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Developing a Toolkit to Support Dissemination and Implementation of the Red Carpet Entry Program

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Abstract

The Red Carpet Entry (RCE) program is an evidence-informed structural intervention to improve linkage to HIV care within 72 h of diagnosis. In this paper, we review a rigorous, novel approach for evaluating an implementation toolkit to support adoption and effective implementation of RCE. We fielded and evaluated an RCE implementation toolkit at two clinic sites over an 8-month period. We evaluated the toolkit by assessing implementation processes, contexts, and outcomes at each clinic site, and by surveying and interviewing key implementation staff (n = 9) to solicit their feedback on the toolkit routinely throughout program implementation. This study offers preliminary evidence that the toolkit can support effective implementation of RCE and bolsters evidence regarding the impact of RCE on linkage to care. Both clinics used the toolkit to implement the RCE program with a high degree of fidelity - clients received 85–100% of intended RCE services at the clinic sites. Moreover, as a result of implementing RCE, one site saw an improvement in linkage to care from 68% at baseline to 77% during the implementation period. Staff reported that toolkit components were well-designed for communicating key information but needed to be more succinct and easier to navigate to increase their utility for busy clinic staff. We refined the toolkit to incorporate key lessons learned from our evaluation. Toolkits, especially those that have been tested with program implementers and are informed by evidence regarding implementation and client outcomes, are a critical tool for supporting the integration of evidence-based practices into routine healthcare.

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Ethical Approval This study was reviewed and approved by the RTI International Institutional Review Board (IRB), as well as the IRBs at Rutgers, University of South Florida, and the Florida Department of Health.

Informed Consent Informed consent was obtained from all participants included in the study. Study participants provided consent electronically prior to each survey and verbally prior to each follow-up interview.

Keywords

HIV prevention; HIV treatment; Implementation science; Linking to care; Toolkit

Introduction

The Ending the HIV Epidemic in the U.S. (EHE) initiative aims to reduce new HIV infections by 90% by 2030 [1]. HIV treatment as prevention is one strategy available to prevent new HIV transmissions. People with HIV (PWH) who take their HIV medicine as prescribed and maintain an undetectable viral load have no risk of sexually transmitting HIV to their partners [2]. Thus, rapidly linking PWH to treatment, retaining them in care, and helping them achieve viral suppression is critical to reducing HIV transmission and meeting the EHE goal.

In 2022, 82% of the 36,470 individuals diagnosed with HIV were linked to HIV medical care within 1 month of their diagnosis [3]. PWH who are linked to care within 1 month of diagnosis have significantly higher rates of viral suppression and take less time to achieve viral suppression than PWH who are linked to care within 2 to 3 months of diagnosis or more than 3 months following diagnosis [4, 5]. Moreover, early initiation of antiretroviral therapy (ART) is associated with improved clinical outcomes among PWH [6–8]. However, even with rapid ART programs, challenges linking newly diagnosed and returning PWH into care and treatment remain. In a national sample of 514 facilities offering rapid ART, 32% of facilities documented delays to be 10 days or greater [9]. Barriers to rapid ART included onerous paperwork, unavailable test results, unavailable starter packs, and treatment cost. Evidence-based, structural interventions that address linkage to HIV care can provide guidance for alleviating such challenges and improving linkage of PWH to HIV care [10].

The Red Carpet Entry (RCE) program is an evidence-informed structural intervention to improve linkage of newly diagnosed and out of care PWH to care [11]. RCE aims to link PWH to HIV primary care within 72 h of diagnosis or referral by employing active client engagement strategies, warm handoffs, and a brief intake process that is followed by a modified initial visit (same day or within 72 h), and access to essential social services. To make this possible, implementing organizations establish a referral network with local HIV testing partners, dedicate one or more staff to facilitate active client engagement, schedule the initial modified care visit for the same day or within 72 h, and link clients to needed social services (e.g., childcare or transportation or mental health services) to support their continued engagement in care. Implemented continuously in Washington, D.C. since the early 2000s, an initial evaluation of RCE showed that 60% of newly diagnosed persons were linked to care within 72 h of diagnosis and 10% received services within 24 h; overall, 70% of newly tested PWH were linked to care via RCE [12]. RCE is currently implemented throughout Washington, D.C. to support provision of rapid ART [13]. RCE has also been adapted for use in international settings to link to and retain adolescents and young adults in HIV care following diagnosis, with dramatic results for improving rates of linkage to

care, treatment initiation, and retention in care [14]. As of 2019, RCE did not have a formal toolkit or implementation guidance.

Toolkits are often used as a knowledge translation strategy to support the integration of evidence-based and evidence-informed programs into routine healthcare practice and are associated with improving clinical outcomes [15–17]. Toolkits assist providers by allowing them to implement an intervention or practice over time with fidelity [18, 19]. The value of toolkits for implementing evidence-based science in practice is commensurate to the extent they are used, which rests on factors such as accessibility of materials, training, and ability to tailor toolkits for specific environments [20]. Yet, many toolkits are not evaluated to determine their utility and, ultimately, effectiveness [15–17]. To help address this gap, we conducted a small implementation study to rigorously evaluate an implementation toolkit to support adoption and effective implementation of the RCE program.

