



Published in final edited form as:

*Int J STD AIDS*. 2023 November ; 34(13): 945–955. doi:10.1177/09564624231185622.

## Lessons Learned from U.S. Rapid Antiretroviral Therapy Initiation Programs

Rupali K. Doshi<sup>1,2</sup>, Shawnika Hull<sup>3</sup>, Aaron Broun<sup>1</sup>, Saanjh Boyani<sup>1</sup>, Darryl Moch<sup>1</sup>, Adam J. Visconti<sup>2</sup>, Amanda D. Castel<sup>1</sup>, Stefan Baral<sup>4</sup>, Jonathan Colasanti<sup>5</sup>, Allan E. Rodriguez<sup>6</sup>, Joyce Jones<sup>7</sup>, Susa Coffey<sup>8</sup>, Anne K. Monroe<sup>1</sup>

<sup>1</sup>The George Washington University Milken Institute of Public Health, Epidemiology Washington, DC, USA

<sup>2</sup>District of Columbia Department of Health, HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA), Washington, DC, USA

<sup>3</sup>Rutgers University School of Communication and Information, New Brunswick, NJ, USA

<sup>4</sup>Johns Hopkins University Bloomberg School of Public Health, Department of Epidemiology, Baltimore, MD, USA

<sup>5</sup>Emory University School of Medicine, Atlanta, GA, USA

<sup>6</sup>University of Miami Miller School of Medicine, Miami, FL, USA

<sup>7</sup>Johns Hopkins University School of Medicine, Baltimore, MD, USA

<sup>8</sup>University of California San Francisco School of Medicine San Francisco, CA, USA

### Abstract

**Background**—Rapid antiretroviral therapy initiation (R-ART) for treatment of HIV has been recommended since 2017, however it has not been adopted widely across the US.

**Purpose**—The study purpose was to understand facilitators and barriers to R-ART implementation in the U.S.

**Research Design**—This was a qualitative design involving semi-structured interviews.

**Study Sample**—The study sample was comprised of the medical leadership of nine US HIV clinics that were early implementers of R-ART.

**Data Collection and Analysis**—In-depth, semi-structured interviews were performed. The Consolidated Framework for Implementation Research (CFIR) was used to guide thematic analysis

**Results**—We identified three main content areas: strong scientific rationale for R-ART, buy-in from multiple key stakeholders, and the condensed timeline of R-ART. The CFIR construct of Evidence Strength and Quality was cited as an important factor in R-ART implementation.

---

rkdoshi@gwu.edu .

Declaration of Interest Statement

The authors have no conflicts of interest to declare.

Buy-in from key stakeholders and immediate access to medications ensured the success of R-ART implementation. Patient acceptance of the condensed timeline for ART initiation was facilitated when presented in a patient-centered manner, including empathetic communication and addressing other patient needs concurrently. The condensed timeline of R-ART presented logistical challenges and opportunities for the development of intense patient-provider relationships.

**Conclusions**—Results from the analysis showed that R-ART implementation should address the following: 1) logistical planning to implement HIV treatment with a condensed timeline 2) patients' mixed reactions to a new HIV diagnosis and 3) the high cost of HIV medications.

## Introduction

Our understanding of the ideal timing of HIV treatment after diagnosis changed as the field developed a better understanding of disease progression with and without treatment.<sup>1</sup> Several key studies have demonstrated improved immune recovery and reduced risk of morbidity and mortality with earlier treatment of HIV with antiretroviral therapy (ART).<sup>2-5</sup> An additional benefit of earlier ART has been reduced HIV transmission.<sup>6,7</sup>

Same-day ART initiation has demonstrated higher rates of ART initiation and viral suppression within the first 12 months after starting therapy in low- and middle-income countries.<sup>8,9</sup> Data from rapid ART initiation (R-ART) programs in the US also demonstrate improved rates of ART initiation and viral suppression,<sup>10-17</sup> but a randomized controlled trial has not been conducted. US DHHS guidelines for ART initiation were revised in 2019 to recommend R-ART for all people diagnosed with HIV.<sup>18</sup> However, R-ART has not been implemented uniformly across the US.

Applying an implementation research framework such as can help distill the key factors affecting implementation of a new HIV treatment program,<sup>19-21</sup> and the Consolidated Framework for Implementation Research (CFIR) has been used previously to evaluate R-ART implementation in the US.<sup>22,23</sup> The objective of this analysis was to use the CFIR to understand factors affecting implementation of R-ART in the US through qualitative analysis of interviews with medical leadership who have implemented R-ART in different locations and care settings.

## Methods

### Participants and Procedures

Potential participants were eligible if they were 18 years or older and identified as a clinical leader of a rapid ART initiation program in the United States. We identified 9 potential participants through a review of the literature and HIV-related scientific conferences (before December 2019) that described existing rapid ART programs (PubMed search terms included “rapid,” “HIV treatment,” “same-day,” and “antiretroviral therapy”).

Potential participants were recruited via email. All recruited participants (n=9) provided verbal consent. Interviews occurred from March to September 2020 and were recorded. Audio recordings were transcribed to written transcripts. Identifying information was removed from file names and written transcripts. The study protocol was approved by the

DC Department of Health Institutional Review Board (IRBPH # 2019-32) with reliance from the George Washington University Institutional Review Board.

### **Data Collection Methods and Instruments**

Interview duration was about 45 minutes followed by a brief demographic survey. The interviewers included 2 physician-scientists who currently practice outpatient HIV medicine and have qualitative research training and experience (RKD, AKM) and one public health professional (SB) with qualitative research training and experience.

A semi-structured interview guide (Appendix 1) was used. A brief demographic survey was conducted.

