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Study protocol for data to suppression (D2S): a cluster-randomised, stepped-wedge effectiveness trial of a reporting and capacity-building intervention to improve HIV viral suppression in housing and behavioural health programmes in New York City

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ABSTRACT

Introduction With progress in the 'diagnose', 'link' and 'retain' stages of the HIV care continuum, viral suppression (VS) gains increasingly hinge on antiretroviral adherence among people with HIV (PWH) retained in care. The Centers for Disease Control and Prevention estimate that unsuppressed viral load among PWH in care accounts for 20% of onward transmission. HIV intervention strategies include 'data to care' (D2C)—using surveillance to identify out-of-care PWH for follow-up. However, most D2C efforts target care linkage, not antiretroviral adherence, and limit client-level data sharing to medical (versus support-service) providers. Drawing on lessons learnt in D2C and successful local pilots, we designed a 'data-to-suppression' intervention that offers HIV support-service programmes surveillance-based reports listing their virally unsuppressed clients and capacity-building assistance for quality-improvement activities. We aimed to scale and test the intervention in agencies delivering Ryan White HIV/AIDS Programme-funded behavioural health and housing services.

Methods and analysis To estimate intervention effects, this study applies a cross-sectional, stepped-wedge design to the intervention's rollout to 27 agencies randomised within matched pairs to early or delayed implementation. Data from three 12-month periods (pre-implementation, partial implementation and full implementation) will be examined to assess intervention effects on timely VS (within 6 months of a report listing the client as needing follow-up for VS). Based on projected enrolment (n=1619) and a pre-implementation outcome probability of 0.40–0.45, the detectable effect size with 80% power is an OR of 2.12 (relative risk: 1.41–1.46).

Ethics and dissemination This study was approved by the New York City Department of Health and Mental Hygiene's institutional review board (protocol: 21–036) with a waiver of informed consent. Findings will be

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The Data-to-Suppression (D2S) trial, conducted in real-world service settings, leverages existing programmatic and surveillance data to assess the effectiveness of a structural intervention with support-service providers.

⇒ Limitations include a lack of blinding and a lack of control over client exposure to other initiatives or interventions that may affect the outcome.

⇒ As with other HIV care quality-improvement activities led by the New York City Health Department, agency participation is voluntary, meaning that agencies assigned to the intervention condition could implement incompletely or decline to implement the intervention. To address this limitation, we are tracking multiple implementation measures.

⇒ For pragmatic reasons and to minimise crossover between intervention conditions, randomisation to D2S is performed at the agency level, which yields fewer clusters than randomisation at the individual level or programme level, thus limiting statistical power for detecting an intervention effect. However, agency randomisation within matched pairs offers advantages akin to those of stratified random assignment: increasing statistical power in a situation where the number of units of randomisation is small, by maximising equivalency between the intervention and control groups on key observable variables, thus helping to isolate intervention effects.

⇒ Intervention effects are also isolated through the conditional analytic approach, which accounts for the unavoidably imperfect matching of agencies by conditioning out any pair-specific agency effects and any pair-specific period effects. Both such effects may vary across agency pairs.

disseminated via publications, conferences and meetings including provider-agency representatives.

Trial registration number NCT05140421.

INTRODUCTION

Treatment advances have improved health and survival for people with HIV (PWH) and opportunities for HIV prevention.[1–4] However, maximising the individual and public health benefits of effective antiretroviral therapy (ART) requires ensuring continuity of HIV care and self-management, from timely diagnosis and ART initiation to consistent ART adherence.[5–11] With ongoing improvement at earlier care continuum stages, prevention of HIV transmission and mortality will increasingly depend on achieving and sustaining viral suppression (VS) among PWH linked to and retained in care.[12] The most oft-cited barriers to treatment success include unstable housing, mental illness and substance misuse.[13–26] With those barriers in mind, we developed an intervention enhancing Ryan White HIV/AIDS Programme (RWHAP) Part A-funded housing and behavioural health service providers' resources to improve VS. This health-department-delivered intervention, known as 'Data to Suppression (D2S)', includes surveillance-based reports flagging virally unsuppressed clients and capacity-building assistance to guide follow-up activities.