This paper describes the toolkit evaluation and refinement process. We first developed a toolkit to support implementation of the RCE program at two clinic sites that serve metropolitan jurisdictions prioritized in the first phase of the EHE initiative: Rutgers New Jersey Medical School Infectious Disease Practice in Newark, NJ, and Florida Department of Health in Hillsborough County, FL, in partnership with the University of South Florida. Next, we tested and validated the toolkit by using evidence-based (i.e., materials testing, process evaluation) and innovative (i.e., assessing multiple stakeholders' perspectives of the toolkit via mixed methods routinely throughout program implementation) methods to better understand the implementation process and context and to evaluate implementation outcomes and service outcomes. Our evaluation was informed by well-known models of implementation science that posit the preconditions of effective implementation of evidence-based interventions, and thus intervention effectiveness [21–26]. Finally, we refined the toolkit based on findings from the evaluation to support dissemination and implementation of RCE. We purposively chose to implement this evaluation study in two very distinct healthcare settings—an infectious disease clinic within a university-based healthcare system and a local health department—to increase the utility of the final toolkit. This study was reviewed and approved by the RTI International Institutional Review Board (IRB), as well as the IRBs at Rutgers, University of South Florida, and the Florida Department of Health. This study was funded by Centers for Disease Control and Prevention.

RCE Program and Toolkit Overview

The RCE program is a patient-centered structural intervention that aims to link people with HIV to care within 3 days of diagnosis or referral. At implementing organizations, RCE will be the standard of care for anyone who is newly diagnosed with HIV infection and for PWH who have not been receiving care. See Fig. 1 for an overview of RCE's core components.

The RCE implementation toolkit comprises eight components designed to support adoption and effective implementation of the RCE program. (1) An orientation video that provides a compelling justification for why interested health care organizations should implement RCE and to secure buy-in from organization leadership. (2) A readiness worksheet that outlines a series of questions implementing organizations can use to assess their

preparedness to implement RCE. (3) A series of training modules to teach implementation and/or non-implementation staff about the core components of RCE. (4) A comprehensive implementation manual that outlines step-by-step guidance for preparation, implementation, and monitoring of RCE. (5) A high-level quick guide that serves as an at-a-glance summary of key RCE steps and a go-to resource for staff to identify their responsibilities at any point during the RCE workflow. (6) A report card that can be used to provide ongoing performance feedback to organizations implementing RCE. (7) A set of marketing materials that consist of social media posts and graphics, posters, a 30-second promotional video, and printed palm cards to raise awareness of RCE among potential clients and staff at implementing organizations. (8) A budget worksheet and sample implementation budgets from the two clinic sites to help implementing organizations financially prepare for RCE.

Methods

To develop the toolkit, we conducted a series of co-creation workshops with five RCE subject matter experts (SMEs)—including three staff from Whitman-Walker Health, where the RCE program originated, and two staff from the District of Columbia Department of Health (DC Health), who bolstered buy-in for program implementation throughout Washington, DC—and three key staff from the two clinic sites with whom we partnered to implement and evaluate the RCE program for the current project. These co-creation workshops involved defining, ideating, and prototyping the various RCE toolkit components. Once we had an initial draft of the toolkit, we tested it with a Community Advisory Board that included two RCE SMEs, five clinic staff, and six patient advocates from the two clinic sites. SMEs and clinic staff provided feedback on the technical components of the toolkit, and patient advocates provided initial impressions and feedback on client-facing marketing materials.

We disseminated the final draft of the toolkit to implementation staff at participating clinics. Both sites prepared for RCE implementation (pre-implementation) from October 2022 through February 2023. Implementation data were collected between March 2023 and October 2023. Our implementation evaluation framework (see Table 1)—specifically Aims 1, 2, and 5—informed refinements to the toolkit. We also conducted a pre-post study to evaluate whether implementation of RCE, using the RCE toolkit, influenced linkage to care (Aim 4). In this paper, we do not detail the methods and results for Aim 3, which was focused on assessing the costs of preparing for and implementing RCE.

Data Collection

We surveyed and interviewed clinic staff in key implementation roles (i.e., RCE Concierge, Internal Counseling, Testing, and Referral [CTR] Partner, and External CTR Partner) and clinic leaders (i.e., Clinic Champion) across the two sites (n = 9 staff) to evaluate key components that contribute to intervention effectiveness according to implementation science research [21–26]. Specifically, we assessed program adaptations and systems changes to facilitate implementation (Aim 1), strategies to overcome implementation barriers (Aim 1), and implementation contexts and outcomes (Aim 2). We also tested the toolkit with implementation staff to understand its utility and identify opportunities

for improvement (Aim 5). Over the pre-implementation and implementation periods, key implementation staff (n = 7) completed brief online surveys via Qualtrics at seven timepoints: once during pre-implementation and monthly during the first 6 months of implementation. Following each survey wave, we scheduled Zoom interviews with key implementation staff. The pre-implementation interview lasted 60 min and the implementation interview lasted 30 min. Clinic leaders at each site (n = 2) completed a 30-minute interview once during pre-implementation and once at the end of the implementation period. Implementation staff and/or clinic leaders provided electronic consent prior to completing surveys and verbal consent prior to interviews.

To evaluate fidelity to the intervention (Aim 2), we had clinic sites record process data for consenting clients, including the RCE services delivered at the RCE visit. Sites recorded these data via a Microsoft Access database that automatically generated de-identified exports to share with the project team. To assess the impact of RCE on linkage to care (Aim 4), clinic sites provided the project team with de-identified, aggregate baseline linkage-to-care rates for a 6-month period prior to RCE implementation. Monthly throughout the implementation period, clinic sites entered consenting clients' data on their date of diagnosis, date of referral to RCE, RCE visit date, and demographics into the Access database and shared de-identified exports with the project team. All eligible clients received the RCE intervention, regardless of their consent to participate in this study.

Measures

Barriers, Facilitators, Adaptations, and Systems Changes (Aim 1)

During in-depth interviews, we asked staff to describe any barriers or facilitators that they encountered in the preparation for and implementation of RCE. We also had staff describe how implementation strategies were used to address barriers to implementation. Finally, we asked staff to describe any systems changes that were necessary to prepare for or implement RCE and any adaptations they made to RCE and why. We assessed these variables at four timepoints: once during pre-implementation and in months 2, 4, and 6 of implementation.