**Data Analysis**—A semantic thematic analysis approach<sup>24</sup> guided by the CFIR<sup>25</sup> was used to understand the salient barriers and facilitators of R-ART implementation. The codebook included all CFIR domains and constructs.<sup>25,26</sup> Qualitative coding was conducted using the HIPAA-compliant Dedoose platform (Version 9, Los Angeles, CA: SocioCultural Research Consultants, LLC). Participant demographics were recorded using a brief demographic survey in REDCap (Research Electronic Data Capture), a secure, web-based data recording platform.<sup>27</sup>

## **Results**

The median age of participants was 47.0 years (IQR 39.5 to 57.5 years). Profession, gender, race, and ethnicity distribution is shown in Table 1. Three common themes touched multiple CFIR domains: a strong scientific rationale for R-ART implementation, the need to secure buy-in from multiple stakeholders, and the condensed timeline of R-ART. Table 2 shows the alignment of content areas, themes, and CFIR constructs. We highlight representative quotations in Table 3.

### **Strong scientific rationale for rapid ART initiation**

Clinician comments about the scientific rationale for R-ART were coded across multiple CFIR domains and codes, including Evidence Strength and Quality (Inner Setting), External Policies and Incentives (Outer Setting), Structural Characteristics (Inner Setting), Knowledge and Beliefs about the Innovation (Characteristics of Individuals), and Design Quality and Packaging (Innovation Characteristics).

### **Rapid ART initiation supports individual and public health**

Participants reported that viral load reduction toward the goal of viral suppression was a tangible benchmark demonstrating that ART was working (CFIR constructs Reflecting and Evaluating [Process] and Knowledge and Beliefs about the Intervention [Characteristics of Individuals]). In addition to supporting individual health, A105 described how expansion of rapid ART, with its secondary effect of treatment as prevention, could support a jurisdiction's goal of ending the HIV epidemic.

### **External groups promoted R-ART as one strategy in ending the HIV epidemic**

Groups external to the implementing clinics believed the scientific data supporting early treatment and used it to encourage rapid ART implementation locally, which aligns with the CFIR construct External Policy and Incentives (Outer Setting). These included state and city governments and the local Ryan White Planning Council.

### **Soliciting buy-in from multiple stakeholders**

Multiple stakeholders are affected by R-ART implementation; therefore, it was important to solicit buy-in from those groups (aligns with CFIR construct Key Stakeholders [Process]). Participants stated that obtaining buy-in from clinicians, clinical and administrative (operations) leadership and staff, and referring and receiving providers was critical.

### **Buy-in from clinicians**

The first champions of R-ART were generally people who were tasked with implementing R-ART; all participants in this analysis would be considered champions. The CFIR constructs that were applied for this theme included Tension for Change (Innovation Characteristics), Relative Advantage (Innovation Characteristics), and Individual Stage of Change (Characteristics of Individuals). Several participants noted one way that champions (CFIR construct Champions [Process]) solicited provider buy-in was to support their confidence (CFIR construct Self-efficacy [Characteristics of Individuals]) to implement R-ART through firsthand examples.

Respondents conveyed their impression that providers who have worked in the HIV field for a longer time were more hesitant about R-ART (CFIR construct Knowledge and Beliefs about the Innovation [Characteristics of Individuals]). The reasons given for their observed hesitation included (1) that it differed from traditional HIV care procedures, (2) concerns about false positive HIV results leading to mistakenly starting a patient on a full ART regimen, and (3) concerns about patient readiness and difficulty in predicting adherence during the first medical appointment.

Whenever they discuss starting ART with their patients, HIV providers assess the patient's readiness to start treatment.<sup>18</sup> Starting ART on the first medical visit made some providers feel somewhat uncertain about their ability to adequately assess readiness. A100 shared that while clinicians in their clinic were trained to assess readiness and thought they could do it well, some members of the health care team did not necessarily agree. A100 further noted that there may be patients who could take ART consistently but who might be deemed 'unready' by a clinician. R-ART upended the typical process for starting ART by assuming that everyone is ready for long-term adherence.

A103 and A104 described that starting ART had historically included much time spent ensuring the patient understood their medication regimen and possible side effects. A103 noted that clinical pharmacists and nurses expressed concern about their time with the patients being too rushed. Despite some providers' perceptions that social barriers need not prevent patients from receiving R-ART, A105 reported that other staff such as case managers

—who are often tasked with coordinating patients’ non-medical support—were concerned about starting ART without a sufficient understanding of patients’ lives and needs.

### **Buy-in from administrative leadership and staff**

Ensuring that administrative leadership and staff supported R-ART was an important part of successful implementation. R-ART champions had to convince administrative leaders that the intervention benefitted their clinic by using financial justifications. A104 noted that for some administrative staff, such as registration staff, rapid ART initiation protocols were perceived as resulting in more work, which resulted in some frustration with R-ART protocols (CFIR construct Compatibility [Inner Setting]).

Multiple participants indicated that R-ART required increased staffing, and at least one participant (A108) was able to use additional funding to hire new, more experienced staff to implement and sustain R-ART. One participant (A105) also reported that staff recognition for successful implementation supported sustainability.

Collaboration between medical provider champions and the operations directors was a critical factor in addressing logistical barriers to R-ART, which aligns with Networks and Communication (Inner Setting). A104 stated that R-ART could not have been successful without enthusiastic support from the clinic’s administrative director, due to the high degree of collaboration needed between clinical and non-clinical staff (coded as Leadership Engagement [Process]).

### **Buy-in and linkage with external organizations**

Several providers emphasized that their clinics’ relationships with external organizations, were critical in both implementing and maintaining their R-ART programs, aligning with Cosmopolitanism (Outer Setting). Close working relationships between HIV testing and treatment organizations allowed for the refinement of logistical processes like linkage from HIV testing to HIV care.

