STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Strengthening the Safety Net: Testing a Novel Data-to-Suppression (D2S) Intervention Strategy in the Ryan White HIV/AIDS Program

NCT Number: NCT05140421
Note: Clinical Trial designation applies only to Aim 1, secondary HIV data analyses

Last Update to Study Protocol:
September 15, 2023

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

Research Study Protocol

Research Study Title: Strengthening the Safety Net: Testing a Novel Data-to-Suppression (D2S) Intervention Strategy in the Ryan White HIV/AIDS Program

Principal Investigator: Mary Irvine for DOHMH (with external P.I. Denis Nash based at CUNY ISPH)

Please complete the sections that are pertinent to the research study.
All sections of the protocol may not apply to the research study.
For all sections that do not apply, please indicate "Not Applicable."

A. Protocol Overview

In a short paragraph, provide a summary of the proposed research study in a lay language.

Our study rationale is that support-service (non-medical) staff are best able to address psychosocial and structural barriers to HIV antiretroviral therapy (ART) use and adherence, through a combination of counseling, coaching, navigation of complex service/benefits systems, and linkage/coordination with other (e.g., food service) providers. Leveraging and strengthening support-service programs with patient navigators (PNs) via a Data-To-Suppression (D2S) approach is a practical, promising route to viral suppression (VS) gains among vulnerable yet service-engaged PWH whose outcomes depend on addressing competing priorities. The proposed D2S intervention will arm support-service staff with actionable client-level, surveillance-based VS status reports and capacity-building for targeted ART adherence support.

B. Research Study Purpose and Rationale

Describe the background, objective, purpose, intent, and scientific aims of the human research.
State the hypothesis(es) to be tested, how the information collected will be utilized.
Describe the proposed research in the context of existing knowledge, identify gaps the proposed research is intended to fill either in terms of scientific knowledge or practice. Include pertinent background description with references that are related to the need to do this study.

A new opportunity. Until recently, NYC RWPA providers often requested line-level surveillance data for monitoring client HIV outcomes, but NYS law restricted such data transfers to physicians. A 2014 amendment to NYS Public Health Law 27-F expanded data sharing for care engagement. 2017 regulations added a provision authorizing line-level HIV surveillance data sharing with mental health providers and entities engaged in care coordination with primary care providers (Title 10, Part 63, §63.4c).[99] In 2019, the NYC Department of Health and Mental Hygiene (DOHMH) General Counsel confirmed all NYC RWPA programs' eligibility to receive D2S reports on clients for whom a therapeutic relationship is documented in RWPA service reporting.

Prior D2C studies, limitations and gaps. Few interventions have demonstrated effectiveness for locating and re-engaging PWH out of HIV care or treatment.[128,129] While national organizations including CDC and NASTAD have broadly promoted health departments' use of D2C,[29,30,130,131] overall effectiveness remains unclear. Several jurisdictions, including NYC, the rest of NYS, Massachusetts, Louisiana, Illinois,

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Tennessee, Virginia, King County in Washington, and San Francisco, have reported some, generally modest success with re-engagement through D2C strategies.[114,132-140] However, with rare exception (notably NYC), prior D2C efforts confirmed ≤40% of targeted PWH as eligible for re-engagement (out of care and living within jurisdiction). Though engagement in care 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.[29,30] Yet few studies have examined VS as a D2C intervention outcome,[95,114,133,139-141] and the only published D2C RCT reported null findings for time to VS.[95] D2C has become a routine function of health departments, without a strong evidence base for best practices. Given the resource-intensity of efforts to contact PWH who appear disconnected based on laboratory data reported to surveillance,[95,129,133] 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. Among the weaknesses of D2C strategies documented to date are: (1) incomplete, inaccurate, or lagged laboratory data; (2) failures to contact patients presumed out of care, due to incomplete/outdated contact details in surveillance; (3) pursuit of PWH who appear lost to care, when in fact most are out of jurisdiction or otherwise ineligible for follow-up; (4) a tendency for PWH to return to care on their own (making D2C redundant); (5) over-reliance on reconnecting patients to HIV medical care settings that failed to engage them previously and/or offer scant support services; and (6) lack of consensus as to how best to support the process of re-engaging PWH in care and treatment after a lapse.[31,95,114,129,133,142-144]

How D2S will advance science and practice. By integrating lessons learned in prior D2C work and targeting VS, we will maximize public health impact and study power. In order of the above-listed limitations, our remedies include: (1) using as the basis for investigation a highly complete HIV surveillance registry, with ≤3-month lag and routine checks against death registries and other jurisdictions' HIV registries; (2) linking RWPA and surveillance data in order to limit lists to recently served RWPA clients (maximizing chances of listed PWH being reached via contact details on file[114] *and* being familiar with the staff contacting them); (3) focusing the intervention on PWH who are retained in care and unsuppressed (to reduce inefficiencies[95] and bolster success in reaching the intended PWH,[114,144] while addressing the major remaining gap in the local RWPA care continuum); (4) using an RCT to isolate intervention effects from desired outcomes that would occur anyway; (5) mobilizing support-service staff, specifically program-embedded PNs, to resolve structural and behavioral barriers to VS; and (6) accompanying surveillance-based reports with provider capacity-building and monitoring on report use and client engagement – to involve staff responsible for client follow-up in shared continuous quality improvement processes throughout D2S adoption and implementation.[29,30,137] With regard to past successes, we are encouraged by findings of D2C acceptability to patients, advocates, and other stakeholders,[123,145] benefits in vulnerable subgroups,[140] and sustainability by health departments.[144] As framed in the conclusion of a report on CDC's 'CAPUS' demonstration project, "D2C is a proactive strategy that, *when implemented as part of a comprehensive… program, can help address disparities* in access to HIV care, particularly among hard-to-reach communities."[114] By basing our trial in the RWPA programs that address basic survival/shelter needs, mental health, and substance use through internal resources and external linkages, we will be starting D2S in the settings best prepared to tackle the barriers characterizing PWH with the worst adherence and VS outcomes regardless of race/ethnicity, gender, or poverty level.[67,68]

Intervention approach. Our premise for D2S is that the most common and severe VS barriers can be effectively targeted by support-service providers guided by enhanced capacity-building and timely reports on

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unsuppressed clients with whom they already have established relationships around meeting nonmedical needs. Merging RWPA program data and surveillance data, DOHMH will generate site-specific reports twice per year, listing active RWPA behavioral health and housing program clients who lack evidence of VS for the past year. To hone sites' use of reports, DOHMH will: (1) conduct D2S site visits to engage staff at all levels,[32] review D2S reports, guide site-specific root cause analyses,[149,150] and develop quality improvement (QI) plans structured by the Model for Improvement;[151] (2) convene provider learning groups for peer-to-peer sharing of D2S QI plans and best practices; (3) offer dedicated TA to carry out D2S QI projects, applying driver diagrams, process mapping and 'plan-do-study-act' cycles to assess project outcomes; and (4) coach sites for completion of final QI project reports and presentations at an annual "Power of QI" conference. This CB/TA approach is structured by the Model for Improvement but necessarily tailored to sites' challenges. DOHMH will also offer trainings/TA on accessing and reviewing D2S reports with other data sources (e.g., electronic health records [EHRs]) to triage cases for follow-up, and delivering patient navigation for PWH with mental health needs. Replication of CB/TA components will be facilitated by documentation on DOHMH's website for HIV provider training, CB/TA and other resources, including webinars for self-guided learning.[152]

Specific aims. The D2S intervention will arm support-service staff with actionable client-level, surveillance-based VS status reports and capacity-building for targeted ART adherence support. We propose to scale and test the D2S intervention with 27 RWPA service agencies.

Aim 1: *Measure D2S intervention effects* on timely VS and time to VS, in a stepped-wedge hybrid Type 1 trial.

Aim 2: *Identify modifiable determinants of D2S response*, by comparing characteristics of D2S-exposed clients who do and do not achieve VS, to recognize opportunities to tailor and strengthen the intervention.

Aim 3: *Assess D2S acceptability and participant preferences and priorities for its implementation*, in eight (client and provider) focus groups and in a discrete choice experiment (DCE) with RWPA staff (n=200).

Our proposed implementation science study applies experimental (Aim 1) and observational methods (Aims 1-3) to evaluate D2S intervention effectiveness and opportunities for refinement. In Aim 1, we employ a cross-sectional stepped-wedge, hybrid trial of D2S intervention effectiveness.[39] Hybrid designs have been used in a variety of clinical and support-service settings to simultaneously assess effectiveness and implementation.[39,153-156] Their advantages include (1) incorporation of mixed-methods studies into RCTs to examine relationships between implementation and effectiveness and (2) the speed of translation of effective strategies into broader practice, facilitated by testing interventions in real-world settings from the outset.[157] Of the three hybrid design types, our proposed study applies Type 1: testing intervention effects while collecting data on implementation. To assess implementation processes and outcomes, we will review RWPA service data reported to DOHMH (follow-up with listed clients) and staff feedback on D2S reports and CB. Data on implementation will be collected in semi-structured interviews with 24 staff (from eight purposively sampled agencies) and tracking sheets (like the Companion Reports used in the D2S pilot), and will be reviewed alongside sites' RWPA service reporting. In Aim 2 secondary analyses, we will identify modifiable drivers of VS among previously unsuppressed PWH exposed to the D2S intervention. VS outcomes for Aims 1 and 2 will be derived from the NYC HIV surveillance registry. Client-level reporting by

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DOHMH-funded programs will supply measures of potential VS drivers, including modifiable factors such as substance use and housing. Organizational factors (e.g., size, age, type)[32] will be pulled from contract documents. Aim 3 focus groups will gather input on D2S and inform DCE design. The DCE will quantify preferences for D2S intervention features. We will use findings from all Aims to refine the intervention for NYC maintenance and for broad dissemination.

Administrative supplement to D2S: In addition to the D2S work described above, we will conduct a participatory research study using a "deliberative democracy" framework to develop recommendations and guidelines for HIV data sharing and privacy. This research activity was funded as an administrative supplement to the D2S parent grant. The data sharing involved in initiatives such as D2C and D2S typically occurs without clients' knowledge or consent. Previous work has shown that clients are comfortable with having their data shared with clinical providers for the purpose of improving their HIV care, but may be less comfortable with having their HIV-related data shared with non-clinical providers. There is a need to develop ethical standards on health information ownership, and to center client autonomy in determining how, with whom, and whether their HIV-related data are shared for D2C, D2S, and similar initiatives going forward.

The purpose of this supplement is to systematically explore client perspectives on the sharing of health information, and to develop standards for data sharing for New York City (NYC)'s D2S initiative. The proposed work will depart from top-down approaches to data sharing interventions in health departments and center the perspectives of communities who have historically been excluded from public health planning. We will use a DD framework to work alongside community stakeholders to develop a data sharing process that reflects their values and priorities from the ground up. DD experiments have been used to engage stakeholders on ethical issues in healthcare delivery, including topics such as allocation of scarce health resources, consent for biobanking, and use of health data for research. [12–17] We will invite clients from Ryan White HIV/AIDS Program Part A (RWPA) sites that are involved in the D2S initiative to participate in the process of discussion and deliberation, voting, and ratifying policies. We will also invite members of the NYC Planning Council's Consumers Committee, whose members have experience receiving HIV services and advise on the planning, delivery, and evaluation of RWPA programs.

This supplement expands upon the D2S project by incorporating additional client perspectives on ethical uses of individual-level surveillance data. These perspectives will influence the version of D2S that may be scaled up as part of routine health department support to RWPA programs. Our administrative supplement (DISCO)'s specific aim is: Using a deliberative democracy (DD) framework, develop client-centered processes for the ethical sharing of surveillance-based HIV laboratory data with RWPA support service providers.

The primary outcome of the supplement is to develop community-driven recommendations on HIV surveillance data-sharing initiatives and arrive at data-sharing practices that reflect the values of the communities RWPA programs are intended to serve. In addition to applying these recommendations to the NYC Health Department's D2S initiative, this project will lay the groundwork for developing similar policies in other D2C/D2S initiatives across the United States.

(References are in the original grant proposal and can be provided if needed.)

