Medical Monitoring Project Data*, *CTRS. For Disease Control & Prevention - Div. of HIV Prevention* (2023).
- 24 See *id.*