### **Condensed timeline**

R-ART means that treatment is started quickly ideally the same day as diagnosis or the first HIV care appointment. With R-ART, the baseline labs are ordered, but providers do not wait to receive the results to start treatment. Instead, when baseline lab results are available, providers make any necessary adjustments to the treatment prescribed. The condensed timeline of R-ART was discussed in multiple dimensions by participants.

### **Immediate access to medication**

Participants consistently emphasized that the condensed timeline of R-ART means that medications themselves and a way to pay the costs of medications should be immediately available, aligning with the CFIR constructs Cost (Innovation Characteristics) and Available Resources (Inner Setting). If the newly diagnosed individual does not have coverage, they will likely have to apply for and obtain active enrollment status in one or more of these coverage options to use the pharmacy benefits. The application process can take time and requires patients to provide identification and income documentation. To bypass

this potentially lengthy and cumbersome process, participants described having alternative sources to pay for ART immediately, including pharmaceutical company samples (A100) and Ryan White funds (A105). All participants emphasized the need for R-ART program implementers to have a strong understanding of the local health care coverage landscape for people newly diagnosed with HIV.

Participants expressed the benefit of having people walk out the door with medication at their initial visits. A107 expressed that any psychological, insurance, or pharmacy barriers to same-day ART initiation could be ameliorated by providing the medication to patients at their appointment. A103 described that patients reported they were taking charge of their health by starting medication immediately and encouraged the clinic staff to cheer them on. In addition to giving medications in hand to patients on day one, two participants (A100 and A107) instituted an observed first dose in their clinics for willing patients.

### **Patient-centered care**

The theme of patient-centered care was described in multiple dimensions by participants. The CFIR constructs used in this theme include Innovation Participants (Process), Knowledge and Beliefs about the Innovation (Characteristics of Individuals), Needs and Resources of Those Served by the Organization (Outer Setting), Relative Advantage (Innovation Characteristics), Culture (Inner Setting).

Participants suggested that R-ART itself, in contrast with delayed initiation, sends patients the message that the treatment providers care about them, aligning with CFIR construct Culture (Inner Setting). (37) Participants indicated that communication, transparency, and responsiveness were especially critical during the first appointment as they strove to gain trust, and prioritize the most important information about HIV and ARTA104 emphasized that while R-ART was generally acceptable to patients, providing HIV care with empathy was a key component of acceptability (CFIR Construct Knowledge and Beliefs about the Innovation [Innovation Characteristics]).

Though not yet a requirement in their jurisdictions, several participants stressed that R-ART should be an integral component of a status neutral care program, which consolidates access to sexual health care.<sup>28</sup> The status neutral approach resulted in “more comprehensive care” (A103) and was viewed as a strength, which facilitated implementation of R-ART (coded as Needs and Resources of Those Served by the Organization [Outer Setting] and Design Quality and Packaging [Innovation Characteristics]). One participant (A107) gave an example that centralizing all processes related to initiating ART, including administering medication, helped individuals avoid possible stigma associated with a new HIV diagnosis.

Participants described that part of offering patient-centered medical care is to address patients’ needs holistically. Needs are diverse and may range from complex medical issues to mental health, substance abuse, and support service needs (e.g., housing, food, transportation, case management). Participants emphasized that it was important in planning for R-ART implementation to address all needs, even if this was done in later appointments after ART was started.

Participants recognized the high potential for distress among their patients upon first visit. Recognizing the prevalence of emotional distress and additional barriers among their patients, participants emphasized the harm in simply giving medicine to patients and sending them off on their own. A107 stated that ongoing attention could come from follow-up appointments with prescribers and calls and meetings with social workers or case managers.

Participants also emphasized the importance of assessing their patients' knowledge of HIV treatment and emotional state, then tailoring their first-visit messaging accordingly. A106 stated that introducing the benefits of R-ART was a way to reassure distressed patients, and information about U=U could be integrated into the message.

Participants indicated that a more attentive and patient-centered approach in their R-ART clinics instilled expectations of support and closeness in their patients. The intense patient-provider relationship was somewhat challenging for the clinics that used a start-and-refer model to navigate, in which one clinic or provider starts ART, and later the patient is referred to another clinic or provider for ongoing care. The two participants whose clinics used a start-and-refer model warned that the closeness that developed between providers and patients could hinder patients' linkage to routine care after ART initiation with a different provider. A103 noted both the importance and the difficulty of setting boundaries with patients to mitigate this threat to adherence and retention in care beyond the R-ART clinic.

Participants reported that the populations served by their clinics faced substantial barriers to engagement and retention in care; many of the excerpts were coded as Needs and Resources of Those Served by the Organization (Outer Setting). Barriers mentioned included housing and transportation needs, substance use, mental illness, medical comorbidities, and socioeconomic disadvantage. Participants indicated that these needs should not preclude the rapid provision of ART to patients, but that they must be addressed alongside HIV treatment itself.

### **Address logistical barriers**

Clinicians cited many logistical barriers faced by their patients as reasons to make services accessible. At one clinic, transportation needs motivated the acquisition of funding for a ride share program for new patients (Needs and Resources of Those Served by the Organization [Outer Setting]). Another participant (A101) desired staffing schedules to provide for late evening clinic hours.

Participants also recognized and responded to the interplay of logistical and psychological barriers to accessing care, exemplified by one clinic's use of patient navigators to connect newly diagnosed patients to external support resources during clinic off hours. A103 described a scenario in which someone receives a positive HIV test result on a Friday evening but is unable to access HIV medical care until Monday, making the availability of support over the weekend very important (CFIR constructs Available Resources [Inner Setting] and Needs and Resources of Those Served by the Organization [Outer Setting]).

