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Using Data-to-Care Strategies to Optimize the HIV Care Continuum in Connecticut: Results from a Randomized Controlled Trial

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Abstract

Background: Re-engaging people with HIV (PWH) who are newly out-of-care remains challenging. Data-to-care (D2C) is a potential strategy to re-engage such individuals.

Methods: A prospective randomized controlled trial compared a D2C strategy using a disease intervention specialist (DIS) vs standard-of-care (SOC) where 23 HIV clinics in 3 counties in Connecticut could re-engage clients using existing methods. Using a data reconciliation process to confirm being newly out-of-care, 655 participants were randomized to DIS (N=333) or SOC (N=322). HIV care continuum outcomes included re-engagement at 90 days, retention in care and viral suppression (VS) by 12 months. Multivariable regression models were used to assess factors predictive of attaining HIV care continuum outcomes.

Results: Participants randomized to DIS were more likely to be re-engaged at 90 days (aOR=1.42, p=0.045). Independent predictors of re-engagement at 90 days were: age>40

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CONFLICT OF INTEREST STATEMENT
No conflict of interest to disclose.

DISCLAIMERS
The findings & conclusions in this report are those of the authors & do not necessarily represent the official position of the Centers for Disease Control and Prevention.
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years (aOR=1.84, p=0.012) and peri-natal HIV risk category (aOR=3.19, p=0.030). Predictors of retention at 12 months included: re-engagement at 90 days (aOR=10.31, p<0.001), drug injection HIV risk category (aOR=1.83, p=0.032), detectable HIV-1 RNA before randomization (aOR=0.40, p=0.003) and county (Hartford aOR=1.74, p=0.049; New Haven aOR=1.80, p=0.030). Predictors of VS included: re-engagement at 90 days (aOR=2.85, p<0.001), retention in HIV care (aOR=7.07, p<0.001), and detectable HIV-1 RNA pre-randomization (aOR=0.23, p<0.001).

Conclusions: A D2C strategy significantly improved re-engagement at 90 days. Early re-engagement improved downstream benefits along the HIV care continuum like retention in care and VS at 12 months. Moreover, other factors predictive of care continuum outcomes can be used to improve D2C strategies.

Keywords

Data-to-Care; D2C; HIV care continuum; Re-engagement in care; implementation science

INTRODUCTION

The Ending the HIV Epidemic (EHE) strategy has four pillars that promote reductions in HIV transmission and increased survival for people with HIV (PWH).[1] An effective treatment response is one of the cornerstones of this strategy. There are 964,002 individuals aged 13 and older diagnosed with HIV in the U.S. (2021);[2] retention in care and viral suppression (VS) are sub-optimal (47% and 58%, respectively),[2] far below the 95-95-95 targets set by the United Nations (UNAIDS).[3] Consequently, PWH who are not retained in care and are not virally suppressed are estimated to account for over 60% of new HIV cases in the U.S.[4,5] The HIV care continuum provides a heuristic for deploying evidence-based practices for each of the steps in the continuum, with retention in care representing the largest implementation gap and an ideal target for intervention.

Data-to-Care (D2C) interventions are potential strategies for improving retention in care. D2C has emerged as a public health practice that uses HIV surveillance data to identify and re-engage out-of-care PWH, and thus, can guide efforts to support the HIV care continuum.[6,7] As part of its programmatic goals, the Centers for Disease Control and Prevention (CDC) advocates for implementation of D2C strategies which include: expansion and uptake of D2C models using data sharing agreements; integration and use of surveillance; utilization of clinical, pharmacy, and social/support services data to identify and engage people not in care and PWH who are not virally suppressed; and identifying and addressing barriers for people who have never engaged in care or who have fallen out of care.[8] D2C interventions are highly diverse and include different levels of engagement and collaborations between public health departments and clinics. Some D2C programs rely solely on HIV surveillance data[9,10] while others use additional clinic data resources[11,12] to identify out-of-care PWH. A hybrid D2C model engages public health departments and clinics to perform intense cleaning of HIV surveillance data and consolidation with clinic records.[13–19]

The CDC has sponsored several trials examining the feasibility of D2C implementation[9,10,17,20] including the Cooperative Re-Engagement Controlled Trial

(CoRECT), which was the first multi-site, randomized controlled trial to examine outcomes for D2C. This multicenter study was conducted between 2014–2018 at three sites (Connecticut, Massachusetts, Philadelphia). Although the implementation of D2C differed by sites, CoRECT broadly examined the use of Disease Intervention Specialists (DIS) employed by health departments to re-engage in care newly out-of-care PWH. In CoRECT, public health surveillance data was supplemented by individual clinic-level data to ensure that the identification and referral to the DIS of out-of-care PWH was accurate and appropriate. The multi-site outcomes were previously published[21,22] and showed that an active public health intervention improved overall re-engagement in care at 90 days and time to VS,[21] but did not significantly improve downstream outcomes like retention in care and durable VS.[22,23,24] One of the key findings was substantial inter-site variability among some outcomes, reflecting different implementation strategies employed by the sites. Given the heterogeneity of health department jurisdictions across the U.S. and the highly variable implementation of evidence-based practices, we examined the data from the Connecticut site which involved 3 counties and 23 HIV clinics to inform future design and implementation of D2C programs. Moreover, as the parent trial did not examine predictors of each of the main outcomes, we provide further information on the characteristics associated with the HIV treatment continuum to better inform D2C programs.

METHODS

Study Background

The parent study, Project CoRECT, was a CDC-funded randomized controlled trial that involved a data reconciliation process to identify PWH who were newly out of HIV care. This process used public health department data from the CDC-developed Enhanced HIV/AIDS Reporting System (eHARS)[25] that assists health departments with HIV reporting, data management and analysis, and transfer of data to CDC. At the Connecticut site, after the list of newly out-of-care participants was identified, it was subjected to a data reconciliation process with each of the 23 HIV clinics in 3 counties to finalize eligibility. These clinics were diverse and included Ryan White-funded, community-based, hospital-based, and private clinics that provided HIV care to over 7,500 patients accounting for over 95% of PWH. Eligible participants were then randomized to either the control standard of care (SOC), or the active intervention that involved disease intervention specialists (DIS) employed by the Department of Public Health. SOC procedures varied at each of the 23 participating clinics and included phone calls, text message reminders, certified mail, or e-mails. Clinics did not have dedicated outreach workers and thus, nurses, front desk staff, or case managers may have performed outreach activities. In general, SOC outreach activities were not standardized or monitored, although in some clinics, written protocols for contacting “no-show” patients existed. It was observed, however, that re-engagement activities increased at some clinics as a result of the case reconciliation process where clinics had to verify that patients were truly out-of-care. At the Connecticut site, the Department of Public Health partnered with Yale School of Medicine to conduct the study.