Since 1990, the federal RWHAP has funded cities/counties (via Part A) to cover those without alternative resources for HIV medical care and support services. RWHAP clients account for over half of US PWH,[27–31] and nearly three-quarters of US PWH in medical care attend RWHAP-funded facilities.[32] In New York, where most HIV medical costs are covered by Medicaid, RWHAP Part A (RWPA) funding is concentrated on social and behavioural health services. NY RWPA primarily represents black (53%) and Latino/a (37%) PWH, who experience the highest burden of comorbidities and lowest VS levels.[33 34] An analysis of 11 252 patients from 186 NY outpatient HIV facilities attributes racial/ethnic disparities in VS to social and behavioural determinants, including unstable housing, mental health disorders, insurance issues and drug use.[35] RWPA clients have high proportions of these potentially modifiable barriers to treatment success. In 2020, 26% of NY RWPA clients were unstably or temporarily housed; 89% were at ≤138% of federal poverty level (Medicaid eligibility threshold); 26% screened positive for depression and 25% for anxiety; 16% reported recent hard drug use; and 40% reported a history of incarceration.[36] Pre-pandemic levels were the same (for per cent of poverty level and incarceration history) or similar (30% for unstable housing, 25% for depression, 24% for anxiety and 19% for recent hard drug use).[37]

While national organisations, including the Centers for Disease Control and Prevention (CDC), have broadly promoted health departments' use of data to care (D2C) for finding and (re-)engaging PWH out of HIV care or treatment,[38–41] D2C's overall effectiveness remains unclear. Several jurisdictions have reported modest success with D2C for HIV care linkage or re-engagement.[42–51] However, with rare exception (notably New York City (NYC)), prior D2C efforts confirmed ≤40% of targeted PWH as eligible for re-engagement (out of care and living within jurisdiction). Though care engagement does not ensure treatment success, a widely accepted assumption is that using surveillance to trigger care linkage or re-engagement will have an indirect effect on VS, a secondary objective of D2C.[38 41] Few studies have actually examined VS as a D2C intervention outcome,[43 49–53] and the only published randomised controlled trial reported null findings for time to VS.[52] Yet D2C has become a routine function of health departments, without a strong evidence base.

Given the resource intensity of outreach to PWH who appear disconnected from care based on laboratory reporting,[43 52 54] research is needed to determine how D2C/D2S activities can be efficiently and effectively scaled up in jurisdictions where they have shown some degree of success. Table 1 summarises common pitfalls documented for D2C[13 43 49 52 54–57] and D2S responses.[38 41 47 49 52 57]

This paper describes the experimental protocol for a study underway to implement, evaluate and refine the D2S reporting and capacity-building intervention. We will test the effect of the intervention in a cluster-randomised controlled trial applying a cross-sectional, stepped-wedge design to D2S delivery in RWPA behavioural health and housing programmes. Specifically, we will use data from three periods (period 0, prior to implementation; period 1, with D2S at sites assigned to early implementation; and period 2, with D2S at all trial sites) to test our hypothesis: that timely VS will be achieved by a higher proportion of PWH whose behavioural health or housing providers receive D2S resources (including reports listing their unsuppressed clients), as compared with PWH whose behavioural health or housing providers do not receive these D2S resources.

METHODS AND ANALYSIS

Participants, intervention and outcomes

Study design and periods

Figure 1 illustrates the stepped-wedge design. Each implementation period includes two reporting rounds 6 months apart and each report summarises data from a prior 12-month period, so consecutive reporting periods overlap by 6 months. Reports for sites not yet implementing D2S (all sites in period 0, half of sites in period 1) are generated for analysis but not distributed. To allow time for data submission and processing, reports are generated 2 months after the end of the 12-month period they describe. Period 0 (pre-implementation) began in December 2020 and period 1 (early D2S implementation) began in December 2021. Follow-up data on VS outcomes will be available by June 2024.