Participants acknowledged a range of opinions on the logistical compatibility of R-ART with existing clinic operations (CFIR construct Compatibility [Inner Setting]). Some expressed

that R-ART meshed well with protocols that were already in place. For example, A100 stated that adding provisions for same-day medication to an ongoing initiative expediting entry into care for newly diagnosed individuals was not difficult for the clinic to implement. Other participants (A104 and A106) recounted more difficulty integrating R-ART into their clinic procedures. Without existing momentum and consensus toward rapid entry into care, the burden of R-ART implementation was greater and fell primarily on champions and operations and administrative staff rather than all providers more equitably.

Many participants discussed the solutions they used to overcome cost-related barriers to R-ART, which aligns with Design Quality and Packaging (Innovation Characteristics). The sense was that R-ART can help condense the bureaucracy associated with initiating and maintaining HIV treatment, but it does not eliminate it completely. A104 stated that the condensed timeline of R-ART resulted in less time when patients worried about not yet being on therapy, which helped their emotional states. In contrast, A103 stated that the usual process to obtain HIV medications did not change with R-ART implementation.

## Discussion

This analysis identified several key facilitators and barriers to successful early implementation of R-ART in the US. A significant facilitator included support for a strong scientific rationale for R-ART (CFIR Evidence Strength and Quality). In addition, external forces, such as federal initiatives or local planning councils, supporting or expecting R-ART implementation (CFIR External Policy and Incentives) facilitated uptake of R-ART. Concerted efforts to disseminate the scientific rationale to non-clinical staff was important for buy-in. Showing that R-ART demonstrates care and a patient-centered approach to HIV treatment was another key facilitator. Important facilitators from the CFIR Process domain include having a champion who desired R-ART and successfully obtained buy-in from organizational leaders and key stakeholders, which was not always straightforward.

Our findings suggest that R-ART is a patient-centered way of providing HIV treatment. A study from San Diego, California, assessed the patient experience with R-ART and found that those who agreed to rapid ART initiation did so because of a fear of delaying treatment, comfort with the clinical setting, and access to medications.<sup>29</sup> In this analysis, we found that acceptance of R-ART by patients was facilitated by using patient-centered approaches, empathy, and shared decision-making in the delivery of R-ART. Well-developed patient engagement procedures and consistent messaging integrating R-ART into HIV prevention efforts could increase the acceptability of R-ART. Provider training and support tools to collaborate with patients would facilitate R-ART.

Obtaining buy-in from critical stakeholders involved in implementing R-ART was important to successful implementation. Participants highlighted that some providers in their clinics had concerns about being able to accurately predict ART adherence and how to handle false positive results. Finally, obtaining buy-in from key stakeholders such as registration staff, clinical pharmacists, nurses, and case managers, required addressing some of their identified concerns, particularly those around the increase in workload and the short time allotted for the patient's first visit.



The high cost of HIV medications was a significant barrier to implementing rapid ART initiation. Because all people diagnosed with HIV in the US are recommended for treatment,<sup>18</sup> payment for medications has been addressed primarily through third-party coverage (including Medicaid, Medicare, and private health insurance) and safety net systems (Ryan White HIV/AIDS Program and state and local funding).<sup>30</sup>

One limitation of this study is the small, convenience sample, making the results have limited generalizability. Two, interviews were conducted during the first six months of the COVID-19 pandemic; as a result, all participants indicated they had significantly increased workload during this time, which could have affected their responses. Three, while the CFIR was selected as the implementation science framework through which we analyzed the interviews, ultimately it was not the best fit for providing results, due to the finding that common themes cut across many CFIR constructs.

Rapid ART initiation is now the standard of care for people newly diagnosed with HIV.<sup>18,31,32</sup> R-ART is a critical tool for improving linkage to care, initiation of ART, and time to viral suppression, which support the goals of the Ending the HIV Epidemic Initiative<sup>33</sup> and National HIV/AIDS Strategy.<sup>34</sup> HIV providers and clinics in the US seeking to implement R-ART should clearly identify the payers and sources of immediate access to medications, address the logistical changes needed in their care delivery sites, and address the concerns of key stakeholders (providers, operations staff, and patients), prior to implementation. Future studies could compare R-ART implementation in different clinical settings and could test quantitative measures of R-ART acceptance by providers and patients.

## Acknowledgments

We sincerely thank the study participants for their insightful responses, including Heather Alt, Susa Coffey, Jonathan Colasanti, Jason Halperin, Joyce Jones, Susan Little, and Debbie Mohamed, and Allan Rodriguez.

## Funding

This publication resulted from research supported by the District of Columbia Center for AIDS Research, an NIH funded program (P30AI117970), which is supported by the following NIH Co-Funding and Participating Institutes and Centers: NIAID, NCI, NICHD, NHLBI, NIDA, NIMH, NIA, NIDDK, NIMHD, NIDCR, NINR, FIC and OAR. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

## Appendices

### Appendix 1. Semi-structured in-depth interview guide

1. What is your profession?
  - a. Physician
  - b. Nurse Practitioner
  - c. Physician Assistant
  - d. Other (please specify): \_\_\_\_\_

2. What is your role in the HIV clinic where you work?
3. In which year did you begin planning for rapid ART?
4. In which year did your clinic begin implementing rapid ART?
5. How did your clinic decide to start rapid ART?
6. Can you tell me about the roll-out of rapid ART? How did it go?
  - a. What went well?
  - b. What did not go well?
  - c. How did your clinic address these challenges?
  - d. Did you experience any challenges with medical management, such as needing to change regimens after getting lab data back, or having false positives or discordant HIV test results? How did your clinic address these medical issues?
  - e. How was your rapid ART program funded?
7. How was the implementation of Rapid ART viewed by:
  - a. Patients (satisfaction, expectations)
  - b. Providers (doctors, nurses, clinical assistants)
  - c. Administrators (operations managers, registration)
8. What advice do you have for other clinics who are considering or just starting to implement rapid ART initiation?
9. What would make it easier to expand rapid ART across DC or another city or state?
  - a. How would knowledge among providers or patients make it easier?
  - b. Which policies, infrastructure, or systems would make it easier?
  - c. How might relationships between providers make it easier?
  - d. What would need to change in order to expand rapid ART to all clinics in DC or another city or state?
10. What would you consider measures of successful implementation of rapid ART?
  - a. Please describe your program outcomes.
11. How does the current COVID-19 pandemic affect how you think about rapid ART initiation?