Protocol for Defining Newly Out-of-Care People with HIV and Study Arm Allocation

Participants were recruited between August 2016 and July 2018. Eligible participants included those 18 or older, residing within the Department of Public Health jurisdiction, and being out-of-care as per the protocol definition. The protocol to identify newly out-of-care PWH in Connecticut has been previously described.[21,26,27] To be eligible for randomization, the eHARS database identified individuals who had received HIV care at one of the 23 clinics within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits. Clinics used clinical records to first identify in-care PWH who visited a clinic within the designated 12-month period followed by a list of PWH who had no clinic visit in the following 6 months. Following the reconciliation of two datasets, the potential participant lists were returned to the 23 participating HIV clinics for triage. During this process, PWH still in care, those with a scheduled upcoming visit, and those defined as “well patients” (2 consecutive undetectable VL of ≤200 copies/ml at least 6 months apart and no evidence of detectable VL during the in-care or out-of-care periods) were excluded from the list of randomizable participants.[27,28] The remaining eligible participants were randomized in REDCap to receive either the DIS intervention or SOC using block randomization within each clinic. Though the clinics were informed of which patients were enrolled, they were not informed about intervention allocation. Both arms had equal opportunity for clinic-based re-engagement strategies, which varied considerably based on clinic size or available resources (e.g., other case managers).

Disease Intervention Specialist Activities

A total of three DIS were stationed at local health departments in the metropolitan areas of Bridgeport, New Haven, and Hartford, the three most populous counties in Connecticut that are most profoundly impacted by HIV. None of the DIS for this research had prior DIS experience and therefore were first trained in principles of DIS, including communications skills, interviewing techniques, field investigation, etc., followed by a supplemental training in strengths-based case management based on the modified Antiretroviral Treatment Access Study (ARTAS) model.[29,30] ARTAS is a time-limited intervention which aims to connect individuals recently diagnosed with HIV to care by the way of assisting clients to overcome barriers by utilizing a strengths-based approach.[29,30] The training was modified for re-engagement in HIV care.

A detailed breakdown of DIS activities in Connecticut has been published elsewhere.[27] Briefly, DIS used several methods to find and contact participants within 30 days of randomization, including through phone calls, social media, certified mail, field visits to home, work, friends, and next of kin. In case of successfully contacting participants, DIS delivered up to three sessions where DIS assessed participants’ readiness to re-engage in care, determined the need for additional interventions, and, when needed, worked with clinics to schedule appointments for participants or, in some instances, accompanied patients to appointments. DIS were equipped to provide other available community resources if necessary.[27] Once a participant was re-engaged in care, no further services were delivered by DIS. The delivery of the intervention was at the discretion of the DIS and was not monitored.

Data Sources and Outcomes

Data sources were limited to the CT Department of Public Health eHARS surveillance database and client-level data from the 23 participating HIV clinics. In addition, DIS were asked to maintain field notes in the newly developed internal DIS database, HARMSWeb, which detailed their encounters. A research assistant was able to access data for both study arms at each of the HIV clinics. Assessment of eHARS provided access to all laboratory monitoring. The HIV care continuum was used to guide the primary outcomes and included: 1) re-engagement in HIV care within 90 days, defined as either the presence of a laboratory reported HIV-1 RNA or CD4 lymphocyte count in the eHARS database within 90 days after randomization; 2) retention in HIV care by 12 months, defined as having two laboratory markers (HIV-1 RNA and/or CD4 lymphocyte count) reported at least 90 days apart; and 3) VS, defined as having an HIV-1 RNA value <200 copies/ml within 12 months of randomization. The parent study compared the proportion achieving each outcome between the DIS and SOC arms. In the current analysis, the primary outcome was defined as the predictors (demographic, HIV exposure risk, and clinical factors like prior CD4 and HIV-1 RNA levels while in care previously) of attainment of each of the three HIV care continuum outcomes. Secondary outcomes included: time to re-engagement in care for each study group; differences in HIV-1 RNA levels and CD4 lymphocyte count among those who were re-engaged within 90 days and those who re-engaged later (91–365 days); and the breakdown of participant engagement outcomes in the DIS arm based on DIS field notes.

Data Analysis

The primary analysis deployed an intent-to-treat approach. Categorical variables were described using frequencies and percentages; continuous variables were characterized as means with standard deviations (SD), and medians with inter-quartile ranges (IQR). To construct the HIV care continuum, we calculated the proportions of participants attaining the continuum outcomes in the DIS and SOC arms. For the primary analyses, we used unadjusted and adjusted logistic regression models with each of the HIV care continuum outcomes as a dependent variable. Independent variables included: study arm, age, sex at birth, race/ethnicity, exposure risk group, time since HIV diagnosis, ever attaining VS, pre-randomization HIV-1 RNA and CD4 lymphocyte count values (adjusted for the time between the last pre-randomization lab and randomization date) and DIS location. As the intervention arm involved an active process to re-engage PWH in HIV care, we included re-engagement in HIV care within 90 days as a potential predictor for downstream HIV care continuum outcomes as a marker of secondary benefits to DIS activities. Odds ratios (OR) and adjusted odds ratios (aOR) are reported with the corresponding 95% confidence intervals (CIs). Models were checked using Hosmer-Lemeshow goodness-of-fit test. In all analyses, statistical significance was determined using a two-tailed hypothesis test at a significance level of 0.05. For the secondary analysis, Kaplan Meier curves and log-rank tests were used to compare the cumulative incidence of re-engagement between intervention groups. The differences between pre- and post-randomization CD4 lymphocyte count and HIV-1 RNA levels were calculated for each study arm and means were compared using Student's *t*-test for the subsets of individuals with laboratory assessments. Finally, we reviewed DIS field notes to better understand participant engagement outcomes in the DIS arm. Because the DIS activities were not conducted in a standardized manner, DIS activities

were described but not included in the multivariable analyses. All analyses were performed using R version 4.2.1.