Table 1 Comparison of conventional D2C interventions with NYC D2S

Intervention feature	Common D2C challenges	NYC D2S solutions
Surveillance data source	► Incompleteness ► Reporting delays ► Inaccuracies	► Use highly complete and current NYC HIV surveillance registry, maintained in part via special investigations and quality-assurance checks and by pulling in data from multiple sources, including electronic laboratory reporting, partner services, perinatal surveillance, other disease surveillance registries, death registries and other jurisdictions' HIV registries
Population	► Limited to patients presumed out of care (but often found to be in care or otherwise ineligible for follow-up)	► Attend to patients virally unsuppressed but in care (thus likely living within jurisdiction and represented with current laboratory reporting)
Outreach	► Based on contact details that may be incomplete or outdated in surveillance data ► Conducted by health department staff (unknown to the patient) or staff of clinics that failed to engage the patient previously	► Outreach based on latest contact information from a programme currently serving the patient ► Mobilise programme staff familiar to the patient and already working with them on patient-identified needs (eg, housing)
Patient support	► Reconnection to HIV medical care settings, which may offer scant non-clinical/supportive services	► Leverage programmes designed to address psychosocial and structural barriers to adherence, in part via supportive services and patient navigation strategies
Provider support	► Notifications/alerts or reports (little if any additional support to providers or their agencies)	► Supplement surveillance-based reports with agency capacity-building for next steps ► Integrate reports and their use with Ryan White continuous QI processes
Primary outcome	► Return to HIV care (usually one visit), which patients may otherwise do on their own	► Focus on VS (VL<200 copies/mL on any test in 6-month follow-up period)
Study design	► Often pre–post or other non-experimental designs	► Use RCT to isolate intervention effects from usual-care outcomes

D2C, data to care; D2S, data to suppression; NYC, New York City; QI, quality improvement; RCT, randomised controlled trial; VL, viral load; VS, viral suppression.

Study setting/site eligibility

The settings selected for this trial are 20 NYC community-based organisations and 7 hospitals funded through the RWPA grant to provide housing and behavioural health (mental health, substance-related harm reduction and psychosocial counselling) services. We excluded 6 RWPA housing and behavioural health programme sites with fewer than 5 eligible clients in any period, based on simulated D2S reports from 2018 to 2021. Sites are listed on the study's ClinicalTrials.gov registry page.[58]

Client eligibility

For each period, clients eligible for trial inclusion must have: (1) at least one viral load (VL) test in the report year; (2) unsuppressed VL (≥200 copies/mL) at last test during that year and (3) a service from at least one of the eligible programmes since the start of the report year. At the time of report generation, clients meeting the above criteria are excluded if they are no longer living or if their qualifying enrollments have ended. Given potential reporting lag, some clients may later be found to have a VL <200 copies/mL dated after their qualifying VL ≥200 copies/mL but prior to D2S report generation; despite

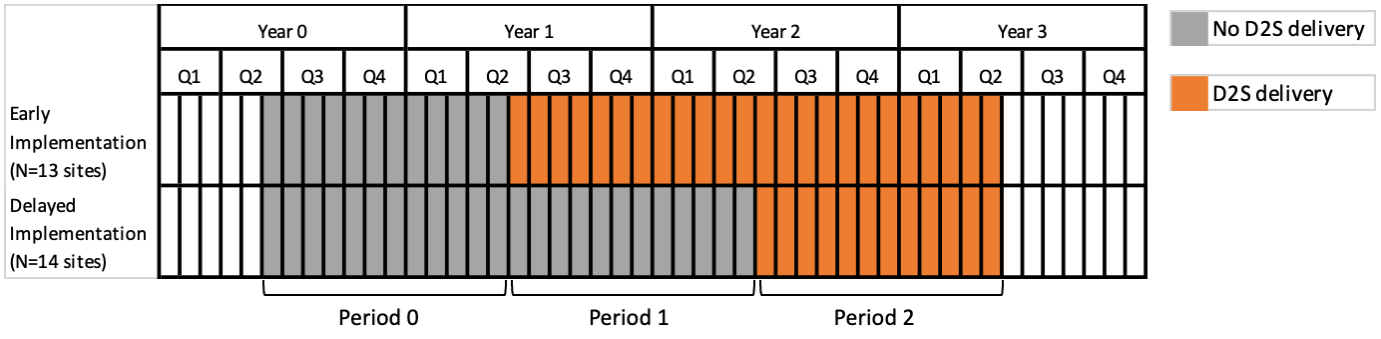

Figure 1 Stepped-wedge design. D2S, data to suppression.