Acceptability, Appropriateness, Feasibility, Implementation Climate, and Organizational Readiness for Implementing Change (Aim 2)

We assessed acceptability, appropriateness, and feasibility of RCE by modifying Weiner and colleagues' 4-item Acceptability of Intervention Measure (e.g., "RCE meets my approval."), 4-item Intervention Appropriateness Measure (e.g., "RCE seems fitting."), and 4-item Feasibility of Intervention Measure (e.g., "RCE seems implementable.") [27]. We assessed implementation climate using six items adapted from Jacobs and colleagues' measure of individuals' perceptions of whether implementation of an innovation is rewarded, supported, and expected within their organization (e.g., "During the past month RCE project staff implementing RCE were expected to enroll a certain number of patients in RCE.") [28]. We assessed organizational readiness using 12 items adapted from Shea and colleagues' Organizational Readiness for Implementing Change measure (e.g., "During the past month RCE project staff implementing RCE are committed to implementing this intervention") [29]. Each item was rated on a 5-point scale ranging from completely disagree (1) to

completely agree (5). We also explored implementation context and outcomes during in-depth interviews with implementation staff. We assessed these variables at all seven timepoints: once during pre-implementation and monthly during the first six months of implementation.

Fidelity (Aim 2)

For each consenting client, we calculated a fidelity score (0 to 7) that indicated the number of RCE visit components received. We operationalized fidelity as the percentage of clients who received all seven RCE visit components.

Linkage to Care (Aim 4)

For each clinic, we calculated the proportion of clients linked to care within 3 days of referral to the RCE program during the implementation period. We operationalized referral date as the date clients self-referred into the RCE program or were connected to the RCE Concierge through a referral partner. We also provided each clinic with an Excel spreadsheet that had detailed instructions for gathering and inputting baseline linkage-to-care data. The spreadsheet contained formulas that calculated an aggregate linkage-to-care rate based on these inputs.

Perceived Usefulness, Objective Achievement, Content Evaluation, Self-Efficacy, Behavioral Intentions, and Recommendations for Improvement (Aim 5)

We had implementation staff rate each toolkit component's usefulness in preparing for and/or implementing RCE on a 4-point scale ranging from not at all useful (1) to extremely useful (4). For each toolkit component, we also asked staff to assess how well it met each of its objectives on a scale of not at all (1) to very well (10). For select toolkit components, we asked implementation staff additional questions including whether they liked the component, the material in the component was easy to understand, and/or an appropriate amount of information was included in the component. Staff indicated their agreement with these items on a scale of strongly disagree (1) to strongly agree (4). Finally, for each toolkit component, we asked implementation staff about their perceived self-efficacy for performing key RCE behaviors covered in the component and their perceived likelihood of performing the key behaviors covered in the component on a 4-point scale ranging from strongly agree (1) to strongly disagree (4). Quantitative ratings of toolkit components informed the questions asked during follow-up, in-depth interviews. For instance, implementation staff were asked what they found useful or not useful, what could be improved, and any additional information that should be included in that component. We assessed these variables at four timepoints: once during pre-implementation and in months 1, 3, and 5 of implementation.

Data Analysis

We used the Statistical Package for the Social Sciences (SPSS) software to calculate descriptive statistics (counts and percentages) for each survey question, including calculating descriptives by time point for questions asked across more than one survey.

We used a framework analysis approach for coding, analyzing, and interpreting qualitative data [30]. This systematic approach involves five stages: familiarization, identifying a thematic framework, indexing, charting, and mapping and interpretation. Our lead qualitative researcher reviewed the interview transcripts (familiarization); identified key themes and sub-themes for each study aim based on research questions and variables assessed and developed a codebook with corresponding parent and child codes (identifying a thematic framework); coded each transcript in Dedoose, linking transcript text to codes (indexing); and exported code reports for each key theme by clinic site and data collection time point. Next, the lead qualitative researcher developed table shells—organized by key theme, clinic site, time point, and implementation staff role—and trained 2 qualitative analysts to “chart” the data through synthesis and abstraction into these theme-based table shells (charting), review and summarize themes within each clinic site and time point (mapping), and assess and summarize broader themes across clinic sites and time points (interpretation). For each clinic site, we performed a two-sample test for equality of proportions to determine whether there was a significant difference between the proportion of people linked to care within 3 days of referral before RCE implementation (baseline) compared with during RCE implementation. One site experienced a major change halfway through implementation; thus, we also performed a two-sample test to compare the baseline proportion with different implementation proportions (first and second half of implementation). All tests were evaluated for statistical significance with alpha set to 0.05.

Results

We report key findings from surveys and interviews with RCE implementation staff ($n = 9$) and discuss how these findings informed refinements to the RCE toolkit. Participating staff included case managers, physicians, nurses, and other program staff (see Table 2). We also report results from our pre-post study to evaluate the impact of RCE on linkage to care at each clinic site. Table 3 summarizes client characteristics at each site.

Aim 1: Implementation Barriers, Facilitators, Adaptations, and Systems Changes

By evaluating the RCE implementation process, we were able to identify how the toolkit could be improved to mitigate implementation barriers and enhance facilitators and how program adaptations and systems changes supported RCE implementation (see Table 4).

Aim 2: Implementation Outcomes and Contexts

Across the two clinics, most implementation staff perceived RCE to be acceptable (85%–100% agreeing or completely agreeing with each acceptability statement), appropriate (62%–100% agreeing or completely agreeing with each appropriateness statement), and feasible (86%–100% agreeing or completely agreeing with each feasibility statement). These positive perceptions of RCE were reiterated in the interviews, especially later in the implementation period, with staff noting how RCE provides clients with a welcoming introduction to HIV care. By contrast, early in the implementation period, some staff reported concerns about the time and effort that implementing RCE would require.