Ethical Considerations

In Connecticut, the study was approved by the State of Connecticut Department of Public Health Human Investigations Committee (Protocol #823) and Yale University Institutional Review Board (#15100166172). Yale University IRB determined that this study was not considered to be Human Subjects Research and waived the informed consent procedures.

The study is registered at www.clinicaltrials.gov as NCT02693145.

RESULTS

Overall, 655 participants at the Connecticut site were randomized to either DIS (N=333) or SOC (N=323). Table 1 compares demographic and clinical characteristics based on participant randomization status. There were no significant differences between the two arms. At 90 days, 170 (51.1%) and 135 (41.9%) participants re-engaged in the DIS and SOC arms, respectively. In the DIS arm, 176 (52.9%) participants were retained at 12 months versus 167 (51.9%) in the SOC arm, and 225 (67.6%) achieved VS at 12 months in the DIS arm versus 198 (61.5%) in the SOC arm (Figure 1 **Panel A**).

Independent Predictors of Achieving HIV Care Continuum Outcomes

Univariate and multivariate associations between demographic and clinical characteristics and outcomes of re-engagement at 90 days, retention in care at 12 months, and viral suppression at 12 months are presented in Tables 2–4. Percentages of achieving each outcome by a demographic or a clinical group are presented in the Supplementary Table 3. Independent predictors of re-engagement at 90 days included: DIS allocation (aOR=1.42; 95% CI 1.01–2.01; p=0.045); age 40 years or older (aOR=1.84; 95% CI 1.14 −2.9; p=0.012); perinatal exposure risk group versus heterosexual (aOR=3.19; 95% CI 1.13–9.31; p=0.030); and Asian or Multi-race category versus White (aOR=0.19; 95% CI 0.03–0.85; p=0.048) (Table 2).

Independent predictors of retention at 12 months included: re-engaging at 90 days (aOR=10.31; 95% CI 6.85–15.81; p<0.001); injection drug use as exposure risk category versus heterosexual (aOR=1.86, 95% CI 1.05–3.29, p=0.033); Hartford (aOR=1.74, 95% CI 1.00–3.03, p=0.049) and New Haven (aOR=1.80, 95% CI 1.06–3.09, p=0.030) locations versus Bridgeport; detectable HIV-1 RNA levels (aOR=0.40, 95% CI 0.22–0.74, p=0.003) and longer time between last HIV-1 RNA levels lab and randomization (aOR=0.90, 95% CI 0.82–0.99, p=0.029) (Table 3).

Independent predictors of viral suppression at 12 months included: re-engagement at 90 days (aOR=2.85; 95% CI 1.74–4.70; p<0.001); retention at 12 months (aOR=7.07; 95% CI 4.32–11.82; p<0.001); detectable HIV-1 RNA levels (aOR=0.23; 95% CI 0.12–0.43; p<0.001); and Other race/ethnicity category versus White (aOR=0.11; 95% CI 0.01–0.56; p=0.014).

Cumulative Incidence Analysis

For the time-to-event analysis, Kaplan-Meyer estimates of the cumulative incidence of re-engagement over time, with assessments for 90 and 365 days are depicted in Figure 1 **Panel B**. The mean time to re-engagement at 90 days was significantly lower in the DIS than in the SOC arm (64.9 vs 71.7 days; log-rank p=0.008). By the end of 12 months, however, the cumulative incidence curves are similar between the DIS and SOC arms, with mean time to re-engagement at 12 months being 141.4 versus 159.3 days (log-rank p=0.093). Overall, 305 (46.6%) participants re-engaged in 90 days (170 [51.1%] for DIS and 135 [41.9%] for SOC) and a total of 545 (83.2%) participants re-engaged within 12 months (280 [84.1%] for DIS and 265 [82.3%] for SOC).

Mean change in HIV-1 RNA and CD4 Lymphocyte Count

Overall, 537 participants had HIV-1 RNA and 484 had CD4 lymphocyte count measurements within 12 months of randomization. We compared laboratory assessments for those that re-engaged early (within 90 days) to those who re-engaged later (91–365 days) and found that those who re-engaged early by any means (DIS or SOC) had a smaller increase in HIV-1 RNA compared to those who re-engaged later (0.26 log10 copies/ml vs 0.73 log10 copies/ml, p<0.001), and a smaller decrease in CD4 lymphocyte counts (−2.8 vs −49.3 cells/μL, p=0.007). (Supplementary Table 1).

Participant Engagement Outcomes in the DIS Arm

Among the 333 participants randomized to DIS, 80 (47.1%) re-engaged by 90 days after randomization and an additional 13 re-engaged after 90 days; 72 (21.6%) participants could not be located, 52 (15.6%) were located but declined to participate in the intervention, and 41 were miscategorized as randomizable (found to be in care or otherwise not eligible at time of DIS intervention). Twenty-one (6.3%) participants were out of jurisdiction, 20 (6.0%) reported that they had planned an upcoming visit, 13 (3.9%) returned to care without DIS intervention. Five (1.5%) participants were incarcerated, 4 (1.2%) were deceased, and 3 (0.9%) had no outcome reported in HARMSWeb. Categorization of participants randomized to DIS, as well as breakdown of those re-engaged at 90 days within the DIS arm is presented in Supplementary Table 2.

DISCUSSION

This study presented a detailed analysis of a D2C strategy that deployed a brief DIS intervention, giving important insights into D2C implementation in Connecticut. Central to this study is the finding that the DIS were substantially better at re-engaging newly out-of-care PWH in the first 90 days compared to SOC. Achieving each step of the HIV care continuum significantly improved the attainment of downstream benefits: those who were timely re-engaged by any means had a higher likelihood of being retained in care and virally suppressed at 12 months, and those retained in care at 12 months were more likely to be virally suppressed, highlighting the reinforcing nature of achieving early HIV care continuum milestones to predict better distal outcomes.