Client ID	Contract of Last Service	Last Service Date in Contract	Programs with Activity		Facility of Last VL	Month of Last VL	HCV	Client Status
			Mental Health	Housing				
AAA102	00-MHV-21	3/30/2023	Yes	No	Hospital A	3/2023		Needs follow-up for viral suppression
BBB315	00-MHV-21	2/28/2023	Yes	Yes	Clinic W	Unknown	Yes	Needs follow up for care and viral suppression
CCC817	00-HPA-20	3/13/2023	No	Yes	Clinic Y	2/2023		Needs follow-up for viral suppression
DDD549	00-MHV-21	11/9/2022	Yes	No	Clinic Z	11/2022		Should be closed due to death

Figure 2 Mock D2S report (simplified). D2S, data to suppression; HCV, hepatitis C virus; VL, viral load.

their inclusion on a D2S report, these clients will be excluded post hoc from analysis.

Intervention and control conditions

Merging RWPA programme data and surveillance data, NYC Health Department staff generate site-specific reports listing RWPA clients who appear to need follow-up (or closure) based on Health Department records (figure 2). Health Department staff then: (1) conduct virtual D2S site visits to review D2S reports, guide site-specific root cause analyses[59 60] and develop related quality improvement (QI) plans; (2) convene provider learning groups for peer-to-peer sharing of best practices; (3) offer dedicated assistance to carry out D2S QI projects and (4) coach sites for completion of final D2S QI project reports and presentations at an annual provider meeting. This capacity-building approach is structured by the Model for Improvement[61] and tailored to sites' challenges. The Health Department also offers guidance on reviewing D2S reports against other data sources (eg, electronic health records) to triage cases for follow-up, and on delivering patient navigation to PWH with mental health needs. The control condition is usual RWPA QI support (table 2).

Individual clients may access behavioural health or housing services at more than one study site, potentially changing their intervention condition. Clients in the trial may also be exposed to other interventions within these programme settings or other agencies where they receive services. Based on the intent-to-treat principle, clients count toward the trial where and when they become eligible.

Outcome measurement

The primary outcome, timely VS (TVS), is defined as VL <200 copies/mL on any VL test reported in the 6-month period following inclusion on a D2S report due to unsuppressed VL. Consistent with our prior work,[62–65] those without any VL measure during follow-up will be considered not to have achieved VS, given their lack of documented clinical monitoring since their last unsuppressed VL. The 6-month follow-up period allows sufficient time to capture changes in VS status, based on US Department of Health and Human Services HIV guidelines, which reinforce the standard practice of VL monitoring every 3–4 months, or more often when adherence difficulties are apparent, and every 4–8 weeks until VS is reached, for PWH starting or changing ART regimens.[66] As a secondary outcome, we will assess time to VS (first VL<200 copies/mL), with up to 12 months of follow-up from each client's appearance on a D2S report. Given this longer follow-up period, observations for time to VS will be limited to trial-eligible clients in the first (round 1) report for each implementation period, to avoid contamination.

Table 2 Usual care versus intervention-specific resources to NYC Ryan White Part A programmes

'Usual care'	D2S intervention-specific activities
Viral suppression data products	
Annual aggregate surveillance-based reports on VS prevalence at each site and across all Part A sites	Semi-annual, client-level surveillance-based reports listing each site's active Part A behavioural health and/or housing programme clients who appear unsuppressed (or deceased or out of care), along with other data on the same clients, to guide next steps
DOHMH-provided TA, quality improvement (QI) and training	
Guidance document for the aggregate VS report product	Training on D2S report transmission, content, interpretation, verification and potential action plans
Annual site visits to monitor programme delivery and offer programmatic assistance	Initial targeted site visits to engage staff/leadership, review site-specific D2S reports, facilitate root cause analyses and outline QI plans
On-demand QI project guidance	≥1 dedicated TA session per site pursuing a D2S QI project
Guide (issued in 2020) on patient navigation for those with mental health issues	Webinar training on the 2020 patient navigation guide and focused TA sessions to reinforce strategies to reduce behavioural health barriers to VS
DOHMH-facilitated peer learning opportunities to promote QI	
Annual conduct of QI projects on site-selected topics, with chance to share project at provider meeting	D2S QI project plan refinement with sites' quality committees, co-creation of final plans and summary reports, and provider panel discussion of D2S QI projects/strategies in D2S peer learning group meetings

D2S, data to suppression; NYC, New York City; QI, quality improvement; TA, technical assistance; VS, viral suppression.