C. Setting of the Human Research

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Describe the locations at which the research study will be conducted. When applicable, describe: 1) At which institutions or sites the research procedures will be performed; 2) the location(s) where potential participants may be identified and recruited; 3) Composition and involvement of any community advisory board for research conducted outside of the NYC DOHMH; and, 4) For activities conducted at a non-DOHMH facility, please identify the location and facility to be used.

Recruitment and data collection activities will take place remotely and at DOHMH (on days when employees are at the office) and NYC RWPA-funded agencies. Some interviews may also take place in a private office or conference room at DOHMH, though most are expected to take place remotely or at DOHMH-funded NYC RWPA agencies. All analyses using identified client-level data will be conducted on secured servers housed and managed at the DOHMH and will be subject to the stringent security protocols in place at the DOHMH for uses of HIV surveillance and other line-level HIV data. Qualitative data analyses and DCE quantitative data analyses *not* involving client identifiers will take place primarily at CUNY's ISPH (55 W. 125th St., 6th Floor New York, NY 10027), with some de-identified data also being reviewed from the home offices of the study team members.

An Advisory Board (AB) will advise on refinement of data collection tools, planning for effective recruitment, interpretation of preliminary findings and dissemination. The AB will include HIV service consumers, HIV medical care providers, support service providers, representatives of other Ryan White jurisdictions and the National Alliance of State and Territorial AIDS Directors (NASTAD), representatives of the local HIV Planning Council, and DOHMH leadership.

Deliberative democracy sessions will be conducted in person in a to-be-determined venue. The DD venue will be in a centralized location that is accessible by public transportation. We will work with our partners at CUNY ISPH and our Advisory Board to identify an appropriate space or spaces for this event to take place.

D. Study Drugs or Devices ☒ N/A

Please list all drugs or devices to be used in this study and describe how the drug or device works and past experience.

☐ FDA Regulated Product (Please provide the IND/IDE number below and relevant documentation)
☐ Exempt from FDA (Please provide relevant documentation)
☐ Drug Form (Appendix A) completed
☐ Device Form (Appendix C) completed

Click here to enter text.

E. Study Participants

Indicate the total number of participants to be accrued or records to be reviewed and if applicable at each site. If applicable, distinguish between the number of participants who are expected to be screened, enrolled (consent obtained), randomized, complete the research-related procedures, and between sub-groups (healthy volunteers vs. treatment cohort)

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Give detailed inclusion and exclusion criteria and number of potential participants to be enrolled based on the statistical description and any other considerations. Describe how participants will be screened for eligibility.

If this study does not involve interactions or interventions with living individuals, please describe how charts, records, biospecimens, or data are selected.

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Is there an intervention or interaction with a living person that would not otherwise be occurring but for research purposes? ☒ Yes ☐ No

Target Accrual: Aim 1: N≈24 staff participants in interviews. Aim 3: N≈72 staff and client focus group participants; N=200 staff participants in DCE surveys. Aim 1 secondary analyses (using observational data from existing sources) are expected to involve approximately 1,283 clients (counting those exposed and unexposed to the D2S intervention), based on preliminary data from eligible programs. Aim 2 secondary data analyses are expected to involve approximately 700 clients (based on the expected number to be exposed to the intervention in Periods 1 and 2 of the trial).
Administrative supplement: N≈50 clients will participate in the deliberative democracy (DD) sessions.

Anticipated Number of Charts to be Reviewed: N/A

For the randomized controlled trial (Aim 1), the following Ryan White HIV/AIDS Program Part A (RWPA) programs are eligible for the trial and in-depth staff interviews (currently at 27 different sites): (1) Housing services, (2) Harm reduction services, (3) Mental health or supportive counseling services. Randomization will be conducted at the level of the agency (randomization to early or delayed D2S implementation, within matched pairs of agencies), though VS outcomes will be assessed at the level of the client, using HIV surveillance data. Clients are eligible to be included in the viral suppression reports to be shared with RWPA providers, as described above, if the clients are: (1) Actively enrolled in one of the above RWPA support-service programs, as documented in eSHARE, both during the reporting year and at the time of report generation; and (2) Reported as having unsuppressed viral load at their last test during the reporting year or having had no viral load test in the year, or reported to have died (though only unsuppressed clients who are in care and presumed living, based on NYC HIV Surveillance Registry deaths data, will be included in the trial). For Aim 1 qualitative interviews, RWPA staff of behavioral-health and housing programs will be purposively sampled from eight (out of 13) early-implementing D2S-engaged agencies, including four clinical sites and four non-clinical community-based organizations (CBOs). At each site, we will interview 3 staff members: 1) a patient navigator (PN) engaged in D2S outreach and training/technical assistance (TA); 2) a PN supervisor engaged in D2S training/TA; and 3) an administrator (e.g., program director) knowledgeable about RWPA quality management, data uses and how D2S fits into the broader setting.

For Aim 2, we will create a retrospective, unduplicated cohort of unsuppressed clients exposed to the D2S condition in the trial. Eligible clients include those exposed at early implementation sites in Period 1 and at all implementation sites in Period 2, for a projected N≈700, using available baseline (2017-19) data from these 27 agencies (and over 45 programs).

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For Aim 3 qualitative data collection (eight focus groups) and Discrete Choice Experiment (DCE), *program* eligibility will be the same as in Aim 1 (above). Two client focus groups will be divided by trial outcome (those achieving versus not achieving VS), and a third will engage Spanish-speaking clients involved in the trial regardless of VS outcome. Staff focus groups will be divided by setting (clinical versus non-clinical) and split within setting by program role: administrative, direct support services delivery or medical care delivery (clinical sites only). For the DCE, data will be collected in the form of surveys with 200 staff in eligible program types at D2S-engaged agencies. Each D2S implementing agency will provide a list of staff names, titles and e-mail addresses for the study team to use to contact each eligible staff member with a survey invitation, link and unique study login for DCE self-administration. Eligible staff for the DCE must have job roles intended to engage in D2S report review, follow-up with listed clients, supervision of PNs, and/or related health-department (DOHMH) trainings and TA. DOHMH will follow up with agency point persons/liaisons as needed when there is a question as to job role eligibility after review of the agency's list of staff with job titles. Given estimates of eligible staff at the 48 programs originally expected to be engaged for the trial and an expectation of an approximately 80% response rate, all eligible staff will be invited for the DCEs.

For the deliberative democracy sessions, we will recruit up to 50 participants from among clients who are actively receiving services at any agency involved in the D2S initiative or members of the HIV Planning Council Consumers Committee. The study team will provide general guidelines for D2S sites to invite and refer clients to the study team (completing Permission to Contact forms for study team follow-up) to learn more about the DD process. Potential participants will be selected to achieve a diverse set of participants, including enough Spanish speakers to hold one small group for primarily Spanish-speaking clients.

F. Vulnerable Populations ☒ N/A

Please indicate if individuals from the following populations will be involved in the study.

☐ Children/Adolescents ☐ Pregnant Women/Human Fetuses and Neonates
☐ Prisoners ☐ Elderly
☐ Terminally Ill ☐ Cognitively Impaired/Mentally Ill/Disabled
☐ NYC DOHMH or other City Employees ☐ Other:

G. Participant Identification and/ or Recruitment Method ☐ N/A

If the study does not involve interactions or interventions with human subjects, describe how individuals will be identified (e.g. through billing records, medical files, purchase lists, existing databases, etc.).

If the study involves interactions or interventions with human subjects, please describe in detail how participants will be recruited including type (e.g., newspaper advertisements, posters) and location (e.g., private practices, clinics). Attach a copy of each written advertisement and the script for each recruitment media or method that is verbal (e.g., video, telephone script). Please identify who will be conducting the recruitment and if this person is affiliated with NYC DOHMH. Please indicate if participants will be compensated along with the amount and timing of the payments.

Will subjects be monetarily compensated for their participation? ☒ Yes ☐ No

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If Yes, please indicate the amount: Aim 1 staff individual interviews: $75. Aim 3 staff and client focus groups: $50; Aim 3 staff DCE surveys: $25; Supplement deliberative democracy sessions: $200/session ($400 total).

Will subjects be compensated through other methods or items (e.g. food, promotional material, etc.)? ☒ Yes ☐ No

If yes, please provide more information: If focus groups are conducted in-person (contingent upon COVID-19 restrictions), client focus group participants will receive a two-trip Metrocard to cover any public transit costs related to their attendance, and snacks and beverages will be provided to staff and client participants.

Deliberative democracy sessions will also include substantial snacks and beverages.

☒ Study Instrument(s) attached *(Aim 1 Interview Guide and Consent Form*, Supplement Informed Consent Form, Supplement Permission to Contact Form, Supplement Interview Guide)

☐ Outreach media attached (i.e. flyers, e-mails, advertisements) – *N/A*

The only primary data collection for Aim 1 entails in-depth individual interviews (N=24) with providers (staff) at participating programs from eight of the agencies in the trial, to be purposively sampled as: four clinical sites and four community-based organizations (CBOs) out of the 13 early-implementation (Phase 1) sites. At each agency, we will conduct three purposively sampled interviews, one each with: 1) a front-line worker (PN) involved in client outreach and the delivery of the interventions prompted by the D2S report and covered in trainings/TA from DOHMH; 2) a PN supervisor (e.g., a social worker/case manager) exposed to D2S in part through related trainings/TA from DOHMH; and 3) an administrator (e.g., program or medical director) knowledgeable about RWPA QM/TA, data uses, and how D2S fits into the broader setting. Aim 1 interview participants will also be purposively selected by DOHMH staff to represent the range of trial-eligible program types (mental health, harm reduction, supportive counseling, and housing). After DOHMH staff collect lists of eligible staff (and their contact details) from RWPA program liaisons at the eight sampled sites, study personnel from CUNY ISPH or from DOHMH will contact sampled staff to introduce the study and invite them to take part in an interview (to be conducted by a CUNY ISPH team member). Those who agree will be taken through an oral informed consent process prior to the interview, followed by written consent collection at the outset of the interview session. Interview participation will be voluntary; refusals should not prevent fulfilling the purposive sampling plan. Each participant will be offered a copy of the consent statement and a $75 gift card to recognize their dedication of time to the interview. This approach has been applied successfully in R01 MH117793, for which 29 provider interviews were completed in early 2020.

Clients to be included in the Aim 1 secondary analyses of the stepped-wedge trial of D2S will be identified through the analysis of merged programmatic (eSHARE) and surveillance (NYC HIV Registry) data, based on the eligibility criteria noted above (concerning enrollment status/timing, vital status and viral suppression [VS] status in a given reporting period). Additional data elements from the NYC HCV Registry will be incorporated into Aim 1 secondary analyses without the modification of existing inclusion/exclusion criteria. Clients to be included in Aim 2 secondary analyses of drivers of VS will represent a subset of clients analyzed for Aim 1 – specifically, those clients who were exposed to the D2S intervention during the course of the trial.

For Aim 3, recruitment for the focus groups is as follows: Primary data collection will include five focus groups with an average of nine providers each (N ≈ 45) and three additional focus groups with an average of nine clients each (N ≈ 27). Provider groups will be organized by setting (clinical versus non-clinical/CBO), and split within setting by program role: administrative (including information-technology/data managers and program directors or medical directors),

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direct support services delivery, or medical care delivery (at clinical sites only – so there will be only one group for medical practitioners, making five total focus groups for service providers). Two client groups will be divided by trial outcome (TVS/no TVS), and a third client group will engage Spanish-speaking clients from the trial regardless of TVS status. Recruitment will be among programs included in the trial (the RWPA support-services programs at 27 agencies). Purposive sampling by DOHMH study personnel will be used to ensure representation of the range of eligible program types (mental health, harm reduction, supportive counseling, and housing) and agency types (clinical and non-clinical). To introduce the focus groups and their role in the larger study, DOHMH study personnel will contact RWPA program liaisons via program contact details already updated at DOHMH and used for routine contractual and quality-management purposes. These program liaisons will be provided with a brief written description of the focus group opportunity and asked to share that description (which will include DOHMH study team contact details) with other program staff and with a subset of active clients that the DOHMH team members have identified from study datasets (to represent those with and without TVS during D2S follow-up, and to represent English-speaking and Spanish-speaking clients). Potentially interested, eligible staff and clients may then contact the DOHMH study team and be screened and registered for one of the focus groups (until purposive sampling has filled all open slots). In advance of the focus group sessions, as part of the registration process, each eligible and interested focus group participant will be taken through an informed consent process, and oral consent will be sought. As will be explained during initial focus group invitations, focus group participation is voluntary, and not all 27 agencies in the trial are expected to participate, nor would all invited staff or clients be expected to participate for a given agency. At the focus group sessions, led by CUNY ISPH facilitators, each participant will be offered a copy of the consent statement and a $50 gift card to recognize their dedication of time to the focus groups. Client participants will also receive a two-trip Metrocard to cover any public transit costs related to their attendance at in-person sessions.