Relative to the SOC, DIS proved to be more effective in re-engaging newly out-of-care PWH in HIV care. Given that SOC clinics intensified their re-engagement activities through the clinic reconciliation process where they learned who their recently out-of-care patients were, our findings represent the most conservative estimates. Though the findings are robust, we cannot quantify which of many of the DIS efforts contributed most to successful re-engagement of out-of-care PWH. Several activities of how the DIS provided these services, however, may have played a part in their effectiveness. The primary responsibility of DIS was to perform outreach to out-of-care PWH and re-engage them as quickly as possible, using various modalities. Outreach activities in the SOC arm was limited to clinic staff, like nurses or case managers, who have competing clinical and administrative duties. DIS were mobile in their work, used a number of administrative data resources and performed field visits to locate out-of-care PWH. DIS offered additional outreach tools to PWH, like assisting in scheduling or, in some cases, even accompanying PWH to their appointments. Finally, DIS received ARTAS training which specifically focused on re-engagement approaches, including education and motivational interviewing. Though the DIS were hired staff that provided services beyond the SOC clinical staff, it was documented that DIS cost was comparable to other similar interventions.[31]

A meta-analysis of D2C strategies for out-of-care PWH conducted before CoRECT generally found that D2C strategies improve re-engagement and retention in HIV care, but not VS.[32] While DIS had clear benefits early on in re-engaging PWH, more distal outcomes like retention in care and VS at 12 months were similar in DIS and SOC arms. A recent study documented considerable implementation strategies of DIS that may have contributed to diverse outcomes.[33] An evidence-based intervention, ARTAS, which links newly diagnosed PWH to HIV care, emphasizes the importance of early linkage to care, and involves multiple strength-based case management sessions, may be more successful in achieving durable long-term effects, but modified ARTAS in our study did not achieve these goals. Instead, the modified ARTAS intervention in the current D2C strategy focused only on re-engagement in HIV care and did not sustain the multiple counseling sessions in the original ARTAS toolkit. The current model aligned more with traditional DIS activities that target case-finding similar to assessment and treatment of sexually transmitted infections that can often be managed with a single treatment episode. HIV, however, is a chronic condition that requires effective retention-in-care strategies with the goal of sustaining VS. A substantial body of literature confirms that retention in HIV care is critical to successful HIV management and is associated with decreased morbidity and mortality, and a reduced HIV transmission risk.[34,35] Therefore, although re-engagement is an important first step of the care continuum, successful management of HIV can only be accomplished through continuous, long-term retention in HIV care. To ensure that the re-engagement in HIV care is sustainable and out-of-care PWH receive optimal assistance, it is important to explore the barriers to accessing HIV care. The CoRECT study collected data on why PWH dropped out of HIV care, but could only do so for those that were contacted. The reasons for dropout included not feeling ill, forgetting about the appointment, having competing school or work duties, or inconvenient clinic hours (unpublished data). To improve access for the identified out-of-care PWH, innovative strategies could include telehealth,[36,37] mobile vans,[28,38] low barrier clinics,[39] financial incentives,[40,41] and novel

social media approaches.[23,24] Clinic-based approaches such as intensive case management for PWH who are at high-risk for dropout, as well as community support centers may play an important role in sustaining engagement in HIV care, yet such strategies may be sub-optimally implemented with clinic staff not extending their work into the community. Future studies could focus on implementation approaches that expand DIS approaches that include telehealth and integrating use of additional “big data” sources.

We found that several demographic and clinical characteristics were associated with re-engagement in care, retention, and viral suppression. These findings can inform future implementation efforts to better target groups that are difficult to reach to engage them in care more fully. Younger people, for example, were less likely to re-engage in care, which highlights the importance of adopting strategies targeting this group (e.g., use of social media, tailored messaging, etc.).[23,24]

Interestingly, we found that PWH who acquired HIV through drug injection were better retained in care relative to other exposure risk groups. This population may have had access to effective treatment for substance use disorders that increased their engagement in HIV care[42,43] as Connecticut has high coverage of medications for opioid use disorder, which provides opportunities for repeated engagement with patients. Those not receiving treatment may have had other opportunities for re-engagement at other touchpoints (e.g., emergency departments, hospitals, drug treatment programs and community based organizations)[44] where laboratory assessments were obtained to meet the retention in care definition, but for which patients were not fully engaged in their HIV care. Another potential explanation is that this group may have more encounters with the criminal justice system that has automated laboratory assessments, which was observed in a longitudinal cohort of PWH who were repeatedly incarcerated.[45,46]

Retention-in-care outcomes differed with higher levels relative to Bridgeport, emphasizing the importance of context and the heterogeneity of implementation strategies deployed. Though we do not have more granular operational data to explain this finding, it may be that community-based case management or other health services delivery differs by site or that there are distinctly different local challenges (e.g., public transportation) that undermine the D2C strategy. Bridgeport is considered substantially poorer than either New Haven or Hartford on several metrics (e.g., unemployment, tax revenue, etc.), which may in part explain the differences in outcomes. Alternatively, the strategies deployed by DIS may have substantially differed but were not measured in terms of fidelity to the intervention.

We found that Asian and multi-race PWH had significantly lower levels of re-engagement and viral suppression, while those who reported perinatal HIV acquisition risk were more likely to re-engage. The number of individuals in these categories was minimal, limiting our ability to draw meaningful conclusions.

Re-engaging newly out-of-care PWH in a timely manner has important personal and public health implications. We found that those re-engaged within 90 days relative to those re-engaged later had lower changes in their HIV-1 RNA levels and CD4 lymphocyte counts after re-engaging in care. HIV-1 RNA levels are the single best predictor of the progression

of HIV disease and mortality, and changes in HIV-1 RNA levels as little as 0.3 log10 are associated with worse clinical outcomes.[47] Thus, re-engagement in HIV care earlier allowed less rebound in HIV-1 RNA and clinically supports active re-engagement efforts by DIS. Moreover, as HIV-1 RNA levels play an important public health role in community HIV transmission, those whose HIV-1 RNA levels are detectable, especially those with HIV-RNA levels that exceed 1500 copies/ml are more efficient at transmitting HIV disease and undermine U=U (undetectable=untransmittable)[48] efforts aligned with treatment as prevention.[49] As such, re-engagement not only improves patient health outcomes, but reduces infectiousness, thus demonstrating the benefits of identifying and prioritizing a more newly out-of-cate group who could benefit from timely re-engagement before further immunologic or virologic deterioration.