Table 3 Agency characteristics, pairings and study arm assignments

Matched pair	Agency type	Location (Borough)	Period of intervention start	Eligible Programmes (count)	Eligible Programme types
1	CBO, no onsite primary care	Brooklyn	1	1	SC
	CBO, no onsite primary care	Brooklyn	2	3	STRA, SC, STH
2	CBO, no onsite primary care	Bronx	1	1	HR
	CBO, no onsite primary care	Brooklyn	2	2	SC, STH
3	CBO with onsite primary care	Manhattan	1	3	HP, MH, STH
	CBO, no onsite primary care	Manhattan	2	1	HR
4	CBO, no onsite primary care	Brooklyn	1	1	HR
	CBO, no onsite primary care	Bronx	2	2	HP, HR
5	CBO, no onsite primary care	Bronx	1	1	SC
	CBO, no onsite primary care	Manhattan	2	2	HR, SC
6	CBO, no onsite primary care	Manhattan	1	3	HR, SC, STH
	CBO, no onsite primary care	Manhattan	2	3	HR, MH, SC
7	CBO, no onsite primary care	Staten Island	1	2	HR, STH
	CBO, no onsite primary care	Queens	2	4	HP, HR, MH, SC
8	CBO, no onsite primary care	Manhattan	1	1	SC
	CBO with onsite primary care	Manhattan	2	1	MH
9	CBO with onsite primary care	Manhattan	1	3	HR, SC, STH
	CBO with onsite primary care	Manhattan/Brooklyn	2	3	HR, MH, STH
10	Hospital/medical centre	Manhattan	1	1	HR
	Hospital/medical centre	Brooklyn	2	1	MH
	Hospital/medical centre	Queens	2	1	HR
11	CBO with onsite primary care	Bronx/ Brooklyn	1	1	HR
	CBO, no onsite primary care	Bronx	2	1	SC
12	Hospital/medical centre	Manhattan	1	1	MH
	Hospital/medical centre	Manhattan	2	1	MH
13	Hospital/medical centre	Brooklyn	1	2	HR, SC
	Hospital/medical centre	Brooklyn	2	1	HR
Total (27 agencies, 13 pairs)				47	All above

CBO, community-based organisation; HP, housing placement; HR, harm reduction; MH, mental health; SC, supportive counselling; STH, short-term housing; STRA, short-term rental assistance.

Recruitment

There is no recruitment for this trial, which relies on data collected as part of infectious disease surveillance and routine RWPA programme reporting.

Assignment of interventions

Randomisation

The unit of randomisation is the provider agency (ie, cluster). Cluster randomisation serves to minimise cross-over between intervention conditions and avert the logistical and ethical dilemmas posed by client-level randomisation.[67–69] Characteristics and study arm assignments of the 27 agencies are summarised in table 3. Agencies were matched and randomised within pairs (including one case in which two smaller agencies were coalesced and matched to a larger one). Matching accounted for characteristics plausibly related to the TVS outcome: agency type, location/borough and programme mix. While randomisation could not feasibly be stratified by each of these variables, the lead analyst suggested pairs maximising similarity on these variables and trial-eligible client counts, and pairings were finalised with input from team members knowledgeable about the programmes/agencies involved. The lead analyst determined agency assignments within pairs using a random number generator in Excel.

Blinding

Due to the need to engage service providers in the intervention through study team-led activities (eg, webinars, report releases), study arm assignments were transparent to site staff and study team members.

Data collection, management, and analysis

Data collection

The outcome measure will be derived from the NYC HIV surveillance registry, a population-based data source of electronically reported longitudinal laboratory records on all diagnosed NYC PWH.[70 71] Use of NYC's HIV registry allows near 100% ascertainment of VS for PWH receiving HIV medical care in NYC, and for periods extending before and after programme participation.

Each client's agency/programme enrolment status is determined from a database of contractually required NY RWPA provider reporting, the Electronic System for HIV/AIDS Research and Evaluation (eSHARE). Programme reporting-based measures are available for all NY RWPA sites and clients.

Data management and quality assurance

All data for the trial are entered as part of established, legally or contractually required reporting, and are protected according to CDC physical and electronic data security and confidentiality policies.[72] Health Department staff extract and clean eSHARE data monthly, clean and freeze surveillance datasets quarterly and conduct matches of programme to surveillance data semi-annually (in the few weeks prior to D2S report generation). Details on the deterministic matching algorithm have been previously described.[73] Through the match, participants are assigned a unique record number used in merging surveillance and programmatic datasets, which are stripped of personal identifiers prior to analysis.