The Aim 3 discrete choice experiment (DCE) will be conducted in Years 3-4 with staff (N=200) at all 27 D2S trial sites. We will focus on staff for the DCE because D2S acts upon sites and providers to improve services and VS among their existing clients, and DCE self-administration requires awareness of the intervention as such (which we expect of staff in this case, not clients). DOHMH study personnel will first reach out to each D2S-participating agency (including multiple program liaisons, if applicable for a given agency) to request a current list of staff names, titles, and e-mail addresses for the study team to use to contact eligible staff with a survey invitation, link, and unique study login for DCE self-administration. The online DCE tool will include a consent statement at the outset, to which each participant will have to agree in order to advance to the actual DCE “questions” or choice scenarios. DCE eligibility will be based on job roles intended to review/use D2S reports, follow up with listed clients, supervise PNs, and/or attend related trainings and TA. DOHMH will follow up with agency point persons/liaisons as needed when there is a question as to job role eligibility after review of the agency's list of staff with job titles. Given estimates of eligible staff at the 48 programs originally expected to be engaged for the trial and a projected response rate of approximately 80%, all eligible staff will be invited for the DCE (via e-mail from DOHMH study personnel). DCE participants will also be provided with $25 gift cards to recognize their time/effort in completing the survey.

For the administrative supplement, recruitment will be conducted at all 27 D2S sites and through the HIV Planning Council Consumers Committee. The study team will provide general guidelines for those sites to invite and refer clients to the study team to learn more about the DD process. Study team members will also distribute "Permission to

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Contact" forms to D2S participating programs. The "Permission to Contact" form (attached) includes spaces for the staff using the form to document permission or refusal (with a reason for refusal, if offered) as well as specific, client-provided current contact details to be used in future contact attempts. Program staff will provide these forms to their clients during their routine program encounters and fill in the clients' eSHARE ID numbers. Clients interested in participating will complete the permission to contact form with the client's name, basic contact information, and any instructions for contact attempts. Filled Permission to Contact forms will be securely transferred to the study team either electronically (through HealthCommerce) or with direct hand-off/pickup at the program site. The study team will contact interested clients to invite them to participate in the deliberative democracy sessions and provide more information about the study. We will also present the DD sessions to the HIV Planning Council Consumers Committee to recruit an additional 3-6 participants. We will include at least one small breakout group for primarily Spanish-speaking clients. In advance of the first DD session, each prospective participant will be taken through the consent process (generally by phone) and oral consent will be sought (See Informed Consent Process). Participants will be provided with a $200 gift card for each session attended, for a possible total incentive of $400 if they attend both sessions. Attendance at the second session will be restricted to participants from the first session.

H. Informed Consent Process

Describe how consent will be obtained, including by whom (i.e., principal investigator, co-investigator, study coordinator), when, and by what method (e.g., in-person, verbally by telephone). Be sure to describe means of communicating if non-English speaking, illiterate, or other vulnerable persons will be included among study subjects. Also if necessary, describe any visual aids or devices that may be used to help explain a complicated procedure or process.

Please select:

☒ A written or electronic **Informed Consent Document** describing the research **WILL** be provided to the subject or the subject's legally authorized representative for signature. *(This applies for the Provider Interviews.)*

☒ **Informed Consent** will be obtained and an **information sheet** describing the research **WILL** be provided to the subject or the subject's legally authorized representative. **NO** signature will be obtained. (Please request for a waiver of documentation of informed consent in the text box below and describe how informed consent will be obtained) *(This applies for focus groups and the electronic DCE.)*

☐ **Informed Consent** will be obtained and the participants **WILL NOT** receive an information sheet. (Please request for a waiver of documentation of consent in the text box below and describe how informed consent will be obtained)

☒ **No Consent** will be obtained. (Please request for a waiver of informed consent process in the text box below; unless exempt) *(This applies to the Aim 1 and Aim 2 secondary analyses of existing DOHMH data sources.)*

For all requests for a waiver of informed consent or alteration of the consent process, the following criteria must be met:

1. The research involves **no** more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;

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New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

3. If the research involves using identifiable private information or identifiable biospecimens, the research could not be practicably be carried out without sing such information or biospecimens in an identifiable format;
4. The waiver or alteration will NOT adversely affect the rights and welfare of the subjects; **AND**,
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

For all requests for a waiver of documentation of informed consent, the following criteria must be met:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subjects wants documentation linking the subject with the research and the subject's wishes will govern;

OR

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;

OR

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting the informed consent was obtained

☒ Consent document(s) attached

We are requesting a waiver of informed consent for secondary analyses (Aims 1 and 2). We expect the waiver to be granted based on those analyses meeting the following criteria:

The research is not FDA regulated;
The research does not involve non-viable neonates;
The research involves no more than minimal risk to the subjects;
The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
The research could not practicably be carried out without the waiver or alteration.

Specifically, the secondary analyses under Aims 1 and 2 of this study involve a type of review of merged DOHMH data sources that is routinely conducted by DOHMH personnel as part of public health surveillance, monitoring and evaluation. Clients whose data will be included will not be "enrolling" in a study, nor likely to even be aware of the intervention or the study. D2S is a structural and provider-directed intervention (DOHMH sharing of actionable data and related capacity-building resources), intended to enhance the quality and effectiveness of services that clients are already seeking and receiving through the RWPA providers to be engaged for this intervention. While this study will evaluate a specific enhancement (D2S) to RWPA support service delivery, and thus focus on records of a subset of clients whose providers are included in the randomization to early or delayed D2S, all RWPA clients' programmatic

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Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
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and HIV surveillance records are subject to merged analysis as part of the routine required reporting and local evaluation for which RWPA grantee agencies (such as the NYC DOHMH) are responsible under their conditions of RWPA award set by the federal funder, HRSA.

We are requesting a waiver of documentation of informed consent for the client and provider focus groups (Aim 3) and for the administrative supplement deliberative democracy sessions. We expect the waiver to be granted because these data collection activities meet the second criterion mentioned above: "2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." In addition, because the focus group data will be anonymized (using only participant pseudonyms) and participant contact information will be destroyed after completion of the participant's focus group session, the only lasting record linking the focus group participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Oral informed consent avoids the generation of a document linking the participant to the study or to a specific focus group session/date.

For the provider qualitative individual interviews and client and provider focus groups, oral informed consent will be obtained from all participants. In preparation for this, the study will be carefully explained to potential participants. They will be advised of the purpose of the study, details of the interview/focus group process, risks and benefits of participation, and procedures for protecting their confidentiality. All potential participants will be apprised of their right to decline to participate or to discontinue at any stage of the process, and informed that neither their specific responses nor any decision to participate, not participate, or withdraw from the study will impact their employment or contractual standing with DOHMH (for program staff) or the services they may receive (for program clients). At the end of the full study explanation, each participant will be invited to ask any questions and will then be asked to say the following if they agree to participate: "I consent to participate in the study." The study team member conducting informed consent will record the outcome, and only participants providing their oral consent will be brought into actual focus group sessions or individual interviews. Those who do not consent will be offered study team contact information for follow-up in case they wish to consider participation at a later time. IRB-approved consent forms will be made available in English and in Spanish (for clients whose preferred language is Spanish for written communications). Individual interviews and focus group sessions will be held in a ISPH or DOHMH private office/conference room or a private space within participating RWPA facilities or remotely (via phone or videoconference), depending upon participant preference.

For the provider DCE, the study team will design an electronic survey tool with clear, appropriate visual representations as well as plain-language text for each item/selection. Because the DCE can and should be self-administered by participants using the survey website, rather than being completed via interview, DCE informed consent will also be administered electronically, through an informed consent statement that will appear prior to the DCE questions and will require the participant to select "I agree," before they can continue to view or submit responses to any of the DCE questions. As confirmed by the DOHMH IRB for DCE surveys conducted as part of R01 MH117793 (Protocol #18-009), the use of the participant's dedicated, unique study identifier (provided with the website details for login), together with the selection of "I agree" following review of the consent statement, should suffice in lieu of a physical signature for DCE consents. DCE participants will be able to print a copy of the informed consent statement, which will include study team and IRB contact information, for those who may wish to follow up with any questions.

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42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
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For the administrative supplement, oral informed consent will be obtained from all participants. In preparation for this, the study will be carefully explained to potential participants. They will be advised of the purpose of the study, details of the DD process, risks and benefits of participation, and procedures for protecting their confidentiality. All potential participants will be apprised of their right to decline to participate or to discontinue at any stage of the process, and informed that neither their specific responses nor any decision to participate, not participate, or withdraw from the study will impact the services they may receive. For members of the Consumers Committee, it will be explained that neither their specific responses nor any decision to participate, not participate, or withdraw from the study will impact their role in the local planning process for RWPA services. At the end of the full study explanation, each participant will be invited to ask any questions and will then be asked to say whether they agree with the final informed consent statement: "I have read this consent form or have had it read to me. I have had the opportunity to ask questions, and my questions have been answered. I know I can receive a copy of this form." The study team member conducting informed consent will record the outcome, and only participants providing their oral consent will be brought into a DD session. Those who do not consent will be offered study team contact information for follow-up in case they wish to consider participation at a later time. IRB-approved consent forms will be made available in English and in Spanish (for clients whose preferred language is Spanish for written communications).

I. Additional Informed Consent Provisions ☐ N/A

☐ Children/Adolescents:

Describe whether child subjects may be expected to attain legal age to consent to the procedures of the research prior to the completion of their participation in the research (including storage of samples). If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Describe the timing of this process, and what will occur if consent is not obtained from the now-adult subjects.

Parental permission will be obtained from:

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Permission will be obtained from individuals other than parents. Describe the process used to determine these individuals' authority to consent to each child's general medical care in the text box below.

☐ No parental permission will be obtained. Justification is to be provided in the text box below.

Assent from the children/adolescents will be obtained from:

☐ All of the children/adolescents.

☐ Some of the children/adolescents. Please indicate which children will be required to assent in the text box below.

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New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
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☐ None of the children/adolescents. Justification is to be provided in the text box below.

☐ **Cognitively Impaired Adults**

If the human research involves adults who may be unable to consent, describe the process to determine whether an individual is capable of consent.

If the Human Research involves cognitively impaired adults:

- If permission of a legally authorized representative will be obtained:
  - List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
  - Describe the process for assent of the subjects. Indicate whether:
    - Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
    - If assent will not be obtained from some or all subjects, an explanation of why not.
    - Describe whether assent of the subjects will be documented and the process to document assent.

☒ **Non-English Speaking Subjects**

Indicate what language(s) other than English are understood by prospective subjects or representatives. If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. If you intend to exclude potential participants who do not speak English, provide a justification for doing so. Please note that an oral translator is not sufficient for the enrollment of individuals who do not speak English. The English, IRB approved consent document must be translated into another language and submitted for IRB approval before a non-English speaking participant is enrolled. Accuracy of the translation must be certified (or attested).

Focus groups will be conducted with both English-speaking and Spanish-speaking patients, and thus, informed consent documents will be provided to participants in the language in which the focus group is being conducted. A native Spanish-speaker will facilitate the Spanish-language focus group. As in the PROMISE study, informed consent tools will be made available in Spanish and English. Data collection tools and consent language will be translated by native speakers. For the administrative supplement, informed consent documents will also be provided to participants in both English and Spanish. Spanish-speaking facilitators will facilitate the Spanish-language small group(s), and provide live translation during the large group sessions. Data collection tools and consent language will be translated by native speakers.

J. Study Procedures

Describe the procedures in sufficient detail so that a reviewer who is not familiar with the research can comprehend what is to be done and can evaluate any risks. Delineate procedures that are already being performed for diagnostic or treatment purposes from those that are being done for research (i.e., clearly identify those procedures that would be occurring whether or not the individual was participating in this research.)