The majority of RCE implementation staff also agreed or strongly agreed with each statement for the implementation context domains of organizational readiness for implementing change (60%–100%) and implementation climate (66%–100%). Staff expanded on the implementation context in interviews, where they shared how the Clinic Champions played key roles ensuring staff buy-in and how open communication with clinic leadership was important for troubleshooting challenges. Staff from both clinics also noted that they had a method to reward or praise staff for their good work.

The first site (Clinic A) achieved 85% intervention fidelity—out of a total of 47 clients linked to care during implementation, four clients received 6 of 7 intended RCE services and three clients received 5 of 7 intended RCE services. Services not received during the RCE visit included laboratory tests to assess medical status ($n = 3$), a brief introduction to an HIV Specialist ($n = 2$), a discussion about insurance and financial assistance programs ($n = 3$), and referrals to wraparound support services ($n = 2$). The second site (Clinic B) achieved 100% fidelity, meaning all RCE clients ($n = 60$) received all intended services at their RCE visit.

To better support future implementing organizations to deliver RCE with fidelity, we tailored roleplay scenarios in our training modules and implementation manual to reflect real implementation challenges. For instance, our training module on delivering the RCE visit includes a roleplay scenario in which a client shares that they do not have insurance and another scenario in which an HIV Specialist is not available to perform a full medical visit.

To help alleviate concerns about the effort required to implement RCE, we offered tips throughout the training modules and implementation manual on how staff can integrate RCE without disrupting their overall workflow. We also modified questions in the readiness worksheet to help implementing organizations identify channels for communicating with clinic leadership and for rewarding staff for their efforts implementing an innovation.

Aim 4: Health Service-Related Outcomes

At the first site (Clinic A), linkage to care (i.e., the proportion of clients whose RCE visit was within 3 days of referral) increased from 68% at baseline to 77% during the implementation period. However, this increase was not statistically significant (see Table 5). At this site, two new staff members joined the team approximately halfway through the implementation period, and their role involved intake of RCE referrals and scheduling of RCE visits. Thus, we also assessed change in linkage to care from baseline to the first versus second half of RCE implementation. Clinic A achieved 53% linkage to care during the first half of implementation and 90% linkage to care during the second half of implementation. There was a statistically significant increase in linkage to care from baseline to the second half of implementation ($X^2 = 4.06$, $p < 0.05$; see Table 5).

The second site (Clinic B) integrated RCE with an existing rapid ART program and had a very high linkage-to-care rate at baseline. We found that linkage to care decreased from 98% at baseline to 90% during the implementation period. This decrease was not statistically significant (see Table 5). As part of their adoption of RCE, this site partnered with a health center in the area to reach new clientele and increase referrals into the RCE program. All

clients not linked to care within 3 days (6 of 60 total RCE clients) were referred by this partnering health center. In interviews, implementation staff noted unanticipated barriers to seeing clients from this health center within 3 days of referral—namely, issues with transportation (a 45- to 60-minute trip via public transportation) and finding a time when the RCE client could meet with their provider.

Aim 5: Materials Testing

By testing each component of the toolkit with key implementation staff—via surveys and follow-up, in-depth interviews—we were able to identify critical refinements to make the toolkit more helpful and easier to use and to ensure that the toolkit met its key objectives of supporting adoption and effective implementation of RCE (see Table 6). Key findings included shortening the orientation video and creating a client-facing video to promote RCE; making the readiness worksheet more reflective of clinic challenges around staffing, workflow, and providing supportive services; streamlining trainings and adding realistic roleplay scenarios; making language overall more accessible; and shortening materials for maximum utility.

Discussion

This small implementation study provides a rigorous, novel approach for evaluating an implementation toolkit to help close the evidence to practice gap. In a recent systematic review of digital health toolkits published between 2009 and 2019, the authors found that only 13 (out of 56) toolkits—developed in North America, Europe, or Australia—had been field tested and only seven had been evaluated [16]. Evaluation consisted of assessing toolkit usability and relevance, and facilitators and barriers to toolkit use. In the present study, we field tested and evaluated the RCE implementation toolkit over an 8-month period by not only surveying and interviewing key implementation staff to solicit their feedback on the toolkit routinely throughout program implementation, but also evaluating implementation processes, contexts, and outcomes at each clinic to inform toolkit refinements.

Toolkit Refinements

Our implementation evaluation in two distinct healthcare settings helped us identify critical refinements to the implementation toolkit to support uptake and successful implementation of the RCE program. A key finding was the need to make toolkit components more succinct and user-friendly for busy implementation staff. This finding is supported in the literature by a recent qualitative study of clinic staff's perspectives of intervention toolkits, in which staff shared their desire for toolkits to contain brief resources in multiple formats with high functionality [20]. To address this need, we made toolkit components shorter and/or easier to navigate, without removing any information required for successful implementation of the RCE program. We streamlined content by writing more concisely, leveraging bulleted lists, removing redundancies, and depicting information visually wherever possible. In line with research findings that 5- to 20-minute videos work best for maximizing adult learners' attention [31], we made our training content more engaging and digestible by turning three time-intensive, recorded training videos (1 to 2 h each) into a set of six brief training modules (15 to 20 min each). We focused each module on a discrete part of the

RCE program (e.g., patient-centered care strategies, referral process, RCE visit, outreach process, monitoring). Finally, we turned our comprehensive implementation manual into an interactive PDF with navigation features to help implementation staff easily find the specific information they are looking for.