Statistical analysis for the matched-pairs stepped-wedge trial

Analysis overview and rationale

We will apply an innovative, fully conditional analysis allowing for arbitrary period effects and arbitrary within-pair site differences. The analysis plan is based on the exact, conditional distribution theory of non-central multiple hypergeometric distributions and their convolutions,[74] which permits estimation of the effect of the intervention as a single parameter. The conventional statistical analysis proposed for cross-sectional stepped-wedge designs (with independent samples of clients enrolled at each step)[75] assumes a mixed model with random cluster effects and fixed period effects, but this is not appropriate for our matched-pairs stepped-wedge trial. For one, the matching of pairs is under the investigators' control and so should be conditioned on. Second, the generalised linear mixed model has limitations, such as a gratuitous and unverifiable assumption of normal distribution for random effects and poor variance estimation performance in small samples (of clusters). The following exact analysis avoids those problems by conditioning out the nuisance parameters.

Analysis approach and assumptions

For each pair of sites, we will produce two 2×3 tables (1 table per site in pair), cross-classifying the number of TVS and non-TVS outcomes in period 0 (no D2S), period 1 (D2S at sites assigned to an early start) and period 2 (D2S at all sites). For identification purposes, we refer to 'site 1' within a matched pair as the site randomised to switch in period 1 (early start) and 'site 2' as the site randomised to switch in period 2 (delayed start) (see *online supplemental table*). We begin by assuming the following logistic regression model for the three binomial outcomes: the logit of the probability of TVS for a given site, period and intervention condition equals an intercept representing an arbitrary, pair-specific log odds on TVS for site 2 in the pair, plus an arbitrary log OR (LOR) for site 1 versus site 2 in the pair (allowing for imperfectly matched sites), plus two arbitrary pair-specific LORs for period 1 and period 2 effects relative to period 0, plus 1 structural LOR of interest, the global intervention effect (non-existent in period 0, applicable to site 1 in period 1, and applicable to both sites in period 2). The exponent of this last parameter is the target of statistical inference, namely, the OR for TVS versus non-TVS comparing the D2S condition to the non-D2S condition. A key assumption is that any site effects apply in each period and any period effects apply to each site, independent of the intervention effect (ie, that there are no site-by-intervention or period-by-intervention interactions). This assumption will be tested and the model elaborated if needed. Note that under the key assumption, the constant site and period effects are allowed to vary arbitrarily from one matched pair to the next.

Estimating the intervention effect

Next, by conditioning on the marginal totals (within each site, numbers of eligible clients in each period and total numbers of TVS and non-TVS outcomes), the joint distribution of the numbers of TVS outcomes for site 1 by period becomes a non-central multiple hypergeometric distribution with only 3 parameters (the period LORs and the intervention LOR); that is, the conditional distribution does not depend on the nuisance site parameters. By further conditioning on the sum of TVS outcomes across the two sites in each period, the fully conditional joint distribution depends on only one parameter, the intervention effect; that is, the fully conditional distribution depends neither on the nuisance site effects nor on the nuisance period effects. In fact, the sufficient statistic for the intervention LOR in the fully conditional likelihood function is simply the number of TVS outcomes from site 1 in period 1. It is then straightforward to calculate the marginal distribution of this outcome as a function of the intervention effect. Therefore, we will calculate that distribution for each of the 13 matched pairs (including the case of 2 sites jointly matched to a 3rd) and convolute those distributions to obtain the sampling distribution of the sum of sufficient statistics. Once we obtain the fully conditional sampling distribution as described above, we will report the conditional maximum likelihood estimate of the intervention LOR with an exact, test-based 95% CI. The test of the null hypothesis at the two-tailed 0.05 significance level will be based on the exact two-tailed p value

(using the point probability definition),[74] and will form the primary outcome analysis. In sensitivity analyses, we will also report the Wald, Score and Likelihood Ratio test results. For the secondary endpoint, time to VS (during 12-month follow-up), we will use Cox regression based on a model analogous to that used for TVS.