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42-09 28th Street, 14th Floor
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Provide a description of all research procedures (e.g. questionnaires, record review, medical exams), when they will be performed (e.g. baseline, initial visit, follow-up visits).

If the study only involves the use of data, please address how the data will be captured, shared, and/or transmitted. Please include a list of data variables that will be extracted, maintained, used, analyzed, or linked for this study.

☒ Study Instrument(s) attached ☐ Data Collection Form(s or Case Report Form(s) attached

Aim 1. The proposed intervention will focus and guide RWPA support-service providers in assisting their clients who are flagged on D2S reports as virally unsuppressed. The D2S reports will be generated based on Registry data on viral load (VL) test dates and values (and client vital status) and eSHARE (RWPA program) data on client activity in the recipient RWPA program. Reports will be delivered (through separate secured transfers to individual accounts for authorized recipients) in two rounds per implementation period, with the first round marking the start of that implementation period and the second round beginning halfway through the period. D2S reports will be generated at the DOHMH using existing data sources (surveillance and programmatic) that are already securely managed and routinely merged and analyzed at the DOHMH. In Period 1, D2S reports and capacity-building will be delivered to 13 of the 27 agencies (13 agencies randomized to early implementation), while D2S will be delivered to all 27 agencies in Period 2. Because of the odd number of agencies determined to have sufficient numbers of unsuppressed behavioral health and housing clients to be eligible for the trial at the time this project actually began in mid-2021, two agencies that had smaller numbers of trial-eligible clients were paired with one agency that had a larger number of trial-eligible clients (and was randomized to early implementation). Period 0 (baseline) data are available on all 27 agencies for retrospective report simulations and determination of TVS and time to VS, and between-site differences in those outcomes, among individuals found to be unsuppressed in the pre-intervention period.

Implementation outcome assessment will include primary data collection (24 in-depth interviews, each lasting up to 60 minutes) with providers at participating programs. Recruitment for each interview will take place using purposive sampling of RWPA service providers included in the trial. Study personnel will initially contact eligible, sampled providers to introduce the study and invite them to take part in an interview. If they agree, in advance of the interview, each provider will be taken through a detailed consent process. Interviews will be digitally recorded using password-protected devices or videoconferencing platform features. Recordings will be downloaded onto CUNY secure servers to be transcribed and analyzed (with help/context from session notes). Password-protected files with session content and summaries will be shared with DOHMH for DOHMH analysis as well. Each participant will receive a $75 gift card for their participation.

Aim 2. Aim 1 results will be used to identify a cohort of RWPA clients exposed to D2S during the trial (those flagged as unsuppressed on D2S reports that were delivered to implementing sites), and distinguish those who did and did not achieve TVS, for assessment of modifiable determinants of the outcome (aside from the intervention, a condition shared by all clients included in Aim 2). As in Aim 1, Aim 2 will entail secondary analysis at the DOHMH of existing data sources that are already securely stored and routinely merged and analyzed at the DOHMH. We will utilize client-level HIV surveillance data, furnished to DOHMH as part of mandatory New York State (NYS) HIV reporting, and merged with routinely collected and evaluated client-level data from RWPA and Housing Opportunities for Persons with AIDS (HOPWA) programs; as well as RWPA agency-level and program-level data also housed at DOHMH and collected as

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
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Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

part of DOHMH contracting, quality management and technical assistance activities. The latter data sources provide rich information regarding potential structural/environmental and psychosocial or behavioral factors for VS. There will be no Aim 2-specific study procedures related to human subjects other than secondary analysis and continually maintaining the security and confidentiality of the study data. We request a waiver of informed consent for secondary analyses of existing data sources at the DOHMH for the purpose of this study, given the minimal risk of these activities and given that secondary analyses using the same data sources are conducted routinely at the DOHMH for other purposes (e.g., ongoing RWPA and HOPWA program planning, evaluation, quality management, and reporting to the federal funders).

Aim 3. Aim 3 focus group findings will be used to inform the development of a discrete choice experiment (DCE) and to provide direct input on D2S acceptability, valued aspects of D2S and possible changes to the intervention. Recruitment for each of eight focus groups will take place using purposive sampling of RWPA service providers (in five groups) and clients (in three groups) who were exposed to D2S during the trial. Study personnel will contact eligible, sampled providers to introduce the study and invite them to take part in the focus groups. For client focus groups, the study team will present the intent of purposive client sampling to sampled D2S sites, and will provide general guidelines for those sites to invite and refer clients to the study team to learn more about the focus groups. Interested, referred clients will be screened for eligibility and selected to achieve a diverse set of participants in each focus group, including two English-speaking client groups divided by VS outcomes from the trial and a third group for primarily Spanish-speaking clients. In advance of focus group sessions, each selected and interested participant will be taken through a thorough consent process (generally by phone), and oral consent will be sought (See Informed Consent and Assent Section). Focus groups will be digitally recorded using password-protected devices, as well as documented via notes. Recordings will be downloaded onto CUNY secure servers to be transcribed and analyzed (with help/context from session notes). Password-protected files with session content and summaries will be shared with DOHMH for DOHMH analysis as well. Participants will receive a $50 gift card for their participation. For Aim 3 DCE, each of the 27 agencies engaged for D2S will provide a list of staff names, titles and e-mail addresses for the study team to use to contact each eligible staff member with a survey invitation, link, and unique login for DCE self-administration. Eligibility will be based on job roles intended to review/use D2S reports, follow up with listed clients, supervise PNs, and/or attend related DOHMH trainings and TA. To gain insight into provider preferences for D2S delivery, the DCE will present a series of choices (“choice sets”) composed of different scenarios (options or alternatives) defined by different attributes and levels for each attribute. Attributes and a full range of defined levels for each attribute are used to create several choice sets, and the respondent must weigh trade-offs between the characteristics of each, to select one preferred alternative for each choice set presented. Through repetition of the process over several randomly presented choice sets representing many possible combinations, investigators can identify which attributes participants value most.

Administrative supplement. The administrative supplement will use a participatory research framework (deliberative democracy) to elicit RWPA client and HIV Consumers Committee member feedback and recommendations for HIV-related data sharing policies. Supplement findings will be used to inform standards for future HIV surveillance data sharing activities in RWPA, including ongoing implementation of D2S. We will recruit participants (target N = 50) from the 27 RWPA program sites participating in D2S and the HIV Planning Council Consumers Committee, which works to ensure meaningful and substantial involvement of people with HIV in all Planning Council activities. To ensure that the

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
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Fax: 347-396-6087
irbadmin@health.nyc.gov

diversity of backgrounds, priorities, and opinions of possible participants are represented in the study, we will aim to recruit at least 1 participant from each D2S site, and 5-6 participants from the Consumers Committee.

Participants will be recruited from D2S sites in a two-step process: first, D2S program staff will obtain "permission to contact" from clients potentially interested in participating in the DD sessions. Next, the study team will contact interested clients to provide them more information about the study and invite them to participate in the DD process. Each participant will receive a $200 gift card for each half-day session attended, for a maximum of $400 per participant, with attendance at the first session/half-day being a prerequisite for attendance at the second session. This incentive is in line with those offered for previous research studies among RWPA clients at the NYC DOHMH, and specifically in line with the $50 incentive for participation in roughly one-hour client interviews or focus groups, since each deliberative democracy session is expected to take slightly over four hours (from arrival/registration time to wrap-up), with a half-hour break in the middle. At the first session, participants will attend an informational session and Q&A on the D2S project and other data sharing activities at the NYC DOHMH, and a presentation on a proposed change to the D2S process. Following informational sessions, participants will break into small groups to deliberate on data sharing policies. The small group sessions will be led by trained facilitators and will take place using a semi-structured interview guide. Each group will be invited to submit at least 1-2 policy proposals on HIV-related data sharing processes. During the second session, which will occur approximately 2-4 weeks after the first session, participants will reconvene to openly deliberate in a large group on the recommendations from the first session. Participants will then anonymously vote on whether to ratify each of the policy proposals. Participants will complete an entirely anonymous pre- and post-process survey for each session, to allow the study team to assess participant attitudes on data sharing and the perceived quality of each DD session. Sessions will be digitally recorded using password-protected devices and later transcribed for thematic, qualitative analysis.

Pre-deliberation information sharing sessions will provide background about the D2S initiative and the use of public health surveillance data in client health care. Information sessions ensure that laypersons are equipped with the appropriate knowledge to engage in deliberation. In line with other DD designs, we will hold an open lecture session and Q&A panel with staff from the research team and/or subject matter experts from the DOHMH General Counsel's Office and/or the Bureau of Hepatitis, HIV, and STIs. Content will cover: background on mandatory reporting of HIV lab results to public health departments, background on New York State HIV laws and the updated regulations that support health department sharing of person-level surveillance-based data with clients' support-service providers (as coordinators of their HIV care), an overview of D2S-related data sharing activities at the NYC DOHMH, and a presentation on example models for client engagement in data sharing decisions and possible formats including written language and/or visual aids. The research team will then present an overview of existing DOHMH workflows and areas where policy recommendations could be integrated. For example, consent could be integrated into the eSHARE system for administration to clients who are receiving RWPA services. The procedures could be incorporated into the workflow of RWPA sites so that clients may review RWPA data-sharing practices and either opt in or opt out. Small-group sessions will discuss ethical considerations around a proposed data sharing policy and policy proposals. Trained facilitators will moderate groups. Prior to the event, all facilitators will attend a half-day orientation and training to prepare for leading small group discussions. The orientation will cover DD processes, D2S, goals of the small group discussions, and the discussion guide. Facilitators will receive cultural humility and equity training for working with diverse populations to ensure inclusivity and respect for diverse perspectives.

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
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The goal of small group discussions is to provide specific feedback on data sharing processes and generate at least 1-2 policy proposals per group. Proposals will not require consensus among all group members, and will be shared if relevant to the goals of the DD process (at the discretion of the group facilitator). We will hold a separate group for Spanish speakers as Spanish, accounting for 22% of clients, is the largest language spoken outside of English across New York RWPA programs. We will also hold a separate group for participating members of the HIV Planning Council Consumers Committee, as these members may have more prior knowledge of surveillance/health data and past experience participating in other advisory groups. Small groups will be digitally recorded for subsequent qualitative analysis of themes.

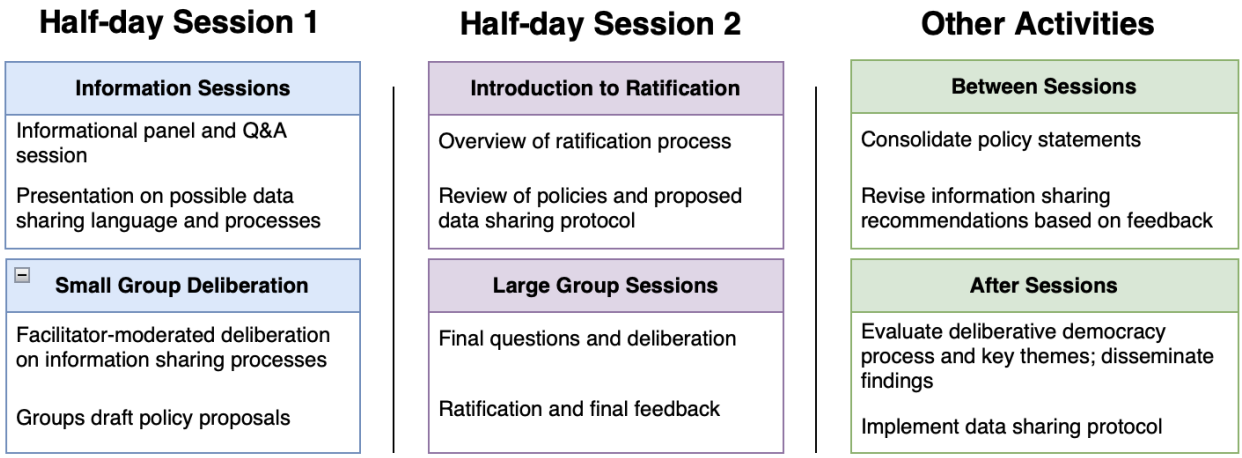
Following the small group sessions, participants will adjourn until the second half-day session. This will provide participants with an opportunity to reflect on discussions from the DD session. Between sessions, the research team will consolidate proposals and evaluate their feasibility for integration within DOHMH and RWPA programs' workflows and systems, including data systems. We will draft a data sharing protocol based on policy statements and qualitative themes that emerged in the small group deliberations.