Another key refinement to the toolkit was providing more context on how implementation staff could adapt RCE for their specific setting. This was addressed by acknowledging that the referral process may need to be slightly different depending on the source of referral (e.g., having a different process for someone who tests positive for HIV in an inpatient setting within the healthcare system than for someone who tests positive at an affiliated mobile testing unit) and that implementation roles are flexible (e.g., a single staff may fulfill multiple roles and/or multiple staff may serve in the same role). Importantly, the ability to adapt an innovation like RCE for local use may increase its acceptability among implementation staff [22].

We found that at both clinic sites, staff reported readiness to implement RCE and perceived that implementation of RCE was rewarded, supported, and expected. Staff across both clinics also reported high acceptability (i.e., the extent to which RCE is perceived to be agreeable, palatable, or satisfactory), appropriateness (i.e., the perceived relevance or compatibility of RCE within a setting and/or the perceived fit of RCE to address a particular problem), and feasibility (i.e., the perceived ability of RCE to be successfully implemented within a setting) of RCE. In interviews, staff underscored the importance of open communication with leadership and having a system in place to praise or reward staff. Thus, we added questions to the readiness worksheet to help future implementing organizations identify channels for communicating with clinic leadership and for staff acknowledgements and rewards, in preparation for RCE.

We identified just a few challenges with program fidelity at one clinic (Site A). Of the 47 clients linked to care during implementation at this site, seven did not receive one or more of the intended RCE services. Services not received included laboratory tests to assess medical status, a brief introduction to an HIV Specialist, a discussion about insurance and financial assistance programs, and referrals to wraparound support services. This may have been due, at least in part, to staffing shortages that this clinic reported as a barrier to implementation. Across nearly all segments of the healthcare workforce, staffing shortages and employment turnover has not yet fully recovered from the COVID-19 pandemic [32, 33]. To help future implementing organizations prepare for turnover among implementation staff, we expanded the readiness worksheet to include strategies to ensure staff coverage for RCE (e.g., building redundancy into roles). Moreover, our efforts to streamline and shorten the toolkit components will support onboarding of new staff in preparation for and throughout program implementation.

To further support organizations with effective implementation of RCE, our toolkit follows two best practices for achieving intervention fidelity: standardizing training and monitoring intervention delivery [34]. To standardize training, our toolkit includes a comprehensive implementation manual, companion quick guide, and series of training modules that offer (1) step-by-step guidance on how to implement the RCE program and (2) roleplay scenarios

that support practical application of this guidance. Our toolkit also includes a report card to help implementing organizations monitor progress and identify and correct any issues with fidelity. Moreover, as a result of our implementation evaluation findings, we added “real-world” tips and/or questions across toolkit components to prompt consideration of how to incorporate delivery of key RCE services into existing workflows. We also incorporated strategies that implementation staff in this pilot study identified as key facilitators to RCE implementation (e.g., having one or more backup RCE Concierges to ensure adequate coverage and support for RCE clients).

Impact of the RCE Toolkit

Our study offers preliminary evidence that the RCE implementation toolkit can support effective implementation of RCE and bolsters evidence regarding the impact of RCE on linkage to HIV care. Overall, both clinics implemented the RCE program with a high degree of fidelity—Site A achieved 85% fidelity and Site B achieved 100% fidelity. This suggests that the toolkit was effective in helping clinics prepare for and implement the Red Carpet Entry program. As a result of adopting and implementing the RCE program, Site A saw an improvement in linkage to care from 68% at baseline to 77% during the implementation period. Furthermore, Site A was able to achieve 90% linkage to care during the second half of the implementation period, after addressing staffing shortages. While Site B did not see an improvement in linkage to care as a result of RCE, they integrated RCE into an existing rapid ART program and had a very high baseline linkage-to-care rate (98%). These findings highlight the potential impact of the RCE program in healthcare settings in which linkage to care is a concern, specifically settings in which there is no existing rapid or same-day ART program.

Limitations

There are several limitations in this study. We conducted this implementation evaluation study at just two clinic sites with a small number of implementation staff. While these sites represented distinct settings—an infectious disease practice within a university health system and a local health department—the toolkit refinements we made as a result of the implementation evaluation may not capture the implementation strategies, adaptations, and systems changes needed to make RCE work in other healthcare settings. While we collected data from all key implementation staff and clinic leaders at the participating sites, we did not include implementation-adjacent staff, such as front-desk staff. Our small sample of participants further limits the generalizability of the toolkit refinements made. Further, we did not assess whether the refinements we made to the toolkit following our implementation evaluation increased perceived effectiveness of the toolkit among implementation staff and/or improvement in implementation and health service-related outcomes. Finally, data collection methods relied on self-report and findings subject to recall and social desirability bias. The field of dissemination and implementation would benefit from future research on whether approaches such as ours yield improvements in toolkit development and effectiveness, and subsequent improvements in implementation effectiveness.

Conclusion

Toolkits have been used to inform practice change in healthcare settings for decades; however, most toolkits are developed and disseminated without any form of evaluation [15, 16]. In this paper, we detail a systematic approach for testing an implementation toolkit with key implementation staff, evaluating program implementation by staff who have been trained on the implementation toolkit, and refining the toolkit based on findings from both the implementation evaluation and toolkit testing prior to broader dissemination. We found that staff at the two implementing clinics perceived RCE to be acceptable, appropriate, and feasible for integration into their healthcare setting, and RCE was implemented with a high degree of fidelity (85–100%). We also found an increase in linkage to care from baseline to the RCE implementation period at one of the two sites that used the toolkit to implement RCE. This site did not have a rapid ART program at baseline, demonstrating the utility of RCE in settings in which there is no existing mechanism to quickly link patients to HIV treatment and care. We refined the toolkit to incorporate key lessons learned from our evaluation—including strategies to overcome key barriers to implementation of the RCE program, adaptations and/or systems changes to support integration of RCE into diverse healthcare settings, opportunities to further support intervention fidelity, and ways to make the toolkit more user-friendly and palatable for busy clinicians. Toolkits, especially those that have been tested with program implementers and are informed by evidence regarding implementation, are a critical tool for supporting the integration of evidence-based practices into routine healthcare.