Review of DIS field notes points to challenges that DIS had in finding newly out-of-care PWH. The most common reason for not finding them is that DIS did not have adequate tools to do so. The future of integrating “big data” or data science strategies with supplemental data sources may be crucial to improved D2C strategies,[50] where the data component of D2C not only involves surveillance data, but includes other records. Previous studies examining D2C programs have also reported difficulties in locating patients.[7,51] One D2C program using surveillance data reported that only 35.5% of those contacted were confirmed as truly out-of-care PWH, while only 26% were eligible for re-engagement in care in another.[9,10] An alternative D2C model is clinic-related/clinic-initiated and relies on clinic outreach resources[11,12] to re-engage patients identified by the clinic, but few clinics have sufficient resources to take on this effort. A hybrid model which engages health departments and clinics to define the out-of-care list uses a *Data to Clinic to Patient* approach where the workload is shared by Departments of Health and clinics who have more detailed knowledge of patient status.[13–19] In Connecticut, we combined surveillance and clinic-level data where surveillance data were first reconciled using input from clinic staff to maximize the accuracy of out-of-care PWH lists. Even with the extensive data reconciliation process, a number of the randomized participants were miscategorized and were later found to be out of jurisdiction, incarcerated, or deceased. Some mis-categorization can be partially attributed to the time lag between randomization and DIS activities (e.g., participants might have moved, returned to care, or experienced incarceration during the time window between randomization and DIS outreach). A strategy to address these challenges in future D2C projects can be ongoing data reconciliation using other data sources such as receipt of social/support services or pharmacy data along with surveillance and clinic-level data.[52,53]

Despite the many important findings, there are some limitations. First, participating clinics actively identified newly out-of-care patients, leading to increased case-finding in the SOC group, potentially decreasing the difference between the two arms. Second, implementation strategies were not examined in the 23 diverse HIV clinics, which may have explained some contextual differences in outcomes. Last, the DIS activities specific for PWH in Connecticut were entirely new and had previously been used only for sexually transmitted infections. This was distinct relative to the other two sites in the parent study. These differences, including a shorter time window for DIS engagement, may have contributed to different outcomes.

CONCLUSIONS

D2C processes in Connecticut employing DIS from the Department of Public Health successfully identified and re-engaged newly out-of-care PWH within 90 days. Re-engagement at 90 days serves to “jump start” the HIV care continuum, translating into better downstream outcomes like superior retention and VS at 12 months, which have important personal and public health implications for the successful management of the HIV epidemic.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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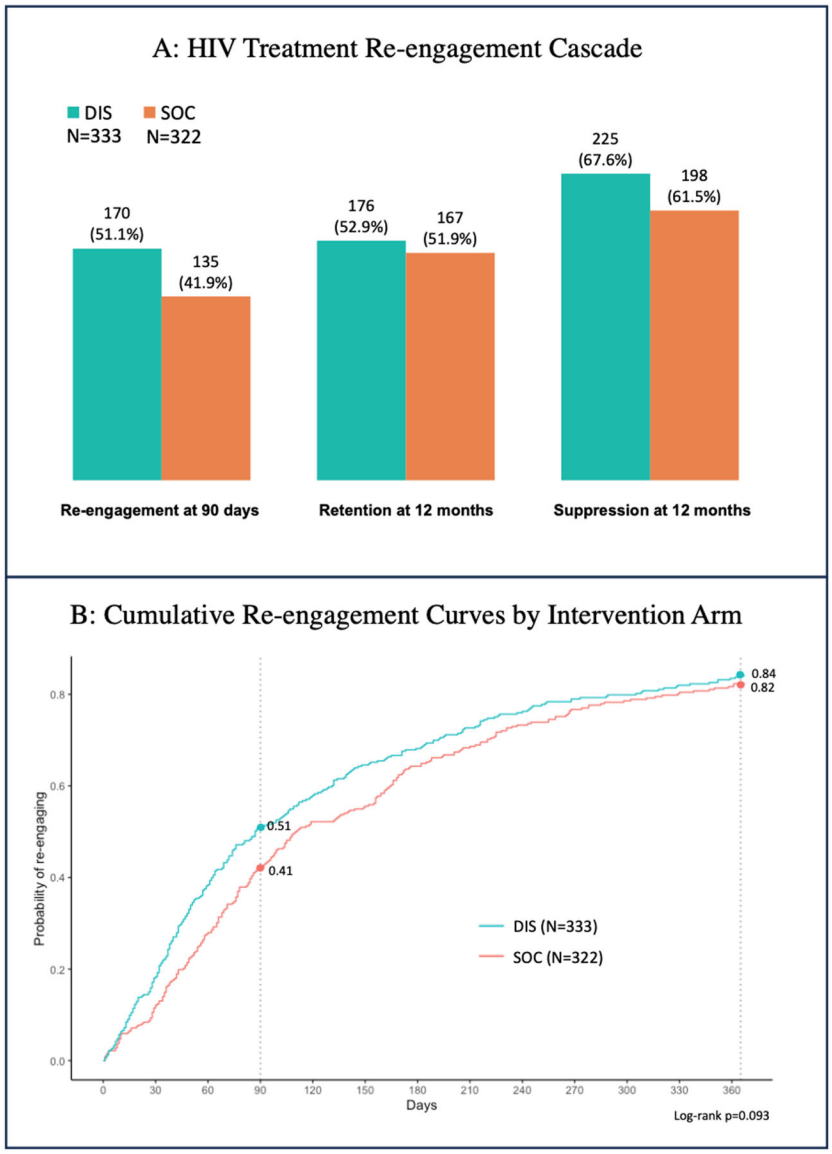

Figure 1.