Large-group sessions will consist of final deliberation, selection of policy statements that were proposed in the small group sessions, and voting to ratify the data sharing protocol recommendations. Ratification (e.g. voting on specific proposals) is a key component of deliberative democracy processes that allows participants to directly influence policies. The session will begin with an overview of the process and an opportunity for final deliberation and questions. In the beginning of the second session, we will review all policy recommendations that will be voted on. We will use a format that allows participants to submit questions directly to the research team for individuals who do not feel comfortable speaking in a large group. The research team will integrate any final feedback into the draft of the data sharing procedures in real-time. The session will then include a final, large-group deliberation. When deliberation has concluded, participants will ratify individual policy recommendation proposals through voting. Votes will be tallied and results will be shared with participants. Proposals will be ratified if the percentage of votes reaches a simple majority.

If proposals do not receive a majority vote, then the remainder of the session will consist of discussions with participants to resolve open issues. Based on the discussion, we will present an amended proposal and hold another round of voting. If the policy recommendations from the deliberative democracy sessions are not ratified, we will identify areas of disagreement and address them specifically in future community engagement activities, such as HIV Planning Council meetings. We will later use qualitative analysis of small group discussions to focus on where areas of agreement and disagreement arose during the sessions. These analyses will serve as a starting point for future discussions, and contribute to a better understanding of the diversity of opinions among people being served by RWPA.

Recordings and transcripts will be downloaded onto DOHMH secure servers to be analyzed (with help/context from session notes). Password-protected files with session content and summaries will be shared with CUNY for CUNY analysis as well. In the time after the first DD session and before the second DD session, the research team will convene to review themes for deliberative democracy small groups and make edits to recommendations. The team will use anonymous pre- and post-process survey responses to assess participant attitudes on data sharing and the perceived quality of each DD session.

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov



K. Statistical Procedures

☐ N/A

Describe the data analysis plan.

OVERVIEW. Using a cross-sectional stepped-wedge hybrid Type 1 trial, we will implement and evaluate the Data-to-Suppression (D2S) intervention in Aim 1. Agencies eligible for the trial will be matched in pairs and then randomized within pairs to early (Period 1) or delayed (Period 2) D2S intervention implementation. Our design will also use baseline data from a 12-month pre-implementation period (Period 0), for which D2S reports will be retrospectively generated. Each period will include two rounds of report releases (six months apart), each with a 12-month look-back period. In both arms, clients without viral suppression (VS) will be followed forward for timely VS (TVS) and time to VS after report issue date. VS outcome data for Aims 1 and 2 will be derived from the HIV Surveillance Registry. From late Period 1 into Period 2, we will interview three staff at each of eight purposively sampled early-implementing sites, and review program data from all 27 sites, to assess RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) outcomes (e.g., integration/use of D2S reports and trainings, staff-perceived benefits of D2S) and implementation barriers or facilitators. In Aim 2, by leveraging linked data on systems, site, and individual factors distinguishing D2S-exposed clients who do and do not achieve VS, we will assess opportunities to refine D2S components to benefit more client subgroups. In Aim 3, to further optimize the D2S intervention, we will conduct three client and five provider focus groups exploring perceptions of intervention attributes and ways D2S might be modified for fit with participant activities/values and organizational settings or systems constraints. Focus group findings will guide the development of the Aim 3 DCE (n=200) eliciting staff preferences for specific intervention implementation approaches. Findings from the DCE and focus groups will inform intervention adjustments to optimize engagement (staff and clients), fidelity to key components (staff), reach (clients), and overall acceptability and sustainability, with potential for further scale-up. In the study as a whole, across all three Aims, we apply a multiphase design as our approach to mixed methods.

AIM 1.

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

Retrospective Analyses to Generate Estimates for Power Calculations. A retrospective analysis of data from the behavioral health and housing programs at the 27 selected agencies was conducted to review the TVS outcome among clients unsuppressed as of last VL test in July 2016 – June 2017 (a mock "Round 1, Period 0" report lookback period), and for additional clients (i.e., clients not flagged in Round 1) who were unsuppressed as of last VL test in January – December 2017 (a mock "Round 2, Period 0" report lookback period). The same process was used to generate simulated data for two rounds of reports (covering July 2017 – June 2018 and January – December 2018) for a mock "Period 1" at those agencies, and two rounds of reports (covering July 2018 – June 2019 and January – December 2019) for a mock "Period 2" at the same agencies. Clients found to have a suppressed VL dated after their qualifying unsuppressed VL but prior to the time when a D2S report could have been issued (two months following the end of the 12-month reporting lookback period) were excluded from the eligible N for follow-up from that simulated report, since they could not be evaluated for timely achievement of suppression following the date of report issue. The remaining eligible clients within each simulated period were followed for VS (any VL <200 copies/mL) within the six-month period starting exactly two months after the end of the report year in which they were flagged as unsuppressed. Through this method, we arrived at (1) an estimate of 1,283 unique unsuppressed people with HIV (PWH) to be included in the trial, and (2) an estimate of 43.7% TVS in the pre-intervention base case. The N to be included in analyses of time to VS is smaller due to the longer (12-month) follow-up time and the start of each implementation period exactly 12 months after the start of the prior implementation period. To allow a full, discrete 12-month follow-up period, while avoiding contamination between intervention and control observations, the time to VS outcome will only be measured among clients flagged as unsuppressed in reports issued at the start of each period ("Round 1" reports). This does not cut the N in half, because Round 1 reports include more clients newly flagged as unsuppressed, as compared with Round 2 reports, and clients unsuppressed at both rounds (duplicated clients) within an implementation period are not eligible for follow-up for Round 2, for either outcome measure.

Viral Suppression Analysis Plan. The analysis plan is based on the exact, conditional distribution theory of non-central multiple hypergeometric distributions and their convolutions, enabling us to estimate the effect of the intervention as a single parameter, while allowing for arbitrary site and period effects within matched pairs. The conventional statistical analysis proposed for cross-sectional stepped-wedge designs (i.e., with independent samples of patients enrolled at each transition step) assumes a mixed model with random cluster effects and fixed period effects, yet this is not appropriate for our matched-pairs stepped-wedge trial, since the matching will be under the investigators' control and so should be conditioned upon. In addition, the generalized linear mixed model requires an unverifiable assumption of normal distribution for random effects and has poor variance estimation performance in small samples (of clusters), even with robust variance estimation, such that jackknifing must be used. Our exact conditional analysis avoids these problems. We initially assume a random-effects model that accounts for clustering by assuming conditional independence of client responses within clusters (sites matched within pairs). As more fully described below, the random effects allow for arbitrary site-level differences within pairs (assumed constant across periods) and for arbitrary period effects (assumed constant for each site within a pair, though allowed to vary between pairs). Unlike the conventional analysis for cross-sectional stepped-wedge designs, however, our exact conditional approach proceeds from the initial assumptions by removing the random site-difference and period effects entirely from the analysis, ultimately allowing inferences about the intervention to be drawn from a single-parameter conditional distribution.

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

Each pair of sites will yield two 2x3 tables (one table per site in a pair), cross-classifying the number of TVS and non-TVS outcomes from the baseline (Period 0, with no D2S intervention), first transition (Period 1, with D2S at early implementers), and second transition (Period 2, with D2S at all sites). For identification purposes we refer to "Site 1" within a matched pair as the site randomized to switch in Period 1 and "Site 2" as the site randomized to switch in Period 2. 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 (D2S versus no D2S) equals an intercept representing an arbitrary, pair-specific log odds on TVS for Site 2 in the pair, plus an arbitrary log odds ratio (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 one 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 odds ratio (OR) for TVS versus non-TVS comparing D2S to no D2S. 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, i.e., 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 of sites to the next.

Next, when we condition on the marginal totals within each site (numbers of eligible clients in each period and numbers of TVS and non-TVS outcomes for each site), and further condition on the sum of TVS outcomes across the two sites in each period, the fully conditional joint distribution depends solely on the intervention effect, rather than depending on nuisance site or period effects. In other words, the nuisance parameters are conditioned out, such that the conditional distribution under which inferences are drawn about the intervention effect does not depend on those nuisance parameters. (This is analogous to how a conditional maximum likelihood analysis for the OR in a fourfold table, conditioning on all the margins of the table, depends only on the true OR and not on the underlying individual true proportions in each row or column.) Thus, 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. We will calculate the marginal distribution of this outcome as a function of the intervention effect for each of the 13 matched pairs and convolute those distributions to obtain the sampling distribution of the summed sufficient statistic. Using this distribution, we will report the conditional maximum likelihood estimate of the intervention LOR with an exact, test-based 95% confidence interval. The primary 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). Special-purpose software has been written in the APL language to accomplish the required calculations. Corresponding SAS and R programs will be prepared, cross-validated, and made available to the public upon request.

To utilize 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, not unlike assumptions typically used in mixed-model analysis. 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

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

for individual clients. As a sensitivity analysis, we will re-estimate the intervention effect omitting repeated observations to confirm there are no material changes.

HCV Cure Analysis Plan. In an added secondary analysis, the effect of exposure to D2S reports on HCV cure will be measured by comparing HCV treatment receipt and cure status among clients with HCV coinfection at agencies that received D2S reports with HCV treatment receipt and cure status among clients at agencies that did not receive HCV reports. HCV treatment receipt will be defined as a client's first negative HCV RNA Qualitative NAA test preceded by a positive RNA test. HCV cure will be defined as two consecutive negative HCV RNA tests any time after the most recent positive HCV RNA test. A 12-week buffer period (after report dissemination) will be applied to avoid attributing to the reports HCV cures resulting from HCV treatment initiated prior to report distribution. The 12-week buffer period applies if the 2nd negative RNA test was within the 12 weeks after reports were disseminated. This analysis will include data from individuals in Period 0 and Period 1. Similar statistical methods as described above will be used to examine the effect of agencies' exposure to D2S reports on HCV cure among PWH with an HCV coinfection. Difference-in-Difference (DID) estimation may also be incorporated to estimate the effect of D2S report exposure on the outcome by comparing changes in the outcome over time (Period 0 to Period 1).

Power Analyses for the Trial. Our power analyses are based on simulated D2S reports on earlier time periods, generated using available and complete merged surveillance and program data (through 2019 for D2S reports and through September 2020 for six-month follow-up, where follow-up begins two months following the end of a given report year). For the 26 sites and 48 programs originally expected to be included in the trial based on preliminary data, six rounds of baseline reports (on July 2016-June 2017, calendar year [CY] 2017, July 2017-June 2018, CY2018, July 2018-June 2019, and CY2019) list 1,283 unique clients who would be eligible for the trial if we imagine that trial as having a Period 0 starting in September 2017. When we allow clients to count in multiple periods, the 1,283 account for 1,782 potential trial outcomes; at baseline, ~43.7% of those outcomes are TVS (VS in a six-month period starting two months after the end of the report year in which clients were unsuppressed). Based on simulation studies using a mock pairing of sites and repeated randomization of sites within matched pairs, we estimate 80% power to detect an OR of 1.86 (RR of 1.35), corresponding to 59.1% achieving TVS with D2S, versus the base rate (43.7%). Due to the smaller N when we omit repeat observations, the sensitivity analysis will have lower statistical power than the primary analysis; however, preliminary calculations indicate that an OR ~2.08 (RR ~1.41) will be detectable. For the secondary endpoint, time to VS (with 12 months of follow-up), we will use Cox regression based on a model analogous to that used for TVS. Insofar as there will be more events for the secondary 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 the intervention versus control condition.

In-depth Staff Interviews. Under Aim 1, we will conduct 24 in-depth individual staff interviews, lasting 45-60 minutes each, across eight purposively sampled early-D2S agencies, including four clinical sites and four non-clinical community-based organizations (CBOs). Using maximum variation sampling, we will interview three staff members at each site who represent the three core provider roles involved in D2S implementation: 1) a PN engaged in D2S outreach and training/technical assistance (TA); 2) a PN supervisor engaged in D2S training/TA; and 3) an administrator (e.g., program director or medical director) knowledgeable about RWPA quality management, data uses and how D2S fits into the broader setting. Organized around the Consolidated Framework for Implementation

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

Research (CFIR) and RE-AIM constructs, the interviews will capture D2S implementation barriers/facilitators at multiple levels (CFIR), staff-perceived outcomes such as reach, adoption, and benefits for clients (RE-AIM), and experience-informed reflections on intervention costs and sustainability. Basic demographics (race, ethnicity, gender, and age) and length of time working in their programs will be collected from interview participants, to assess diversity achieved in interview sampling and permit some subgroup analyses. Interviews will also investigate implementation in relation to effectiveness, as observed in the organizational and client outcomes. Based on our knowledge of the service settings and provider roles involved, we anticipate that a total sample size of 24 will be sufficient to reach saturation on these themes.