## References

1. Richardson ET, Grant PM, Zolopa AR. Evolution of HIV treatment guidelines in high- and low-income countries: Converging recommendations. *Antiviral Res* 2014; 103: 88–93. [PubMed: 24374148]

2. SPARTAC Trial Investigators. Short-Course Antiretroviral Therapy in Primary HIV Infection. *N Engl J Med* 2013; 368: 207–217. [PubMed: 23323897]
3. Herout S, Mandorfer M, Breitenacker F, et al. Impact of Early Initiation of Antiretroviral Therapy in Patients with Acute HIV Infection in Vienna, Austria. *PLOS ONE* 2016; 11: e0152910. [PubMed: 27065239]
4. Le T, Wright EJ, Smith DM, et al. Enhanced CD4+ T-Cell Recovery with Earlier HIV-1 Antiretroviral Therapy. *N Engl J Med* 2013; 368: 218–230. [PubMed: 23323898]
5. Antiretroviral Therapy in Early HIV Infection. *N Engl J Med* 2016; 374: 393–394.
6. Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. *N Engl J Med* 2016; 375: 830. [PubMed: 27424812]
7. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365: 493–505. [PubMed: 21767103]
8. Koenig SP, Dorvil N, Devieux JG, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. *PLoS Med* 2017; 14: e1002357. [PubMed: 28742880]
9. Rosen S, Maskew M, Fox MP, et al. Initiating Antiretroviral Therapy for HIV at a Patient's First Clinic Visit: The RapIT Randomized Controlled Trial. *PLoS Med* 2016; 13: e1002015. [PubMed: 27163694]
10. Bacon O, Chin J, Cohen SE, et al. Decreased Time from HIV Diagnosis to Care, ART Initiation, and Virologic Suppression during the Citywide RAPID Initiative in San Francisco. *Clin Infect Dis Off Publ Infect Dis Soc Am*. Epub ahead of print May 2020. DOI: 10.1093/cid/ciaa620.
11. Coffey S, Bacchetti P, Sachdev D, et al. RAPID antiretroviral therapy: high virologic suppression rates with immediate antiretroviral therapy initiation in a vulnerable urban clinic population. *AIDS Lond Engl* 2019; 33: 825–832.
12. Colasanti J, Sumitani J, Mehta CC, et al. Implementation of a Rapid Entry Program Decreases Time to Viral Suppression Among Vulnerable Persons Living With HIV in the Southern United States. 2016; 1–8.
13. Halperin J, Butler I, Conner K, et al. Linkage and Antiretroviral Therapy Within 72 Hours at a Federally Qualified Health Center in New Orleans. *AIDS Patient Care STDs* 2018; 32: 39–41. [PubMed: 29432044]
14. PROJECT RHAЕ: A PILOT STUDY OF RAPID ART START AND RESTART IN BALTIMORE CITY. CROI Conference, <https://www.croiconference.org/abstract/project-rhae-pilot-study-rapid-art-start-and-restart-baltimore-city/> (accessed 31 March 2023).
15. Mohammed DY, Martin E, Brewer R, et al. Same-Day Medical Visit Increases Viral Suppression, Peter Ho Memorial Clinic, 2014–2015 and 2016–2017. *J Assoc Nurses AIDS Care* 2019; 30: 292. [PubMed: 30676360]
16. Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting. *J Acquir Immune Defic Syndr* 1999 2017; 74: 44–51.
17. Rodriguez AE, Wawrzyniak AJ, Tookes HE, et al. Implementation of an Immediate HIV Treatment Initiation Program in a Public/Academic Medical Center in the U.S. South: The Miami Test and Treat Rapid Response Program. *AIDS Behav* 2019; 23: 287–295. [PubMed: 31520241]
18. 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 16 February 2023.
19. Glasgow RE, Eckstein ET, Elzarrad MK. Implementation science perspectives and opportunities for HIV/AIDS research: integrating science, practice, and policy. *J Acquir Immune Defic Syndr* 1999 2013; 63 Suppl 1: S26–31.
20. Havlir D, Gandhi M. Implementation challenges for long-acting antivirals as treatment: *Curr Opin HIV AIDS* 2015; 10: 282–289. [PubMed: 26049955]
21. Schwartz SR, Rao A, Rucinski KB, et al. HIV-Related Implementation Research for Key Populations: Designing for Individuals, Evaluating Across Populations, and Integrating Context. *J Acquir Immune Defic Syndr* 1999 2019; 82 Suppl 3: S206–S216.