HIV care cascade and cumulative re-engagement curves for the sample of newly out-of-care people with HIV in Connecticut.

The study was conducted over the time period between August 2016 and July 2018. Being newly out-of-care is defined as receiving HIV within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits.

The cumulative incidence curves of re-engagement during the first 90 days were significantly different with 51% re-engaged in the DIS arm versus 41% in the SOC arm (log-rank p=0.008). The cumulative incidence curves over the 12 months were similar between the two arms with 84% re-engaged in the DIS arm and 82% in the SOC arm (log-rank p=0.093).

Abbreviations: DIS Disease Intervention Specialists; SOC Standard of Care.

Table 1.

Demographic and clinical characteristics of the sample of newly out-of-care people with HIV identified through surveillance and clinical data in Connecticut.

Characteristics	DIS (N=333)	SOC (N=322)	Total (N=655)	P
Sex at birth				
Male	212 (63.7%)	197 (61.2%)	409 (62.4%)	0.565
Female	121 (36.3%)	125 (38.8%)	246 (37.6%)	
Age				
18–29	40 (12.0%)	51 (15.8%)	91 (13.9%)	
30–39	59 (17.7%)	59 (18.3%)	118 (18.0%)	
40–49	90 (27.0%)	82 (25.5%)	172 (26.3%)	0.691
50–59	94 (28.3%)	85 (26.4%)	179 (27.4%)	
60<	49 (14.7%)	45 (14.0%)	94 (14.4%)	
Mean (SD)	46.3 (12.3)	45.3 (13.0)	45.8 (12.6)	0.317
Median (IQR)	48 (36, 56)	46 (34, 55)	47 (35, 55)	
Race/ethnicity				
White	64 (19.2%)	72 (22.4%)	136 (20.8%)	
Black	123 (36.9%)	141 (43.8%)	264 (40.3%)	0.072
Hispanic	138 (41.4%)	104 (32.3%)	242 (36.9%)	
Other *	8 (2.4%)	5 (1.6%)	13 (2.0%)	
Exposure risk				
HET	97 (29.1%)	93 (28.9%)	190 (29.0%)	
MSM, MSM/HET	94 (28.2%)	100 (31.1%)	194 (29.6%)	0.848
IDU †	104 (31.2%)	97 (30.1%)	201 (27.2%)	
Perinatal	10 (3.0%)	11 (3.4%)	21 (3.2%)	
Other ‡	28 (8.4%)	21 (6.5%)	49 (7.5%)	
HIV diagnosis duration in years				
<5	70 (21.0%)	80 (24.8%)	150 (22.9%)	
6–10	54 (16.2%)	51 (15.8%)	105 (16.0%)	0.174
11–20	105 (31.5%)	114 (35.4%)	219 (33.4%)	
>20	104 (31.2%)	77 (23.9%)	181 (27.6%)	
Mean (SD)	14.5 (36.62)	13.3 (8.19)	13.9 (8.43)	0.065
Median (IQR)	15 (7, 21)	13 (6, 19)	14 (6, 20)	
Ever suppressed				
No	43 (12.9%)	29 (9.0%)	72 (11.0%)	0.141
Yes	290 (87.1%)	293 (91.0%)	583 (89.0%)	
CD4 count before randomization (cells/μl)				
<200	44 (13.2%)	52 (16.1%)	96 (14.7%)	
200–349	51 (15.3%)	41 (12.7%)	92 (14.0%)	0.617
350–499	59 (17.7%)	55 (17.1%)	114 (17.4%)	
≥500	153 (45.9%)	150 (46.6%)	303 (46.3%)	

Characteristics	DIS (N=333)	SOC (N=322)	Total (N=655)	P
Mean (SD)	556 (338)	559 (369)	558 (353)	
Median (IQR)	498 (286, 766)	503 (301, 758)	501 (288, 764)	0.927
Missing	26 (7.8%)	24 (7.5%)	50 (7.6%)	
Time between last CD4 and randomization (months)				
Mean (SD)	10.3 (4.5)	10.0 (4.4)	10.2 (4.4)	0.277
Median (IQR)	10.3 (7.8, 13.2)	10.0 (7.2, 12.1)	10.2 (7.5, 12.4)	
HIV-1 RNA levels before randomization				
Non-detectable [§]	248 (74.5%)	228 (70.8%)	476 (72.7%)	0.273
Detectable	83 (24.9%)	94 (29.2%)	177 (27.0%)	
Mean (SD)	10,500 (46,300)	8,810 (35,800)	9,650 (41,400)	
Median (IQR)	20 (20, 206)	20 (20, 560)	20 (20, 339)	0.354
Missing	2 (0.6%)	0 (0%)	2 (0.3%)	
Time between last HIV-1 RNA levels and randomization (months)				
Mean (SD)	10.1 (4.2)	9.8 (4.2)	9.9 (4.2)	0.336
Median (IQR)	10.2 (8.0, 12.4)	9.9 (7.2, 11.9)	10.0 (7.8, 12.1)	
County				
New Haven	127 (38.1%)	124 (38.5%)	251 (38.3%)	0.351
Bridgeport	77 (23.1%)	87 (27.0%)	164 (25.0%)	
Hartford	127 (38.1%)	107 (33.2%)	234 (35.7%)	
Missing	2 (0.6%)	4 (1.2%)	6 (0.9%)	

The study was conducted over the time period between August 2016 and July 2018. Being newly out-of-care is defined as receiving HIV care (having a recorded visit and CD4/HIV viral load test) within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits.

[*] Asian and Multi-race;

[†] includes any person reporting injection drug use single or one of the multiple risk categories;

[‡] includes other, not identified or reported risk categories;

[§] >200 copies/ml.

Abbreviations: SOC standard of care; DIS disease intervention specialists; HET heterosexual; MSM men who have sex with men; IDU injection drug use.

Table 2.

Demographic and clinical characteristics associated with re-engagement in HIV care within 90 days within the sample of newly out-of-care people with HIV in Connecticut.