Qualitative Analysis. Interviews will be audio-recorded and transcribed. Thematic analysis will be conducted in Dedoose using a 'framework fit' technique, applying pre-defined codes derived from CFIR and RE-AIM. We will also use grounded exploration to interpret categories' meaning and attend to emergent themes salient to participants. This combined inductive-deductive approach suits the structured nature (well-defined domains) of the implementation science (IS) frameworks being applied. Initial codes will be identified by independent review of three transcripts by two study team members in dialogue with the senior qualitative methods advisor. The draft codebook will then be independently applied to a single transcript, with discrepancies resolved in consensus sessions to optimize inter-rater reliability, yielding a final codebook to be applied to the entire dataset. Also in this phase, we will use process analysis to map implementation trajectories by program as a means of comparing programs' intervention uses, which may be associated with programs' better or worse outcomes. Qualitative and quantitative analyses will be integrated by examining thematic patterns reflecting RE-AIM and CFIR implementation constructs as they explain client and organizational outcomes across programs. Aim 1 qualitative and quantitative phases will proceed concurrently, with the qualitative analysis serving a primarily explanatory function in relation to quantitative findings, while also having direct applications in terms of informing future refinements to the D2S intervention to optimize implementation and sustainability.

AIM 2.

Overview. We will create a retrospective, unduplicated cohort of unsuppressed clients exposed to the D2S condition in order to identify modifiable determinants of D2S response. VS outcome data for Aims 1 and 2 will be derived from the Registry. Client-level DOHMH-funded program reporting will supply measures of potential VS determinants, including modifiable factors such as substance use and housing stability – assessed semi-annually in RWPA. Organizational factors will be pulled from agency contract documents.

Study Population and Eligibility. We will create a retrospective cohort of RWPA clients exposed to the D2S intervention. Eligible clients include those exposed at early implementation sites in Period 1 (about half of the clients entering the trial in Period 1) and at all 27 sites in Period 2 (all clients entering the trial in Period 2), for a projected N≈700, using available (July 2017 through December 2019) data from the originally expected 26 sites.

Analysis Plan. Statistical analyses for Aim 2 will include data exploration via bivariate analyses and descriptive statistics to assess required statistical modeling assumptions. We will identify modifiable factors for TVS among

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

eligible clients on each D2S report at implementing sites. For these analyses, we will use logistic regression to calculate unadjusted and adjusted odds ratios (ORs of TVS), with generalized estimating equations to account for clustering within RWPA agencies. Multivariate models will be adjusted for non-modifiable yet confounding characteristics including demographics (e.g., sex, age, income, education) and Period (1 or 2) to account for temporal trends. We will separately and jointly map variables to the CFIR to understand the independent and combined VS effects of inner and outer setting constructs, thus informing refinements to D2S features. Aim 2 analyses will be conducted via R and SAS software. Hypothesis tests will use a two-tailed, 0.05 significance level. Statistical analyses will be guided by the CFIR and directed acyclic graphs (DAGs) based on our hypotheses, published RCTs, and other literature on potential mediators or confounders of exposure-outcome relationships, which may require more than one model, given DAG specifications regarding causal relationships. Missing data: In our experience with eSHARE and the HIV Registry, missingness for most exposures and confounders of interest is <5%, in which case we will assign the most common value. For missingness ≥5%, we will employ multiple imputation along with sensitivity assessment of the inferences under varying conditions. Though we believe the missing-at-random assumption to be reasonable for many variables in the merged dataset, we will assess this by chi-square test of association between missingness of each exposure or confounder with the outcome.

Power Analyses. Among 700 clients exposed to D2S in the trial, using an estimate of an exposure of interest, E, with frequency >5%, we estimate we will have 80% power to detect an AOR of ≥1.65. For higher-level (e.g., site) factors, assuming the original 26 RWPA sites and using a 2019 estimate of the median caseload as 32.5 (IQR: 32, Q1: 20, Q3: 52) and a conservative estimate of the Intraclass Correlation Coefficient (ICC) as 0.1, we estimate 80% power to detect an AOR ≥2.3 as statistically significant, at exposure frequencies of 20%-80%.

AIM 3.

Overview. We will gather data on participant views of D2S and preferred D2S intervention features, to inform future refinements, in eight (client and provider) focus groups and in a DCE with RWPA site staff (n=200).

We will convene RWPA client and staff focus groups with D2S implementing agencies to gather data on perceived acceptability and particular aspects of the D2S intervention seen as most relevant to participants, most potentially burdensome (staff) or intrusive (clients), most valuable for enhancing capacity (staff) or existing services (clients), and/or most effective at increasing client treatment engagement. This qualitative work will inform selection of attributes and choice levels for the DCE to ensure robust results. To further inform future delivery of D2S, in Years 3-4 we will conduct the DCE with staff (N=200) at all 27 D2S trial sites.

Focus Group Study Population. We will conduct a total of eight focus groups (three client groups and five staff groups). This number of focus groups was selected to represent the range of relevant variation in terms of program setting and provider role (staff) and intervention experience (clients). Thus, two client groups will be divided by trial outcome (TVS/no TVS), and a third group will engage Spanish-speaking clients involved in the trial regardless of TVS status. Staff groups will be divided by setting (clinical versus non-clinical) and split within setting by program role: administrative, direct support services delivery, or medical care delivery (at clinical sites only – which is why we plan five versus six staff groups). To cushion against the likelihood of some prospective participants failing to show up for the group at

Institutional Review Board
New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

the appointed time and place, we will register up to 12 participants for each group and will expect approximately nine to participate (based on prior experience with similar focus group sessions).

Qualitative Analysis Plan. Focus groups will be audio-recorded, transcribed, and coded using the process described for Aim 1. As in Aim 1, thematic analysis will use a 'framework fit' technique with select, grounded exploration to interpret categories' meanings. Findings will be discussed with the Advisory Board (AB) to inform the consensus-based selection of attributes and levels to be represented in the DCE, and to identify any adjustments to the D2S intervention that may be recommended based on focus group findings alone (e.g., related to acceptability or burden). The qualitative and quantitative phases of Aim 3 work are sequential, with the qualitative phase preceding the quantitative phase (DCE) and serving a primarily formative function.

DCE Study Population. In Years 3-4 we will conduct the DCE with staff (N=200) at all 27 D2S trial sites. Eligibility will be based on job roles intended to review/use D2S reports, follow up with listed clients, supervise PNs, and/or attend related capacity-building trainings/TA. Based on early estimates of eligible staff numbers at the behavioral health and housing programs at D2S trial sites, and assuming an ~80% response rate, we expect to invite all eligible staff to participate in the DCE, rather than a subsample, given that we would end up sampling nearly all eligible staff in order to account for a ~20% refusal rate. Basic demographics (race, ethnicity, gender, and age) and program experience will be collected as part of the DCE survey instrument, to assess representativeness of the final sample and to permit DCE subgroup analyses.

DCE Analysis Plan. To gain insight into provider preferences for intervention delivery, DCEs present a series of choices ("choice sets") composed of different scenarios (options or alternatives) defined by different attributes and levels for each attribute. Attributes and a full range of defined levels for each attribute are then used to create several choice sets, and the respondent must weigh trade-offs between the characteristics of each, to select one preferred alternative for each choice set presented. Through repetition of the process over several randomly presented choice sets representing many possible combinations, we can identify which attributes participants value most. We will develop a D-efficient, fractional factorial design with each respondent evaluating eight to 12 choice sets.

DCE Sample Size. Minimum sample size (N) for DCEs is dependent on the maximum number of levels for any attribute (L), the number of choices in each choice set (S), and the number of choices presented to each respondent (J): $N \geq 500*(L/S*J)$. Thus, the N depends on efficiency of the study design, which will be based on formative qualitative work. Generally, precision of estimates for main effects can be optimized with a sample of 150-200, after which the efficiency gains from increasing the N begin to diminish. With 200 DCE survey responses, our study will be well powered to identify aggregate preferences and to assess subgroup heterogeneity in preferences.

Administrative supplement: All small group deliberation sessions will be audio-recorded and transcribed, with the removal of any names or other personal identifiers that may have been mentioned by participants. We will assess session content using grounded exploration to interpret categories' meaning and attend to emergent themes salient to participants. We will also assess the quality of deliberation using frameworks developed by other DD experiments, focusing on: 1) deliberative output (e.g. whether participants reach consensus or disagreement), 2) concerns, hopes, and expectations of participants, 3) equal participations (the number and length of all comments by participants) and 4) reasoned justification of ideas.

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New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
Tele: 347-396-6118
Fax: 347-396-6087
irbadmin@health.nyc.gov

Evaluation surveys will be administered prior to and after each DD session. The survey will be developed de novo by the research team. Surveys will address attitudes toward health privacy, considerations important to developing a client-centered data-sharing process, knowledge of health privacy and data-sharing policies, and attitudes toward DD. In the post- survey, we will also assess the actual DD process by asking questions related to quality and usefulness of the session in a 5-point Likert scale from "Strongly Disagree" to "Strongly Agree." We will assess survey responses through descriptive statistics and through change in surveys pre- and post- on knowledge and attitude items.

L. Confidentiality of Study Data

Describe how the study data will be maintained locally, and during transmission to another site, if applicable. Include a clear description of how data will be stored, specifically indicating whether data will contain direct or indirect identifiers. Describe protections related to accessing the study data, whether in an electronic or paper form.

Please note that "de-identified" means that identifiers have been removed and no one (research team or others) can identify from whom the data or sample was collected. If any of the variables include in the dataset are identifiers listed under the Safe Harbor de-identification method, the data set is not considered "de-identified."

"Coded" means that the data/specimens are labeled with a code number, and there is a link between the respondent/donor and the data/specimen, i.e., someone can identify from whom the data/sample was collected if they have the link to the code. For any coded data/samples, indicate who, if anyone on the research team has access to the identifiable data.

Will identifiable private information be obtained for this research in any form directly or indirectly associated with a living individual?
☐ Yes ☒ No

If personal identifiers are to be collected, please indicate in the text box below which identifiers will be obtained (i.e., name, date of birth, addresses, telephone numbers, social security numbers, medical records, license numbers, IP addresses, photos, images, unique identifiers and/or etc.)

This study will involve the following agreements (please select):
☐ Data Use Agreement ☐ Memorandum of Use ☐ Confidentiality Agreement
☐ Other: Click here to enter text.

For all clients, privacy protections will be the same as those taken in Bureau of Hepatitis, HIV, and Sexually Transmitted Infections (BHHS) analysts' work with HIV surveillance data, which requires the strictest handling to protect confidentiality, as per the security protocols for BHHS. The personal identifier used for patients/clients will be the surveillance-based unique numeric identifier ("CityNo"), which is stored as the primary key for all combined surveillance-programmatic datasets, after stripping of other identifiers used in the initial match of records between systems (e.g., full first, last, and middle name; date of birth; sex; social security number; address or ZIP code). This study involves secondary analyses (Aim 1 and Aim 2) using existing client-level (and program-level and site-level) data,

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New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
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Fax: 347-396-6087
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but no primary data collection of identifiable data on clients. All merged analyses using existing client-level data sources housed at NYC DOHMH will be conducted on secured BHHS servers for storage of line-level data on people with HIV (PWH). These servers can only be accessed by authorized individuals through workstations within the DOHMH BHHS secured area (limited to staff with DOHMH ID badge access to that area) or via VPN to those workstations with prior authorization.