The Red Carpet Entry Toolkit is available upon request.

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RCE Core Components

The RCE program supportively engages people with HIV to make their transition into HIV care as smooth as possible.



Referral Network

The implementing organization establishes a referral network with partner organizations and markets RCE to increase awareness of the program.



Discreet Phrase

The implementing organization establishes a phrase (e.g., "Red Carpet Entry") as a way for people to discreetly request RCE services.



RCE Visit

The implementing organization conducts RCE Visits to establish a connection between the client and members of the client's HIV care team. The visit should always start with an RCE staff member greeting the client and end with a wrap-up; however, the other components can happen in any order. The client receives the following services during a visit to the implementing organization **within 3 days of referral**:

- ☐ Speaks with an RCE Concierge.
- ☐ Completes a brief intake process (30 minutes or shorter).
- ☐ Receives a confirmatory viral load test and other laboratory tests to assess medical status.
- ☐ Receives information about insurance and financial assistance programs.
- ☐ Receives referrals to wraparound support services, if necessary.
- ☐ Meets with an HIV Specialist.
- ☐ Schedules their next HIV primary care visit.



Client Referrals

The RCE Concierge(s) receive client referrals through two pathways:

Self Referrals: Clients refer themselves, either by asking for HIV services or by using the discreet phrase ("Red Carpet Entry" or "Red Carpet").

Referral Request: Internal staff or external organizations (e.g., emergency departments, urgent care clinics, testing sites) refer the client.



Key Points to Cover During the HIV Specialist Introduction

- The name, role, and title of the HIV Specialist the client is meeting.
- The current status of the client's care.
- Initial questions the client may have at the time.



RCE Outreach and Reengagement

If an RCE staff member is unable to establish contact with the client or if the client does not attend their RCE Visit, the implementing agency initiates RCE Outreach and Reengagement.



Client Engagement

The implementing agency and referral partners engage the client through active client engagement and warm handoffs at all steps in RCE.

Figure 1.
Red Carpet Entry Core Components

Red Carpet Entry Implementation Study Research Design, Research Questions, Expected Toolkit Refinements, and Data Collection Methods by Study Aim

Table 1.

Study Aim ^a	Study Design	Research Questions	Expected Toolkit Refinements	Data Collection Methods
Aim 1. Describe the RCE implementation process	Multi-stakeholder assessment and analysis	- What were the barriers and facilitators to RCE implementation? What strategies addressed these implementation barriers? - What systems changes were necessary to prepare for or implement RCE? - What adaptations were made to RCE and why?	- Describe strategies that RCE agencies can use to facilitate implementation of RCE (and overcome implementation barriers) - Describe systems changes and RCE program adaptations that RCE agencies can make to facilitate integration of RCE into their workflow while maintaining fidelity to core components	Interviews with key implementation staff
Aim 2. Evaluate implementation contexts and outcomes	Mixed-method, multi-stakeholder assessment and analysis	- To what extent did implementation staff perceive a positive implementation climate and report organizational readiness for implementing change? - To what extent did implementation staff see RCE as acceptable, appropriate, and feasible?	Revise the implementation toolkit to increase perceived acceptability, appropriateness, feasibility, and sustainability based on themes identified and interviews and surveys results	Surveys and interviews with key implementation staff
Aim 3. Evaluate costs	Micro-costing study	- To what extent was RCE implemented as intended (i.e., fidelity)? - What is the cost of preparing to implement RCE? - What is the cost of implementing RCE?	- Proactively address issues that may contribute to low fidelity - No refinements to existing toolkit components expected; this aim was intended to support initial development of sample implementation budget worksheets to be included in the final toolkit prior to broader dissemination	Process data, collected via a Microsoft Access Database Labor and non-labor cost questionnaires; one time salary data request
Aim 4. Evaluate health service-related outcomes	Pre-post study	Does the RCE program influence linkage to care?	No refinements to existing toolkit components expected; this aim was intended to provide additional evidence for efficacy of RCE in improving client outcomes	Process and outcome data, collected via a Microsoft Access Database; one-time baseline data request
Aim 5. Toolkit materials testing	Mixed-method, multi-stakeholder assessment and analysis	How could the toolkit be improved to facilitate preparation and/or implementation?	Revise the implementation toolkit to increase its utility based on themes identified in interviews and survey results	Surveys and interviews with key implementation staff

^a Aims 1, 2, and 5 are described in detail in this paper, as these aims supported refinements to the RCE implementation toolkit.

Table 2.
Red Carpet Entry Implementation Study Clinic Staff and Leader Characteristics, March – October 2023

Characteristic	(N = 9) ^a n (%)
Sex	
Female	6 (66.7)
Male	3 (33.3)
Race and ethnicity^b	
Asian—not Hispanic or Latino	1 (11.1)
Black or African American—not Hispanic or Latino	4 (44.4)
White—Hispanic or Latino	1 (11.1)
White—not Hispanic or Latino	3 (33.3)
Highest degree^c	
High school or equivalent	1 (11.1)
Associate's degree	1 (11.1)
Bachelor's degree	2 (22.2)
Master's degree	3 (33.3)
Doctoral degree or equivalent	2 (22.2)
Years worked at current organization	
0–1 years	3 (33.3)
2–5 years	1 (11.1)
6–10 years	4 (44.4)
11+ years	1 (11.1)
Role at current organization	
Case manager	1 (11.1)
Clinical Director and Physician	2 (22.2)
Clinical Research Coordinator	1 (11.1)
Nurse	1 (11.1)
Program Manager	1 (11.1)
Research Support Specialist	1 (11.1)
Senior Prevention Coordinator	1 (11.1)
Other	1 (11.1)

^a Staff were distributed across the 2 clinics as follows: Clinic A collected data from 3 staff and 1 leader, and Clinic B collected data from 4 staff and 1 leader.