	Re-engagement in 90 days					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
Study arm (*N=655*)				***(N=598)***		
SOC	Ref			Ref		
DIS	1.44	1.06 – 1.97	0.019	1.42	1.01 – 2.01	0.045
Age, years						
18–39	Ref			Ref		
>40	1.79	1.28 – 2.52	0.001	1.84	1.14 – 2.98	0.012
Sex at birth (*N=655*)						
Male	Ref			Ref		
Female	0.94	0.68 – 1.29	0.692	0.92	0.60 – 1.40	0.692
Race/ethnicity (*N=655*)						
White	Ref			Ref		
Black	0.74	0.49 – 1.12	0.155	0.73	0.45 – 1.18	0.196
Hispanic	0.8	0.53 – 1.22	0.304	0.76	0.47 – 1.23	0.263
Other *	0.27	0.06 – 0.94	0.057	0.19	0.03 – 0.85	0.048
Exposure risk (*N=655*)						
HET	Ref			Ref		
MSM (MSM, MSM/HET)	0.92	0.62–1.39	0.704	1.10	0.63 – 1.93	0.729
IDU †	1.51	1.00 – 2.28	0.051	1.47	0.92 – 2.35	0.107
Perinatal	1.79	0.73 – 4.59	0.208	3.19	1.13 – 9.31	0.030
Other ‡	1.95	1.04 – 3.74	0.040	1.56	0.78 – 3.24	0.210
HIV duration in years (*N=655*)						
<5	Ref			Ref		
6–10	1.51	0.91 – 2.51	0.111	1.02	0.57 – 1.82	0.936
11–20	1.81	1.19 – 2.78	0.006	1.13	0.66 – 1.95	0.652
>20	1.67	1.08 – 2.61	0.023	0.88	0.48 – 1.61	0.688
Ever suppressed (*N=655*)						
No	Ref			Ref		
Yes	1.1	0.67 – 1.81	0.702	0.95	0.47 – 1.94	0.895
HIV-1 RNA levels before randomization (N=653)						
Not detectable §	Ref					
Detectable	0.87	0.62 – 1.23	0.437	0.84	0.50 – 1.38	0.486
Time between last HIV-1 RNA test and Randomization ¶ (*N=653*)						
1 month	0.94	0.90 – 0.97	0.001	0.93	0.85 – 1.01	0.071
CD4 cell count before randomization, cells/μl (*N=605*)						

	Re-engagement in 90 days					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
<200	Ref			Ref		
200–349	1.47	0.83 – 2.62	0.189	1.54	0.83 – 2.87	0.168
350–499	1.14	0.66 – 1.97	0.635	1.23	0.68 – 2.23	0.492
≥500	0.96	0.61 – 1.53	0.871	1.03	0.60 – 1.77	0.923
Time‖ between last CD4 lymphocyte count and randomization[¶] (*N=605*)						
1 month	0.95	0.92 – 0.99	0.010	1.01	0.93 – 1.09	0.878
County (*N=649*)						
Bridgeport	Ref			Ref		
Hartford	0.74	0.49 – 1.10	0.134	0.65	0.41 – 1.04	0.072
New Haven	0.84	0.57 – 1.25	0.402	0.83	0.53 – 1.30	0.409

The study was conducted over the time period between August 2016 and July 2018. Being newly out-of-care is defined as receiving HIV care (having a recorded visit and CD4/HIV viral load test) within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits.

[*] Asian and Multi-race;

[†] includes any person reporting injection drug use single or one of the multiple risk categories;

[‡] includes other, not identified or reported risk categories;

[§] >200 copies/ml;

[¶] time between HIV-1 RNA/CD4 count and randomization is a continuous measure.

The sample size for each univariate model is presented in parentheses next to the characteristic. The sample size for the multivariable regression is equal to 598.

Abbreviations: SOC standard of care; DIS disease intervention specialists; HET heterosexual; MSM men who have sex with men; IDU injection drug use.

Table 3.

Demographic and clinical characteristics associated with re-retention in HIV care at 12 months within the sample of newly out-of-care people with HIV in Connecticut.

	Retention at 12 months					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
Study Arm *(N=655)*				*N=598*		
SOC	Ref			Ref		
DIS	1.04	0.77 – 1.41	0.800	0.83	0.55 – 1.25	0.370
Re-engagement at 90 days (*N=655)*						
No	Ref			Ref		
Yes	10.14	7.09 – 14.70	<0.001	10.31	6.85 – 15.81	<0.001
Age, years (*N=655)*						
18–39	Ref			Ref		
40<	2.06	1.48 – 2.89	<0.001	1.29	0.74 – 2.24	0.372
Sex at birth (*N=655)*						
Female	Ref			Ref		
Male	1.12	0.81 – 1.53	0.500	0.84	0.51 – 1.39	0.501
Race/ethnicity (*N=655)*						
White	Ref			Ref		
Black	0.95	0.62 – 1.43	0.790	1.08	0.61 – 1.92	0.786
Hispanic	0.95	0.62 – 1.45	0.823	0.97	0.54 – 1.72	0.910
Other *	0.54	0.16 – 1.70	0.300	1.06	0.20 – 4.99	0.938
Exposure risk (*N=655)*						
HET	Ref			Ref		
MSM (MSM, MSM/HET)	0.9	0.60 – 1.35	0.621	1.20	0.62 – 2.32	0.584
IDU †	2.07	1.37 – 3.16	0.001	1.83	1.06 – 3.20	0.032
Perinatal	2.84	1.10 – 8.24	0.039	3.47	1.01 – 13.08	0.055
Other ‡	1.18	0.63 – 2.22	0.602	0.85	0.36 – 1.99	0.709
HIV duration in years (*N=655)*						
<5	Ref			Ref		
6–10	1.57	0.95 – 2.61	0.078	1.15	0.59 – 2.24	0.682
11–20	1.94	1.27 – 2.97	0.002	1.15	0.61 – 2.15	0.663
>20	2.33	1.50 – 3.65	<0.001	1.17	0.58 – 2.38	0.655
Ever suppressed (*N=655)*						
No	Ref			Ref		
Yes	1.62	0.99 – 2.68	0.056	0.77	0.33 – 1.78	0.544
HIV-1 RNA levels before randomization (*N=653*)						
Not detectable §	Ref			Ref		
Detectable	0.67	0.47 – 0.94	0.023	0.40	0.22 – 0.74	0.003