22. Harkness A, Wawrzyniak AJ, Kolber MA, et al. Multilevel Determinants of Rapid Antiretroviral Treatment Implementation and Demand in Miami-Dade County. *JAIDS J Acquir Immune Defic Syndr* 2022; 90: S177. [PubMed: 35703770]
23. Koester KA, Moran L, LeTourneau N, et al. Essential elements of and challenges to rapid ART implementation: a qualitative study of three programs in the United States. *BMC Infect Dis* 2022; 22: 316. [PubMed: 35361148]
24. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*, 2006; 3: 77–101.
25. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci IS* 2009; 4: 50. [PubMed: 19664226]
26. Qualitative Data – The Consolidated Framework for Implementation Research, <https://cfirguide.org/evaluation-design/qualitative-data/> (accessed 31 March 2023).
27. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, *J Biomed Inform.* 2009 Apr;42(2):377–81. [PubMed: 18929686]
28. Issue Brief: Status Neutral HIV Care and Service Delivery Eliminating Stigma and Reducing Health Disparities. <https://www.cdc.gov/hiv/pdf/policies/issue-brief/Issue-Brief-Status-Neutral-HIV-Care.pdf> (accessed 31 March 2023)
29. Amico KR, Miller J, Schairer C, et al. I wanted it as soon as possible: a qualitative exploration of reactions to access to same-day ART start among participants in San Diego’s ART-NET project. *AIDS Care - Psychol Socio-Med Asp AIDSHIV*. Epub ahead of print 2019. DOI: 10.1080/09540121.2019.1687831.
30. Kates J, Dawson L, Horn TH, et al. Insurance coverage and financing landscape for HIV treatment and prevention in the USA. *The Lancet* 2021; 397: 1127–1138.
31. World Health Organization. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, July 2017. Geneva: World Health Organization, <https://apps.who.int/iris/handle/10665/255884> (2017, accessed 31 March 2023).
32. Saag MS, Gandhi RT, Hoy JF, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2020 Recommendations of the International Antiviral Society–USA Panel. *JAMA* 2020; 324: 1651–1669. [PubMed: 33052386]
33. Fauci AS, Redfield RR, Sigounas G, et al. Ending the HIV Epidemic: A Plan for the United States. *JAMA - J Am Med Assoc*; 321. Epub ahead of print 2019. DOI: 10.1001/jama.2019.1343.
34. White Office of National AIDS Policy (ONAP). (2022). National HIV/AIDS Strategy (2022-2025). <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>

**Table 1.**

Demographic characteristics of study participants (clinical leaders of rapid ART initiation programs) (n=9)

	Number	Percent
<b>Profession</b>		
Physician	7	78%
Nurse Practitioner	1	11%
Registered Nurse	1	11%
<b>Gender</b>		
Men	4	44%
Women	5	56%
<b>Race</b> *		
White	7	78%
Asian	2	22%
Black	0	0%
Prefer not to answer	1	11%
<b>Ethnicity</b>		
Not Latino/a	8	89%
Latino/a	1	11%
Prefer not to answer	0	0%

\* Race was not mutually exclusive, and one individual did not select a race.

**Table 2.**

Alignment of content areas, themes, and CFIR constructs

Content Area	Theme	CFIR Construct and Domain
A strong scientific rationale for rapid ART initiation	Rapid ART initiation supports individual and public health	<ul style="list-style-type: none"> <li>Evidence Strength and Quality (Inner Setting)</li> <li>External Policies and Incentives (Outer Setting)</li> <li>Structural Characteristics (Inner Setting)</li> <li>Knowledge and Beliefs about the Innovation (Characteristics of Individuals)</li> <li>Design Quality and Packaging (Innovation Characteristics)</li> </ul>
	External groups promoted R-ART as one strategy in ending the HIV epidemic	<ul style="list-style-type: none"> <li>External Policy and Incentives (Outer Setting)</li> <li>Planning (Process)</li> </ul>
Soliciting buy-in from multiple stakeholders	Buy-in from clinicians	<ul style="list-style-type: none"> <li>Champions (Process)</li> <li>Self-efficacy (Characteristics of Individuals)</li> </ul>
	Buy-in from administrative leadership and staff	<ul style="list-style-type: none"> <li>Cost (Innovation Characteristics)</li> <li>Compatibility (Inner Setting)</li> <li>Organizational Incentives and Rewards (Inner Setting)</li> </ul>
	Buy-in and linkage with external organizations	<ul style="list-style-type: none"> <li>Cosmopolitanism (Outer Setting)</li> </ul>
Condensed timeline	Immediate access to medication	<ul style="list-style-type: none"> <li>Needs and Resources of Those Served by the Organization [Outer Setting]</li> <li>External Policy and Incentives [Outer Setting]</li> </ul>
	Address logistical barriers	<ul style="list-style-type: none"> <li>Available Resources (Inner Setting)</li> <li>Needs and Resources of Those Served by the Organization (Outer Setting)</li> <li>Compatibility (Innovation Characteristics)</li> <li>Adaptability (Innovation Characteristics)</li> <li>Complexity (Innovation Characteristics)</li> </ul>
	Patient-centered care	<ul style="list-style-type: none"> <li>Innovation Participants (Process)</li> <li>Knowledge and Beliefs about the Innovation (Characteristics of Individuals)</li> <li>Needs and Resources of Those Served by the Organization (Outer Setting)</li> <li>Relative Advantage (Innovation Characteristics)</li> </ul>

Table 3.