^b Additional response options available that were not selected for race and ethnicity were: “American Indian or Alaska Native,” “Native Hawaiian or other Pacific Islander,” “Other race,” and “Unknown.” Race was a “select-all-that-apply” field, but only one race was selected for each client.

^c Percentages do not sum to 100% due to rounding

Table 3.
Red Carpet Entry Client Characteristics, by Clinic Site, March – October 2023

Characteristic	Clinic A (N = 47) n (%)	Clinic B (N = 60) n (%)
Sex		
Female	21 (44.7)	10 (16.7)
Male	26 (55.3)	50 (83.3)
Age Upon Referral		
18–29 years	11 (23.4)	16 (26.7)
30–39 years	19 (40.4)	20 (33.3)
40–49 years	5 (10.6)	11 (18.3)
50–59 years	7 (15.0)	12 (20.0)
60–69 years	5 (10.6)	1 (1.7)
Insurance Provider^a		
Medicaid	29 (61.7)	7 (11.7)
Medicare	3 (6.4)	1 (1.7)
No insurance	11 (23.4)	31 (51.7)
Private	3 (6.4)	10 (16.7)
Ryan White/AIDS Drug Assistance Program (ADAP)	3 (6.4)	5 (8.3)
Other	2 (4.3)	6 (10.0)
Unknown/unreported	0 (0.0)	1 (1.7)
Race^b or Ethnicity		
Asian—not Hispanic or Latino	1 (2.1)	0 (0.0)
Black or African American—Hispanic or Latino	0 (0.0)	3 (5.0)
Black or African American—not Hispanic or Latino	33 (70.3)	24 (40.0)
White—Hispanic or Latino	8 (17.0)	16 (26.7)
White—not Hispanic or Latino	0 (0.0)	4 (6.7)
Other race—Hispanic or Latino	4 (8.5)	10 (16.7)
Other race—not Hispanic or Latino	0 (0.0)	2 (3.3)
Unknown/not reported race—Hispanic or Latino	0 (0.0)	1 (1.6)
Unknown/not reported race or ethnicity	1 (2.1)	0 (0.0)

^aInsurance provider was a “select-all-that-apply” field, so percentages do not add to 100%.

^bRace was a “select-all-that-apply” field, but only one race was selected for each client.

Table 4.
Key Red Carpet Entry Implementation Evaluation Findings and Resulting Toolkit Refinements, March 2023 – October 2023

Key Barriers, Facilitators, and Systems Changes Shared by Clinic Staff	Examples of Resulting Toolkit Refinements
Barriers	
Staff turnover	• Training Modules: Developed 6 brief (10 to 20-minute) videos that new staff can review for onboarding to RCE • Implementation Manual: Added text to encourage ongoing staff training, especially if staff turnover is high • Readiness Worksheet: Added strategies to ensure staff availability (e.g., hiring to fill potential gaps and creating “backup” positions)
Challenges finding time for patients to be introduced to an HIV Specialist during RCE Visit	• Training Modules: Added roleplay scenarios to work around providers’ schedules for the initial introduction • Implementation Manual and Quick Guide: Reviewed key points to cover during HIV Specialist introduction to reinforce that this is just a brief conversation (vs. a full medical visit)
Lack of available wraparound support services in the area	• Implementation Manual and Readiness Worksheet: Added tips and/or questions to prompt implementing agencies to build out a list of available wraparound support services (that can be routinely referenced and updated) as they form partnerships with organizations to support implementation of RCE
Facilitators	
Good coordination with front desk staff	• Readiness Worksheets: Added questions to help clinics think through how RCE staff will coordinate with front desk staff
Frequent communication	• Implementation Manual: Noted the importance of communication throughout the client’s RCE journey, including communication strategies that can be used at various stages of the RCE workflow
1 or more staff serving as a backup to the primary RCE Concierge	• Quick Guide and Implementation Manual: Clarified that there is flexibility around RCE staff roles
Adaptations	
vDifferent workflows depending on where RCE clients are referred from	• Implementation Manual: Added a tip to think through how RCE’s core components might need to be tailored or reordered to best accommodate RCE referrals from different locations.
Flexible RCE implementation roles	• Implementation Manual: Noted that a single staff member may fulfill multiple RCE roles, or multiple staff members may serve in the same RCE role. Also noted that roles and responsibilities may shift based on RCE team members’ availability.
Systems changes	
Added flag to clinic schedule and/or EHR system to alert staff that a client had been scheduled for an RCE Visit	• Implementation Manual: Added a tip about updating clinic systems to include flags and prompts around RCE scheduling

Table 5.
Results from Chi-Square Two Sample Tests to Assess the Impact of RCE on Linkage to Care

Site	Baseline Proportion	Implementation Proportion	X ² Test Statistic ^a	95% Confidence Interval	df	P Value
Clinic A	67.9% (38/56)	76.6% (36/47)	0.58	−0.28, 0.10	1	0.45
	67.9% (38/56)	First half of implementation: 52.9% (9/17)	0.70	−0.16, 0.45	1	0.40
	67.9% (38/56)	Second half of implementation: 90.0% (27/30)	4.06	−0.41, −0.03	1	0.04 *
Clinic B	97.6% (80/82)	90.0% (54/60)	2.44	−0.02, 0.17	1	0.12

* P < 0 .05 indicates a significant difference between baseline and implementation proportions.

^aX² = Chi-square statistic from two-sample test for equality of proportions comparing baseline and implementation linkage to care

Table 6.