	Retention at 12 months					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
Time between last HIV-1 RNA test and randomization[¶] *(N=653)*						
1 month	0.89	0.85 – 0.92	<0.001	0.90	0.82 – 0.99	0.029
CD4 before randomization, cells/μl *(N=605)*						
<200	Ref			Ref		
200–349	1.1	0.62 – 1.97	0.740	0.85	0.41 – 1.77	0.671
350–499	1.2	0.69 – 2.08	0.517	1.04	0.51 – 2.10	0.915
≥500	0.76	0.48 – 1.21	0.254	0.64	0.33 – 1.20	0.166
Time between last CD4 lymphocyte count and randomization[¶] *(N=605)*						
1 month	0.91	0.88 – 0.95	<0.001	0.99	0.91 – 1.08	0.818
County (*N=649)*						
Bridgeport	Ref			Ref		
Hartford	1.03	0.69 – 1.53	0.895	1.74	1.00 – 3.03	0.049
New Haven	1.21	0.82 – 1.80	0.341	1.80	1.06 – 3.09	0.030

The study was conducted over the time period between August 2016 and July 2018. Being newly out-of-care is defined as receiving HIV care (having a recorded visit and CD4/HIV viral load test) within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits.

[*] Asian and Multi-race;

[†] includes any person reporting injection drug use single or one of the multiple risk categories;

[‡] includes other, not identified or reported risk categories;

[§] >200 copies/ml;

[¶] time between HIV-1 RNA/CD4 count and randomization is a continuous measure.

The sample size for each univariate model is presented in parentheses next to the characteristic. The sample size for the multivariable regression is equal to 598.

Abbreviations: SOC standard of care; DIS disease intervention specialists; HET heterosexual; MSM men who have sex with men; IDU injection drug use.

Table 4.

Demographic and clinical characteristics associated with viral suppression at 12 months within the sample of newly out-of-care people with HIV in Connecticut.

	Suppression at 12m					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
Study Arm ***(N=655)***				***N=598***		
SOC	Ref			Ref		
DIS	1.3	0.95 – 1.80	0.104	1.06	0.68 – 1.63	0.798
Re-engagement at 90 days ***(N=655)***						
No	Ref			Ref		
Yes	5.15	3.60 – 7.47	<0.001	2.85	1.74 – 4.70	<0.001
Retention at 12 months ***(N=655)***						
No	Ref			Ref		
Yes	8.51	5.88 – 12.51	<0.001	7.07	4.32 – 11.82	<0.001
Age, years ***(N=655)***						
18–39	Ref			Ref		
40<	1.72	1.22 – 2.41	0.002	1.18	0.66 – 2.11	0.583
Sex at birth ***(N=655)***						
Female	Ref			Ref		
Male	0.78	0.56 – 1.08	0.135	1.31	0.76 – 2.27	0.324
Race/ethnicity ***(N=655)***						
White	Ref			Ref		
Black	0.56	0.36 – 0.87	0.011	0.63	0.34 – 1.15	0.133
Hispanic	0.93	0.58 – 1.47	0.761	1.17	0.63 – 2.17	0.613
Other *	0.12	0.03 – 0.42	0.002	0.11	0.01 – 0.56	0.014
Exposure risk ***(N=655)***						
HET	Ref			Ref		
MSM (MSM, MSM/HET)	1.25	0.82 – 1.93	0.303	0.86	0.43 – 1.72	0.669
IDU †	1.11	0.46 – 2.87	0.827	0.62	0.34 – 1.11	0.111
Perinatal	1.48	0.57 – 4.29	0.442	1.49	0.38 – 6.21	0.572
Other ‡	1.48	0.76 – 3.01	0.266	1.48	0.55 – 4.10	0.439
HIV duration in years ***(N=655)***						
<5	Ref			Ref		
6–10	1.87	1.05 – 3.39	0.036	0.93	0.46 – 1.88	0.841
11–20	2	1.15 – 3.51	0.015	1.34	0.69 – 2.62	0.384
>20	2.09	1.31 – 3.34	0.002	1.63	0.76 – 3.53	0.212
Ever suppressed ***(N=655)***		***N=655***				
No	Ref			Ref		
Yes	3.53	2.14 – 5.93	<0.001	0.73	0.31 – 1.71	0.469

	Suppression at 12m					
	Bivariate associations			Multivariate associations		
	Odds ratios	95% CI	p	Adjusted odds ratios	95% CI	p
HIV-1 RNA levels before randomization *(N=653)*						
Not detectable [§]	Ref			Ref		
Detectable	0.27	0.19 – 0.39	<0.001	0.23	0.12 – 0.43	<0.001
Time between last HIV-1 RNA test and randomization [¶] *(N=653)*						
1 month	0.92	0.88 – 0.96	<0.001	0.92	0.82 – 1.02	0.113
CD4 before randomization, cells/μl (*N=605)*						
<200 cells/μl	Ref			Ref		
200–349 cells/μl	1.1	0.62 – 1.97	0.740	1.61	0.75 – 3.49	0.220
350–499 cells/μl	1.2	0.69 – 2.08	0.517	1.68	0.81 – 3.50	0.167
≥500 cells/μl	0.76	0.48 – 1.21	0.254	1.92	1.00 – 3.70	0.051
Time between last CD4 lymphocyte count and randomization [¶] *(N=605)*						
1 month	0.95	0.91 – 0.98	0.004	1.03	0.93 – 1.14	0.546
Location (*N=649)*						
Bridgeport	Ref			Ref		
Hartford	1.16	0.75 – 1.78	0.500	1.51	0.83 – 2.75	0.177
New Haven	0.75	0.50 – 1.13	0.169	0.86	0.49 – 1.51	0.609

The study was conducted over the time period between August 2016 and July 2018. Being newly out-of-care defined as receiving HIV care (having a recorded visit and CD4/HIV viral load test) within the past 12 months followed by a period of at least 6 months with no laboratory assessments or clinic visits.

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