Themes and excerpts for factors affecting implementation of rapid ART initiation

Content Areas and Themes	Example Quote
<b>Content Area 1: A strong scientific rationale for rapid ART initiation</b>	
Rapid ART initiation supports individual health.	"I would say, one of the most strong feedbacks we got was people liked taking the drug and seeing how rapidly their viral loads went down...our mean time to suppression is about 30 days. And so, watching people go from a viral load of 10 million to undetectable in 30 days was just astonishing to them. And so, that - that was really powerful feedback." [A103] (CFIR constructs Reflecting and Evaluating [Process] and Knowledge and Beliefs about the Intervention [Characteristics of Individuals])
Rapid ART initiation supports public health.	"If the city...has already signed on to the U=U message, well, it just follows...it just doesn't make sense— advocate U=U and then say, 'Oh, you know, this could take a few weeks. There's...obstacles. Gotta get the right insurance.' No. It's gotta be U=U equals immediate ART...I think that really helps...to do this on a city scale." [A105] (CFIR construct Knowledge and Beliefs about the Intervention [Characteristics of Individuals])
External groups promoted r-ART as one strategy in ending the HIV epidemic.	Pressure from external forces, such as the national Ending the HIV Epidemic initiative (Fauci et al., 2019)(Fauci et al., 2019)(Fauci et al., 2019), facilitated the development and maintenance of rapid ART programs. Groups external to the implementing clinics believed the scientific data supporting universal early treatment and used it to encourage rapid ART implementation, which aligns with the CFIR construct External Policy and Incentives (Outer Setting). One participant (A108) noted that the state and city governments provided substantial funding for the local ending the HIV epidemic initiative, some of which was used to fund R-ART implementation (coded as Planning [Process]). Another participant (A105) noted that an expectation from the local Ryan White Planning Council provided the impetus for R-ART implementation in their clinic.
Buy-in from clinicians	"So, at first, um, in 2016, people were not comfortable. And then...[it helps] if you have that champion who's sort of doing it and, like, being available to walk people through it. [Some] people who were super cynical were then like, I want to do rapid...[they] now are very, very comfortable with it." [A106] (CFIR constructs Champions [Process] and Self-efficacy [Characteristics of Individuals])
Buy-in from clinicians	"I almost feel like people who have been working in HIV for a long time have a harder time accepting it...I know that I was specifically told, treating HIV is not an emergency...and because the medications were so much more complicated and there was such a higher risk of resistance, there was a real sense that you really needed people to be very ready before they started medications." [A106] (CFIR construct Knowledge and Beliefs about the Innovation [Characteristics of Individuals])
Buy-in from clinicians	"People not being certain that how could they best assess someone's treatment readiness the same day that they're meeting someone. I think what was brought up, was that sometimes medical providers aren't the best predictors of treatment adherence." [A100] (CFIR construct Tension for Change [Innovation Characteristics])
Buy-in from clinicians	"So, it was—it's already a stressful encounter...now, we have to start therapy and cover all of this and the risks and everything else. It was stressful. So, I think for both the pharmacy staff and the nursing, nurse practitioner staff, they were supportive, but they found it stressful. And it was doubly stressful because I was sort of saying, 'You guys have gotta cut down the amount of time you're spending with patients. You're overwhelming them.'" [A103] (CFIR construct Reflecting and Evaluating [Process])
Buy-in from clinicians	"Case management was - was by far the hardest to get involved, to get buy-in for this. To this day, I still think that my case management team is the most hesitant or very concerned that I do not get enough of a social history to start ART." [A105] (CFIR construct Inner Setting [Structural Characteristics])
Buy-in from administrative leadership and staff	"I've significantly increased the visit numbers for the population that I serve, [and] it's brought in a lotta grants. On our revenue side, areas where you have the 340B programs, if you can get patients in and on therapy, even if you support them in that during their initial month and, maybe, is not generatin' revenue, but then, in the long run, you're gettin' 340B revenue, that probably, again, works out better for the clinic administrators on the backend." [A105] (CFIR construct Cost [Innovation Characteristics])
Buy-in from administrative leadership and staff	"[Rapid ART initiation] means you have to register a patient that wasn't on the schedule. You have to accommodate. You have to do vital signs on people that were not on the census. So we have more resistance [to R-ART implementation by administrative staff and medical assistants]." [A102] (CFIR construct Compatibility [Inner Setting])
Buy-in from administrative leadership and staff	"I think we've shifted our system a bit—enough that a lot of the original headaches aren't as bad. But at the end of the day, [rapid ART] can still be tough on certain departments. And, if they don't kinda fully understand the clinical urgency and stuff of antiretrovirals, both for the benefit of the patient and the community, they, I think, still, at times, get frustrated with it. So I would say they probably see it in more of a negative light than the patients or the providers." [A104] (CFIR construct Compatibility [Inner Setting])
Buy-in from administrative leadership and staff	"Have time where you recognize the staff...we do a monthly meeting around rapid start but make sure it's catered and have food. And then every three months, I try and have a champagne toast...I give how many have linked, how many have suppressed." [A105] (CFIR construct Organizational Incentives and Rewards ([Inner Setting])