While we will restrict follow-up to unique clients in each implementation period, we will allow clients followed in period 0 or period 1 to be followed again in the next period (period 1 or period 2) in which they meet eligibility criteria. To use repeated observations from clients eligible in two or three periods, the exact, conditional analysis will be prepared under the assumption of conditional independence of TVS outcomes. In this case, the analysis is valid if the conditional distribution of the number of TVS events in site 1 of a given pair in a given time period does not depend on the corresponding number of TVS events for site 1 in prior periods. Insofar as many new clients are introduced in successive periods and insofar as opportunities for TVS may depend only on the site, period and intervention effect, not on past TVS failures, the conditional independence assumption is tenable. Note that such conditional independence does not preclude marginal correlations over time for individual clients. As a sensitivity analysis, we will re-estimate the D2S effect omitting repeated observations to confirm there are no material changes.

Sample size

For the pre-award planning of this study, we used 6 rounds of preliminary reports (on July 2016–June 2017, calendar year (CY) 2017, July 2017–June 2018, CY2018, July 2018–June 2019, and CY2019) to provide a set of marginal totals and proportions of TVS in 13 matched pairs of sites. We then prepared a simulation study with 10 000 replications to estimate the power of the primary test of intervention effect. For any given simulation replication, each site within the 13 matched pairs was randomly assigned to switch to D2S at period 1 or period 2 (with independent randomisations per replication). For the site and period effects, we used the past period 0 data for the 2 sites to provide the within-pair site effect and the (randomly selected) second site's TVS proportions in period 1 and period 2 to provide the period effects. We then applied a given intervention effect to site 1 in period 1 and to both sites in period 2, for a set of plausible TVS proportions. For each such replication, we recorded the results of the exact conditional analysis described above. The pre-randomisation power of the primary test was estimated as the proportion of exact two-tailed p values ≤0.05. The resulting detectable effect size (80% power with exact type I error rate≤0.05 two-tailed) was an OR of ~1.86 (relative risk (RR) of 1.35), corresponding to 59.1% achieving TVS with D2S, versus the base rate (43.7%).

For an updated estimate, we apply actual post-randomisation numbers of eligible clients for period 0 (N=619) and period 1 (N=500), and we project numbers for period 2 by carrying forward from period 1 (N=500). Sites' study conditions (early or delayed implementation) are now considered fixed as randomised. We use real period 0 TVS proportions for the within-pair site effects, and late-implementing sites' TVS proportions from period 0 and period 1 (prior to their D2S exposure) for the period effects. The resulting detectable effect size (80% power with exact type I error rate≤0.05 two-tailed) is an OR of ~2.12. This corresponds to 58.5% achieving TVS with D2S, versus the 40.1% base rate observed at late-implementing sites for period 0 (RR: 1.46), or 63.4% achieving TVS with D2S, versus the 45.1% base rate observed at late-implementing sites for period 1 (RR: 1.41). Statistical power decreases as the overall base rate for TVS increases. Insofar as there will be more events for the time *to* VS outcome than for TVS, and insofar as time-to-event analyses can be more powerful than binary outcome analyses, we expect power >80% to detect a doubling of the hazard ratio for intervention versus control.

Patient and public involvement

Local HIV health services agencies shaped the D2S study proposal via input at several points. Prior to the regulatory updates expanding permissible sharing of client-level surveillance data, Health Department staff received multiple requests for such data from support-service providers. During a 2018–2019 pilot test of D2S reports with RWPA HIV medical case management programmes, the Health Department surveyed recipients on the reports' utility. Of responding providers, 64% said the report had guided next steps with individual clients, and 79% said reports should be shared routinely.[76] Participant suggestions of other programmes that could benefit included harm reduction and mental health. In another pilot with non-RWPA-funded housing providers, 93% indicated their desire to continue receiving D2S-type reports.[77] In late 2018, the Health Department held a D2S forum with RWPA behavioural health programme staff. Attendees discussed optimal settings for D2S reports and integration into operations/workflows. They indicated reports would fill an information gap due to limited access to HIV laboratory data in behavioural health settings. Providers noted that Health Department capacity-building assistance could transmit best practices to supplement programmes' existing follow-up routines and expressed interest in D2S peer learning groups.