Red Carpet Entry Implementation Study Key Toolkit Materials Testing Findings and Resulting Toolkit Refinements, March – October 2023

Toolkit Component	Key Findings	Key Refinements
Orientation Video	1 All staff agreed that the orientation video provides compelling justification for why clinics should implement RCE. 2 Nearly all staff (83%–100%) agreed or strongly agreed that after watching the orientation video, they were confident in their ability to explain the goals of RCE and list RCE's key components, describe the impetus for RCE and explain how RCE will help their client population, and secure buy-in and support for RCE from key decision-makers. 3 One staff member noted that the video was too long to share during staff meetings. They recommended developing an abbreviated version (1–2 minutes). 4 Another staff member recommended creating a client-facing orientation video to introduce potential clients to RCE.	1 We developed an abbreviated version of the orientation video for staff at implementing organizations. 2 We also developed a 30-second client-facing RCE video to help implementing organizations promote RCE.
Readiness Worksheet	1 Most staff (80–100%) indicated in their surveys and confirmed during their interviews that the readiness worksheet was helpful during the pre-implementation period. 2 Two staff highlighted the need for more questions on wraparound support services in the readiness worksheet—specifically around which services their partner organizations do/do not provide and what capacity they have for referrals. 3 Additionally, one staff member suggested that the worksheet should prompt them to think through more of the RCE referral process. They noted that different referral sources may require different workflows.	1 We expanded on questions in the readiness worksheet to help future implementing organizations identify all the avenues for RCE referrals and to think through what the RCE workflow would be like for each referral type. 2 We also expanded on questions to help staff identify the wraparound services provided by other organizations in their community and those organizations' capacity for referrals.
Training Modules	1 Overall, staff members reported that they found the training modules to be helpful, informative, detailed, and well-thought-out. 2 Staff ratings of how well each module met its objectives varied, with between 75% and 100% of staff indicating moderate-to-high achievement of each objective. 3 Several staff members shared that the trainings were too long and suggested streamlining the content to focus on the most important information. 4 There was confusion about RCE roles and eligibility. One staff member commented that the procedures documented in the trainings may not reflect what happens in the clinic.	1 We reformatted the trainings to include six shorter training modules (e.g., 10 to 20 minutes each) that: provided an overview of RCE, outlined RCE's patient-centered care strategies, discussed preparing for and referring into RCE, went over how to schedule and deliver the RCE Visit, detailed the RCE outreach and reengagement process, and provided recommendations for monitoring RCE implementation for quality improvement. 2 Throughout the training modules, we identified areas where clinics may want to adapt strategies to better fit their workflows. 3 We also provided role-playing scenarios to help staff practice elements of the RCE workflow and prompt discussion on how the workflow will work best in their organizational settings.
Implementation Manual	1 Overall, staff found the implementation manual to be helpful and comprehensive.	1 To increase ease of use, we turned the implementation manual into an interactive PDF with easy navigation so that staff

Toolkit Component	Key Findings	Key Refinements
	2 Most staff (67%) indicated that the implementation manual highly met its objectives to provide a step-by-step guide to plan, implement, monitor, and evaluate RCE. 3 While all staff agreed or strongly that they liked the implementation manual, and that it was easy to follow and provided them with the information they needed to implement RCE, half of the staff thought the manual had too much information. 4 One staff member acknowledged additional confusion around the RCE components. 5 There were additional suggestions for flexibility in how RCE staff roles are described.	can skip to the information that is most pertinent to them. 2 We reviewed the implementation manual with a focus on clarity and conciseness—we pared down information and moved non-essential information to an appendix. 3 We revised language to convey flexibility on how RCE roles are conceptualized, depending on the needs and staffing structure of the organization implementing RCE.
Quick Guide	1 Overall, staff found the quick guide easy to follow; however, half of the staff agreed or strongly agreed the quick guide had too much information. 2 One staff member recommended the quick guide be broadened to include additional information, such as how client referrals into RCE might occur.	1 We shortened the quick guide from six pages to one printed page (front and back) so that it is a more useful tool for busy clinic staff and can easily be referenced in exam rooms. 2 We also updated the implementation steps to broaden language about referrals.
Report Card	1 All staff agreed or strongly agreed that they liked the report card, the information was easy to follow, and its domains were useful for quality improvement. 2 In particular, staff liked the narrative portion, commenting that it clarified how implementation was going and helped inform how to make improvements. 3 Several staff noted how it was beneficial for multiple staff at a clinic to complete the report card.	1 We added introductory text to the report card recommending that it be completed and/or discussed as a group as part of quality improvement and that it be shared with leadership to showcase RCE impact.
Marketing Materials	1 According to survey findings, all staff agreed or strongly agreed that the marketing materials (social media content and client and staff palm cards) provided the right amount of information and were easy to understand. 2 Across marketing materials, staff reported the lowest likability for the social media post images. One staff member noted that the social media post images seemed very clinical, and another said there was a lack of representation in the images (i.e., images did not reflect the client population). 3 Staff across both clinics provided feedback during interviews that the staff-facing palm card was too wordy. 4 Regarding the client-facing palm card, a few staff felt it was burdensome to write the clinic's phone number each time, and other staff suggested adding a space to write the client's next appointment details.	1 We re-designed the staff palm card to highlight key information and replace extraneous text with a graphic that visually indicates how to connect clients with the RCE program. 2 We updated the client-facing palm card to be an editable PDF so that implementing organizations can populate the RCE Concierge's phone number and RCE "password" before printing the palm cards to avoid having to hand write these each time. 3 We added a space for organizations to write in the RCE Visit appointment date and time, so that the card can serve as an appointment reminder. 4 We increased the number of social media graphics included in the toolkit and included more diversity in setting (e.g., by incorporating lifestyle photos in addition to clinical settings) and client demographics (e.g., more racial and ethnic diversity, more young people).