For Aim 1 and Aim 3 primary data collection with Ryan White Part A (RWPA) service providers (staff), the personal identifiers to be used in recruitment and follow-up with participants will include each staff person's first and last name, job role, and e-mail address and/or phone number (for arranging and confirming appointments). These program staff details can be stored on lower-security drives than client identifiers, and are used routinely at the DOHMH to contact providers for contractual and programmatic technical assistance communications. DOHMH will compile potential provider participants' contact details, and will share that information electronically with the City University of New York (CUNY) Institute for Implementation Science in Population Health (ISPH) study personnel involved in focus group/interview scheduling and follow-up, using a password-protected file. Immediately upon completion of a particular form of primary data collection (focus groups or individual interviews), the password-protected file with participants' contact details will be destroyed. For DCE surveys, DOHMH staff will send the survey link and login details to eligible program staff members' e-mail addresses, and will conduct follow-up with survey reminders. No appointments are needed for DCEs, as they are designed for self-administration. As soon as a focus group or individual interview is completed and the incentive(s) distributed, any hard copies of the participant contact details pertaining to that session will be filed away in a locked drawer within the secured area of the DOHMH BHHS, for retention only until such documents can be destroyed, following the terms of the Institutional Review Board (IRB) protocol.

The only potential identifiers to be included in datasets constructed from audio recordings, transcripts, and notes of focus groups (Aim 3) and qualitative individual interviews (Aim 1) are: coded individual participant study identifiers (for individual interviews only), site and program identifiers (as aggregate data for focus groups, individual data for interviews), basic demographics (as aggregate data for focus groups, individual data for interviews), and job roles (as aggregate data for staff focus groups, individual data for interviews). Similarly, the DCE survey to be used with RWPA staff will include basic demographic and program/role background questions, to assess representativeness and permit subgroup analyses. These data collected for the study will be available for analysis by DOHMH and ISPH study personnel. Though these datasets will include no personally identifying information, the site and program identifiers with the job role could be sufficient for both CUNY and DOHMH analysts to deduce an individual RWPA staff member's identity. However, confidentiality will be protected, and site or program identity will never be reported in connection with any specific response, and thus will not be available to individuals outside the study team. Informed consent statements for the interviews, DCE, and focus groups will address the potential for study team members from both institutions to associate provider identity with individual responses, will describe the confidentiality protections in place, and will provide assurance that neither staff responses nor decisions to withdraw from participation will affect employment or the program's contract status/standing with DOHMH.

The only data collection with clients for this study will occur in three focus groups, for which individual clients will be referred to the study team by their support-service providers and will be identified by pseudonyms, versus names or numeric/alphanumeric codes. Only pseudonyms (or first names, if clients prefer that) will be used in follow-up or

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Queens, New York 11101-4132
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reminder calls about focus group times/locations, and only after clients have contacted the study team personnel to communicate their interest in focus group participation and to provide their phone number for study team use to convey focus group time/location details. There will be no effort or capacity to associate individual focus group participant responses with individual client profiles or client-level data in other available data sources.

Data will additionally be collected in the administrative supplement for the purpose of study recruitment and matching to demographic information. The study team will only collect participants' name and eSHARE ID to be retained only as long as needed for the planning and confirmation of session attendance and release of participant incentives. Only first names or chosen nicknames will be used in follow-up communications, and only after participants have agreed to participate in the DD experiment and to be contacted with date/time and location details or reminders. In addition, the strictest, state-of-the-art data security and privacy measures (already in place as part of routine program implementation and monitoring, routine conduct of NYC HIV surveillance, and interviewing procedures used in prior research by this study team) will be employed to ensure the confidentiality of all participant information shared and analyzed as part of this protocol. However, as with all studies involving individual-level data, there is always a slight risk of loss of privacy for study participants. Procedures put in place to maintain privacy and meticulously followed to minimize risk include: intensive training of study staff on participant confidentiality; maintenance of detailed field security protocols and standards of practice related to physical and electronic protections of participant data; and (in the case of individual surveys) the use of study identification numbers (rather than personal identifiers) on study documents and analytic datasets.

M. Privacy Protections ☐ N/A

Describe how subject privacy will be protected, and the limits to protection. Privacy protection may be summarized as safeguarding an individual's expectation that the information they offer will be held in confidence. Protections should cover (e.g.,) screening activities, HIPAA provisions, forums such as focus groups where private information may be shared, and recordings of research activities, as applicable. Limitations such as compelled disclosure and mandatory reporting should also be described.

This study will involve the following agreements (please select):

☒ Private Space for Interactions with Human Subjects ☐ Non-Disclosure Agreement

☐ Other: Click here to enter text.

Information gathered in this study will be permanently protected by a Certificate of Confidentiality, which is automatically granted to NIH-awarded research. This means the study team cannot be compelled, even through a court order, to share information about study participants. However, if a participant in a focus group or interview discloses an intent to harm themself or others (including any sign of child or elder abuse), study personnel may have to report that to protect the participant and/or others at risk. Even in that situation, the rest of the participant's statements will remain confidential. The only other exception would be if the investigators were audited, in which case some study records might have to be provided to the audit employees. Given plans to destroy focus group participant contact information after completion of each session, we anticipate no scenario in which client/patient identifiers collected for the purpose of this study would even be available to share with a potential auditor.

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In addition to the usual privacy and confidentiality protection measures described previously for patient-level data, specific techniques pertaining to qualitative methodology (for focus groups) include the following. To minimize the potential loss of privacy or confidentiality during data collection procedures and analysis: (1) In-person sessions will be conducted in a private location to avoid the risk of study participation disclosure to participants' acquaintances; (2) Videoconference options will be offered only if needed to permit participation across county lines and/or if needed to adhere to social distancing protocols, and participants will be asked to register only if they can ensure their privacy for the duration of the videoconference; (3) Participants will be reminded not to state personal identifying information (their own or others') when they are being recorded (and in the event of an inadvertent disclosure, this information will be redacted from the produced transcript); (4) Participants will be reminded to disclose only that which they feel comfortable sharing; and (5) The transcription service will use data encryption and secure servers to download files, which minimizes the risk of breaches when transferring digital audio files.

To minimize discomfort or negative feelings during or after focus groups and individual provider interviews: (1) Participants will be assured that their answers are confidential and what they say will not be shared with their employer (for providers) or their service providers (for patients) or have any bearing on their employment or contract funding status (for providers) or the services they may receive (for patients); (2) Participants will be able to decline to answer questions they find uncomfortable or objectionable for any reason, which will be stated clearly in the initial oral informed consent process and at the beginning of each session; (3) Contact information (for the study team and IRB) will be available to participants in case of any questions or concerns; (4) DOHMH staff will seek RWPA providers' or RWPA provider-adjacent stakeholders' review of question guides, to avoid the inclusion of any unnecessarily intrusive or potentially inappropriate questions.
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N. Data Safety Monitoring ☐ N/A

Describe how data and safety will be monitored locally to identify unanticipated problems (i.e., events, outcomes, or occurrences that are unexpected, at least possibly related to the research, and suggest an increase in risk of harm to subjects or others).

This study does not involve the testing or new application of any drug, medical treatment, or device. No participant will be enrolled in RWPA services or recruited to deliver RWPA services for the purpose of this trial. Rather, we will work with existing staff of participating RWPA-funded programs, who will triage their existing enrollees for adherence-related support based in part on the D2S reports provided by the DOHMH. Given the minimal-risk nature of the proposed study, this project should not require a separate Data and Safety Monitoring Board. Instead, we propose monitoring by the joint Principal Investigators (PIs) and the IRB of record, based at the NYC DOHMH. The PIs (D. Nash and M. Irvine) will report to the IRB any adverse events or unexpected problems that could potentially influence the IRB's decision to allow the trial to continue. The PIs will also directly notify the NIMH Program Official (PO) of any reportable events, and will cover study monitoring activities, along with any resulting changes to the study, in the annual progress report to the NIMH. The investigators will *not* be delivering any services to clients, but have close communication with site staff who do deliver services and monitor clients' well-being.

Serious adverse events (SAEs) are highly unlikely to be precipitated by the activities of this study. As described above, the PIs, with the DOHMH IRB, will oversee all procedures designed to continuously monitor participant safety. The

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New York City Department of Health and Mental Hygiene
Gotham Center – 31A
42-09 28th Street, 14th Floor
Queens, New York 11101-4132
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study team will have regular meetings to discuss actual or potential issues that may affect participants' safety. During these meetings, the investigators will review the progress of all study participants (including relevant data obtained for each participant) to ensure adherence to all standards for maintaining participants' safety and confidentiality.

Reporting of events. If a SAE, death or other problem involving risk to a participant or other person is reported to one of the PIs, they will immediately communicate the event to the DOHMH IRB Chair. This verbal report will be followed by a written report to the IRB within three business days. If the event is determined to be unexpected and related to study participation, the PIs will report the event in writing to the NIMH PO within 5 business days, in the case of a death, or within 10 business days of first awareness of any other (non-fatal) event. Documentation of reportable events will including the following: identifying information for the protocol (project title, grant number and PI names); the date on which the event occurred and the date on which a PI first became aware of the event; a detailed description of the event and impact on the participant(s); a detailed description of the measures taken in response to the event (if any); confirmation that the appropriate monitoring entities and regulatory bodies have been notified as needed; and a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the event. The PIs and the DOHMH IRB will review the event and determine whether there is sufficient evidence to necessitate suspension or early termination of the study, further IRB review, modification of the study protocol, or other changes. The NIMH PO will receive a written report within three business days of any suspension or termination of the study. The PIs will provide an annual summary report of all reportable events to the DOHMH IRB as part of the annual review and to the NIMH as part of the annual Progress Report. The PIs, with the DOHMH IRB, are ultimately responsible for the Data and Safety Monitoring Plan. The PIs are also responsible for requesting IRB and NIMH approval of any amendments to the protocol.

O. Potential Risks

Describe risks including data on risks that have been encountered in past studies. That is, if the occurrence of a certain adverse event was 20%, include those data in this description. Please include steps that will be taken to minimize the risk or harms to protect the welfare of subjects.

Level of Risk (please select):
☒ Minimal Risk
☐ Greater than Minimal Risk

Please note that the regulations indicate that *minimal risk* is risk that is not greater that those ordinarily encountered in daily life or during the performance of routine procedures.

Aim 1. The proposed intervention and analyses present minimal risks to clients and participating providers. The D2S intervention will be implemented at the program level (sometimes with multiple eligible programs at a given site, which may constitute all RWPA programs at that site), and usual client services will not be negatively impacted (e.g., receipt of mental health services). The intervention is designed to enhance and focus existing RWPA services to promote client VS. Risks to clients include potential violation of confidentiality. However, the level of risk is not substantially increased by the conduct of the proposed study, since each program will receive a program-specific list of clients in their existing caseload, whose HIV-related services data the program has already reported to DOHMH. In addition, only coded (sequentially-generated) eSHARE client identifiers (linkable to personal identifiers only by authorized users of eSHARE for that program) will be used in the client lists sent to programs, and no mention of HIV

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will appear on the reports. These report features minimize the potential risk in the event that a list is intercepted by some person other than the intended recipient/user. In addition to these precautions, the lists will always be transmitted securely (not via regular e-mail), such that they can only be downloaded by the individual recipient(s) for whom they are intended at a given site. In terms of any risks associated with report generation or the analysis of VL outcomes from the stepped-wedge trial, DOHMH already regularly conducts analyses of HIV program data merged with HIV surveillance data and site-/program- level data, to carry out its monitoring and evaluation responsibilities as the RWPA and HOPWA grantee; the analyses proposed for this study pose no additional risk. Analyses involving HIV program data merged with HCV surveillance data are also conducted routinely at DOHMH, including by BHHS staff based in the HIV Care and Treatment Program's Research and Evaluation Unit. Regarding client outreach and follow-up prompted by the D2S reports and capacity-building, the level of risk to clients is minimized through the use of existing, trained RWPA patient navigators (PNs) already integrated on the staff of the participating programs, as opposed to the use of health department staff or outreach workers hired for the purpose of the project. Most or all clients outreached for D2S should already be familiar with the PNs leading those interactions; all will be familiar with the participating RWPA programs represented by those PNs.

Aim 1 primary data collection presents minimal risk to participating providers. Individual interviews pose some potential risk of raising uncomfortable feelings for participants; however, interviews will be focused on work-related objectives, observations, and conditions, rather than staff personal experiences or health.