Content Areas and Themes	Example Quote
Buy-in and linkage with external organizations	"...depending on how close your connection is from testing sites to a place where treatment can be started. And you have to have that piece there, or you're unlikely to be successful. So depending on what that relationship was like. What kind of a handoff is that like? And then you build on it. So, the reason I think it was so successful with the ED is because we had already this close linkage to care." [A106] (CFIR construct Cosmopolitanism [Outer Setting])
Content Area 3: Condensed timeline	
Immediate access to medication	"Access to the medication was one of the things we have to continually work on because there's no process in place that the patient actually gets the medication the same day. We have to negotiate with the insurance company. We have to use samples." [A101] (CFIR constructs Needs and Resources of Those Served by the Organization [Outer Setting] and External Policy and Incentives [Outer Setting])
Address logistical barriers	"So, if you test on a Friday night, we're not open Saturday morning. So, you have to live with that diagnosis, first of all, over the weekend. Then, we'll pay for you to come in, um, Monday morning. We'll Lyft you in on Monday morning, and we'll Lyft you back home...So, what their navigator does is make contact Friday night...we give them referrals to support lines that they can talk to, but we don't have a person on our staff who is talking to them about their diagnosis." [A103] (CFIR constructs Available Resources [Inner Setting] and Needs and Resources of Those Served by the Organization [Outer Setting])
Address logistical barriers	"We, one, had a same-day, um, medical visit program for years and years. ... Um, and, so, it wasn't such a huge leap for us to go from, like, same-day medical appointments to, 'Okay, let's, like, fit medications into it.'" [A100] (CFIR construct Compatibility [Inner Setting])
Address logistical barriers	"When I did that [changed visit 1 to visit 0], it shifted the focus, uh, from her to "I don't just need to hand them off to the provider, and I'm done. I need to make sure that they see the provider, get their labs, you know, leave the clinic with an appointment, and then if they don't make the appointment, it's my responsibility as a linkage coordinator to link them until that first appointment." And that was huge." [A105] (CFIR construct Adaptability [Innovation Characteristics])
Address logistical barriers	"All they have done is taken all of the usual bureaucratic steps and shoved 'em into one day. They haven't figured out how to ... modify the usual steps and shorten them." [A103] (CFIR construct Complexity [Innovation Characteristics])
Patient-centered care	"[R-ART] better matches patients' expectations because when I've seen lots of folks who test HIV-positive, they're like, 'Okay. I'm positive. Now what? I'm ready to start meds.' And they were disappointed to learn that that wasn't an option for them that day as it might be for learning about most other diagnoses." [A100] (CFIR construct Relative Advantage [Innovation Characteristics] and Innovation Participants [Process])
Patient-centered care	"They were very enthusiastic about it. There was not a lot of pushback about concerns about side effects and things of that nature...I was quite surprised...there was some concern about...how am I gonna pay for my drugs?" [A103] (CFIR construct Reflecting and Evaluating [Process])
Patient-centered care	"What you don't wanna create is the sense, from a patient, that you're just throwin' medications at me and not providing warm clinical care, which I think is somethin' that our patient population, at least locally, craves. These are broad strokes, but I think while there's some that just want drugs, a lot want drugs with personalized clinical care." [A104] Knowledge and Beliefs about the Innovation [Innovation Characteristics])
Patient-centered care	"I think some patients are perhaps surprised like, 'Oh, and I can start meds today?' 'cause it's a lot to ingest, that they receive these test results and they have this whole busy day. They're still processing this information and then they're starting meds." [A100] (Knowledge and Beliefs about the Innovation [Characteristics of Individuals])
Patient-centered care	"So if they come in and- and we say... 'We gonna see how well you keep your next three medical appointments before we give you medication,' compared to, 'This is what we do in our clinic. We give people medications on the same day because we want to make sure we kill the virus and improve your immune system and so you stay healthy as long as possible.' The message is different." [A101] (CFIR construct Knowledge and Beliefs about the Innovation [Characteristics of Individuals])
Patient-centered care	"So the easier the entire Rapid process can be made in-house, everything, labs, meds ... the less likely people will experience obstacles, and then not start or continue their their Rapid meds and not come back for their next appointment, right? And there's so much shame and stigma and stuff, people don't wanna call and say, "I'm here at the pharmacy and they're not giving me my meds, and I don't know why, and can you help me?" And just like that kills it for a lotta people." [A107] (CFIR construct Other Personal Attributes [Characteristics of Individuals])
Patient-centered care	"It's just that first visit, we are getting a lot of information, but we're constantly checking in with how somebody's doing. And so, we take the person's cues, and if they're in there sobbing, we might not necessarily be asking them about...employment status and stuff like that." [A100] CFIR construct Individual Stage of Change [Characteristics of Individuals])
Patient-centered care	"You can't let people just disappear for a month and be on their own. In my opinion, most people, um, we need to see them again in one to two weeks, and probably another week or two after that. And the social workers really need to sit down with them a few times, and if they're extremely distraught, they might need a lot of attention, like calls every day for a while, or, uh, maybe even meetings every day, or every couple of days or once a week or something for a while." [A107] CFIR construct Individual Stage of Change ([Characteristics of Individuals])



Content Areas and Themes	Example Quote
Patient-centered care	“[It was important to build] in that messaging about life expectancy and living well and healthy and U=U. You can give that message and give people the means to do it. And have that experience be like, that’s the beginning of this new thing that people are gonna incorporate into their lives.” [A106] (CFIR construct Design Quality and Packaging [Innovation Characteristics])
Patient-centered care	“We have a bit of trouble getting some people to go to primary care. That’s why we’ve put this 90-day rule in place. Because they don’t want to. They like us. They don’t wanna see anybody else because we’re the people that ‘saved them’...I think our nurses are the best in the world, but I also think it is a very challenging job to set up boundaries... because you get very close to these patients. You go through the worst of the worst with them. And you—they have to graduate. They have to fly.” [A103] (CFIR construct Self-Efficacy [Characteristics of Individuals])
Patient-centered care	“A lotta times, people are very distraught about the HIV diagnosis when they come in, and they may or may not know much about HIV. They may or may not have much experience of being in healthcare and taking a medication every day or medications every day, that sort of thing. They may have other sort of competing priorities, housing, mental health, drug use, kinda stuff going on, just dealing with poverty issues. And so around all of that in different ways, people may need ongoing education about HIV, and why we’re doing these lab tests, and why we’re pushing these medicines, and why we’re talking to them about preventing and transmission.” [A107] (CFIR construct Knowledge and Beliefs about the Innovation [Characteristics of Individuals])
Impact of COVID pandemic on rapid ART initiation	“People with worse immune status would have worse outcomes with COVID. To me, that heightens the need for this type of an intervention to get people on meds and suppressed...That’s one of the things that we can’t lose sight of this epidemic because we’re only focusing on this other one.” [A106]