Once the study was selected for award in mid-2021, it was presented for feedback at a meeting with NY RWPA-funded service-provider agencies, including staff with lived experience as patients with HIV. The study team convened the study advisory board for input in the immediate pre-implementation period (November 2021), and again in March 2022, November 2022 and June 2023. Advisory board members, who consult on implementation, interpretation of findings and dissemination for the larger research project (ie, which results to highlight and how and where to share them), include RWPA clients/patients with HIV, direct-service providers

and administrators from NY and other jurisdictions; representatives of national HIV organisations; external researchers; and members of the HIV Health and Human Services Planning Council of NY.

Monitoring

Given the determination of minimal risk and the routine nature of secondary analyses of merged programmatic-surveillance data, the study team will not convene a Data Safety and Monitoring Board. No medical device or treatment is being tested in this trial. Study investigators have no direct contact with clients. Clients are offered and/or enrolled in RWPA services independent of the trial, and RWPA services may or may not be enhanced by the D2S intervention.

ETHICS AND DISSEMINATION

This trial was approved by the NYC Department of Health and Mental Hygiene's institutional review board (IRB; protocol: 21-036) and is registered with ClinicalTrials.gov (identifier: NCT05140421). The trial was granted a waiver of informed consent in accordance with the pre-2018 requirements set forth in 45 CFR 46.116(d), based on its reliance on secondary data analysis. Any changes to the trial eligibility criteria, outcome measures or analysis plans would be mutually agreed on between the principal investigators, vetted with the advisory board, and submitted to the IRB as protocol modifications.

Study results will be reported in accordance with the Consolidated Standards of Reporting Trials extension to cluster-randomised trials[78] and disseminated through scientific conferences, peer-reviewed publications and meetings with local stakeholders. The investigators have also been sharing this work with colleagues in other jurisdictions and will disseminate findings via NY's Ending the Epidemic Dashboard website.[79]

Data statement

The full IRB protocol and statistical code will be made available on request. NY State Public Health Law prohibits the study team from releasing a public-use dataset containing information tending to identify the subjects of its research. NYC Health Department staff retain sole custody of study datasets and designated staff are available to answer any inquiries.

CONCLUSION

Research at scale in service–delivery settings is critical to inform programme and policy development and implementation. Reviews of care continuum research have noted the need for practice-based evidence.[80–82] The US National HIV/AIDS Strategy and National Institutes of Health have also called for implementation science to produce evidence-based models of care.[83 84] In the case of D2C interventions, the evidence is mixed,[42–53] and even less is known about the impact of D2C interventions on VS.

We aim to measure the VS effects of a surveillance-based reporting and capacity-building intervention (D2S) designed to guide individual follow-up and broader quality-improvement activities, thus targeting patient-level, agency-level and systems-level barriers to treatment success. By conducting this trial in RWPA housing, mental health, psychosocial counselling and harm reduction programmes, we are testing D2S in settings charged with addressing the three most oft-cited barriers to VS.[25 26] Random agency assignment to early or delayed implementation offers a means of feasibly scaling and rigorously evaluating a novel intervention while ensuring fair access to any benefits. Findings from this trial will inform efforts to advance progress along the HIV care continuum and ultimately end the epidemic as a public health crisis.

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Contributors MKI is the health department principal investigator and led the conception of the overall study and the writing of the R01 proposal. FA led analyses of all programmatic and surveillance data for the R01 proposal and the generation of D2S reports, as well as report-related assistance to providers during the initial implementation phase. BL led the conception of the matched cross-sectional stepped-wedge design and wrote the detailed statistical analysis plan. BL, MMR and DN contributed substantively to the study design and analysis plan, conducted analyses and provided tables/figures. JT oversaw programmatic data systems and the preparation of NY Ryan White Part A datasets, as well as providing code review for secondary analyses. TA, MP and RZ prepared data, facilitated data to suppression (D2S) intervention implementation, participated in ongoing planning and contributed to communications to service providers and other stakeholders, while managing other aspects of the larger D2S study. SLB oversaw the preparation of NYC HIV surveillance-based datasets and developed relevant surveillance data use agreements, as well as participating in the advisory group responsible for NY HIV regulation updates that made D2S possible. DN is the university-based, lead agency principal investigator and shares responsibility for the conceptualisation and oversight of the overall study and this trial, serves as the primary contact with the grant funding agency and guides dissemination. MKI drafted the manuscript, and all authors (MKI, FA, BL, JT, TA, MP, RZ, SLB, MMR and DN) revised it for critically important intellectual content and provided final approval of the manuscript.

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