Aim 2. The proposed analyses present minimal risk to patients/clients. Only secondary analyses of existing data (i.e., programmatic data, surveillance data, and administrative site- or program-level data) are proposed for Aim 2. Risks to subjects include potential violation of confidentiality. However, the level of risk is in no way increased by the conduct of Aim 2 analyses. DOHMH already regularly conducts secondary analyses of HIV program data merged with HIV surveillance data and site-/program- level data. The proposed assessment of individual and higher-level modifiable drivers of VS will not increase the risk of confidentiality violations for clients.

Aim 3. Primary data collection presents minimal risks to participants. The study team will not collect individual health-related data or personal identifiers, except for minimal contact details. In the case of RWPA program staff, contact details are already shared with the DOHMH for RWPA contractual and technical assistance communications. In the case of clients, only first names or client-chosen nicknames will be used in follow-up communications, and only after clients have agreed to participate in a focus group and to be contacted with date/time and location details or reminders. In addition, the strictest, state-of-the-art data security and privacy measures (already in place as part of routine program implementation and monitoring, routine conduct of NYC HIV surveillance, and interviewing procedures used in prior research by this study team) will be employed to ensure the confidentiality of all participant information shared and analyzed as part of this protocol. However, as with all studies involving individual-level data, there is always a slight risk of loss of privacy for study participants. Procedures put in place to maintain privacy and meticulously followed to minimize risk include: intensive training of study staff on participant confidentiality; maintenance of detailed field security protocols and standards of practice related to physical and electronic protections of participant data; and (in the case of individual surveys) the use of study identification numbers (rather than personal identifiers) on study documents and analytic datasets, with the exception of the master 'key' (securely maintained at DOHMH). The master 'key'/crosswalk linking study identification numbers to minimal personal identifiers will be stored separately from other study files and will be opened only when needed for purposes of

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matching/ merging data across sources and for confirming participant completion of participation (for tracking of recruitment/primary data collection progress and identifying participants who require further follow-up). In this study, only site-level or program-level data will be merged with DCE data, since the participants are program staff. No individual-level data will be merged with client focus group responses, as no full names will be collected and client descriptive information (basic demographics and referring program/site information gathered during the screening/ registration process) will only be kept in the aggregate. Risks include the loss of privacy and/or confidentiality during data collection and analysis, and negative or uncomfortable feelings brought up by focus group or survey questions. However, since provider data collection will focus on potential data uses, technical assistance needs, follow-up activities with clients, other aspects of staff members' jobs, and D2S intervention elements, the sessions and surveys are not expected to bring up feelings related to participants' personal experiences. Client focus groups will also be guided to home in on aspects of the intervention, how it might be improved or altered, and how acceptable and/or valuable specific elements were to clients in the trial, rather than exploring clients' experiences outside of their program/provider interactions and service needs related to the D2S intervention.

Administrative supplement: The administrative supplement presents minimal risks to participants. The DD process will not impact usual RWPA services (e.g., receipt of mental health services). Risks to participants include potential violation of confidentiality. However, the level of risk is not substantially increased by the conduct of the proposed study, relative to the risks of regular participation in RWPA services (which involves routine client-level data reporting to the DOHMH) or regular participation in the HIV Planning Council's Consumers Committee. The study team will not collect individual health-related data or personal identifiers, except for minimal contact details and the client's eSHARE ID, to be retained only as long as needed for the planning and confirmation of session attendance and release of participant incentives. Only first names or chosen nicknames will be used in follow-up communications, and only after participants have agreed to participate in the DD experiment. In addition, the strictest, state-of-the-art data security and privacy measures (already in place as part of routine program implementation and monitoring, routine conduct of NYC HIV surveillance, and interviewing procedures used in prior research by this study team) will be employed to ensure the confidentiality of all participant information shared and analyzed as part of this protocol. However, as with all studies involving individual-level data, there is always a slight risk of loss of privacy for study participants. Procedures put in place to maintain privacy and meticulously followed to minimize risk include: intensive training of study staff on participant confidentiality; maintenance of detailed field security protocols and standards of practice related to physical and electronic protections of participant data; and (in the case of individual surveys) the use of study identification numbers (rather than personal identifiers) on study documents and analytic datasets.
In this study, only site-level or program-level data will be merged with evaluation surveys and qualitative data. Risks include the loss of privacy and/or confidentiality during data collection and analysis, and negative or uncomfortable feelings brought up during DD sessions or evaluation. We will mitigate
these risks by hiring facilitators to lead small groups who are specifically trained in equity and cultural humility. Sessions will also be guided to home in on issues related to data privacy, data sharing, and client autonomy, rather than exploring clients' own service needs or personal health care or illness experiences.

P. Potential Benefits

This description should also be based on accrued data from related studies that have been completed. Anticipated benefits of this study may include to society, knowledge, and/or direct benefit to the subjects.

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Please note that compensation cannot be a potential benefit for participating in the study.

For all Aims, there are no anticipated direct benefits of the research to subjects. Potentially, an indirect benefit for RWPA clients included in study secondary analyses or focus groups (as well as other people with HIV [PWH]) would be improved health or well-being through the continual improvement of HIV services, based on findings from the proposed study. The analyses conducted and intervention strategies tested and refined as part of the proposed study may inform future programs, service delivery models, and policies. They may specifically support decisions that will maximize the efficiency of HIV service delivery for achieving and sustaining VS, in NYC and other jurisdictions.

Clients included in D2S reports delivered to their RWPA providers as part of the intervention may receive more rapid follow-up and assistance than they would in the absence of the intervention. They may indirectly benefit through supportive services delivered to reduce barriers to suppression, and through increased or accelerated ability to adhere to ART and achieve/maintain VS, and thus improve/maintain overall immunity and health.

Addressing barriers to VS may also indirectly improve overall quality of life. We expect that the barriers to be addressed will include individual and higher-level factors such as patient-provider relationships, mental health issues, substance use, unstable housing, and unemployment. It is possible that support-service providers will be able to mitigate or remove these barriers through, for example, placing clients in safe and stable housing and/or aiding in the transition to a preferred, culturally competent medical provider.

Providers participating in the focus groups, interviews, and DCEs will receive no direct benefits as targets of the D2S intervention, but there may be psychosocial benefits accrued by contributing to the improvement of the healthcare system. There may also be downstream improvements to organizational culture and job satisfaction (and prevention of burnout), due to being better able to care effectively for vulnerable/ unsuppressed PWH.

For the administrative supplement, there are no anticipated direct benefits of the research to subjects. Potentially, an indirect benefit for RWPA clients as well as other people with HIV (PWH) would be improved processes for the use of HIV-related data in program implementation and ending-the-HIV-epidemic/data-to-care/data-to-suppression activities, based on findings from the proposed study.
The activities to be conducted may inform future programs, service delivery models, and policies. They may specifically inform the integration of consumer perspectives in initiatives to improve HIV viral suppression, in NYC and other jurisdictions. The DD process may also empower RWPA clients and better engage RWPA clients in their own HIV care, by recognizing their autonomy and increasing their day-to-day control over the uses of their HIV laboratory data.

Q. Alternatives

Describe alternative therapies providing data to support their efficacy or lack of efficacy. An important alternative is also not to participate in this research.

The alternative to agreeing to participate is not to participate in the study. Care that patients receive at the program sites will not be affected by a decision to participate, withdraw or not participate in the study. Similarly, program staff

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decisions to participate, withdraw or not participate will not affect their employment or Ryan White contract status with the DOHMH.

R. External Sites ☐ **N/A**

Please indicate all external parties that will be involved in the study. If investigators will be conducting research at one or more non-DOHMH site(s), additional information is required. This includes, but is not limited to, plans for authorization and/or IRB approval at each site, explanation of funding and organizational relationships, description of procedures at each site, and plans for data and safety monitoring. Details, as applicable to the various types of situations that may occur. Describe whether results will be shared with subjects or others (e.g., the subject's or their primary care physicians), and if so, describe how it will be shared. As applicable, this may include individual patient results (genetic testing), incidental findings, or overall study findings.

☐ External IRB Document(s) attached
☐ This research study involves a contract with an approved vendor

CUNY ISPH will function as the lead agency and academic partner for the proposed project, while DOHMH will serve as the subcontracting agency and government partner. DOHMH will conduct screening for purposive sampling (for focus groups), and will lead recruitment of both providers and patients through communications with its RWPA contractors, who are already in regular communication with DOHMH regarding their RWPA programs. ISPH will participate in final sampling decisions and in instrument/ discussion guide development, and will conduct focus groups and provider interviews. ISPH will also lead qualitative analyses and DCE survey analyses, though DOHMH analysts may contribute to qualitative focus group coding. DOHMH analysts will be the sole handlers of client-level BHHS secondary data sources. Both institutions will be responsible for the overall synthesis, interpretation, and dissemination of data, and the engagement of the AB. Dr. Irvine of the DOHMH will function as the point person coordinating AB communications.

It is not expected that individual program sites (where some recruitment and data collection will take place) will require IRB approvals from their own agencies, since the agency staff will never be responsible for recruiting patients and collecting informed consent, nor will they be responsible for collecting or storing any study data. They will only be asked to support recruitment by the DOHMH-CUNY study team, through staff assistance with the initial introduction of the study opportunity and referring any willing focus-group participants to the study team (by providing study team members' contact details) for further communications. If those sites later determine there is a need to engage their agency IRBs, the DOHMH-CUNY study team will work closely with those sites to obtain and maintain their IRB approvals, and will restrict data collection falling under their IRBs to periods in which their IRB approvals are current/active.

DOHMH evaluation and quality management of RWPA programs are built into the services contract agreement with each RWPA-funded agency. The DOHMH is the RWPA Grantee (recipient of federal funds from HRSA) for the New York eligible metropolitan area, and is responsible for the contract administration, evaluation, planning and continual quality improvement of New York Ryan White Part A programs.

Results of the study will be shared only in the aggregate, with RWPA providers, patients/consumers, and HIV Health and Human Services Planning Council of NY members (representing a mix of patients/consumers, policy makers,

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advocates, and service providers or administrators who partner with DOHMH in planning and decision-making related to Ryan White Part A services). More preliminary and in-depth presentations and discussion of study findings will take place in AB meetings, for the input and guidance of AB members, representing multiple stakeholder groups. In addition, study findings will be shared (also in the aggregate) beyond these local stakeholders, with other researchers, policy-makers, healthcare professionals, consumers, advocates and students or other interested audiences – at local, national and international conferences and in peer-reviewed journals.

S. NYC DOHMH as Lead Institution ☐ **N/A**

If NYC DOHMH will serve as the lead institution for a multi-site study, specific information about management of information related to safety of subjects must be provided. This includes, but is not limited to: 1) obtaining and maintaining IRB approval at each site; 2) ensuring that each site follows consent procedures and utilizes consent documents approved by the designated IRB (if the designated IRB is not the NYC DOHMH IRB, then the IRB-approved consent document must be similar to the NYC DOHMH IRB-approved consent document with regards the content and style of the document); and 3) plans for data and safety monitoring.

☐ Individual Investigator Agreement(s) attached
☒ IRB Authorization Agreement(s) attached

This is a multi-site study involving non-exempt human subjects research (HSR). In accordance with National Institutes of Health (NIH) policy, all sites confirm the use of a single Institutional Review Board (IRB).

Single IRB of Record: The New York City (NYC) Department of Health and Mental Hygiene (DOHMH) IRB will serve as the single IRB of record for the proposed study. The partnering institutions agree to this reliance upon the review of the DOHMH IRB. Participating NYC Ryan White Part A (RWPA) agencies will be advised of the DOHMH IRB's role as the IRB of record for this project, once the study is funded (expected July 2021), and the DOHMH IRB contact information will be included on all informed consent documents.

The DOHMH IRB is registered with the federal Office for Human Research Protections. The IRB that will review the protocol has appropriate membership, including the professional competence necessary to critically review the proposed research.

Communication Plan: As the institution housing the existing person-level and agency-level data sources to be leveraged for this study (e.g., HIV programmatic and surveillance datasets and RWPA HIV services contract documents) and the only institution storing participant personal identifiers, DOHMH will be the central point of contact for the IRB. As such, DOHMH commits to the following:

- Coordinate communication with other sites;
- Request and receive information and documents from relying sites;
- Develop template materials for review by the DOHMH IRB and for limited modification by other sites;

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- Submit materials from all sites to the DOHMH IRB and coordinate responses to any IRB queries; and
- Provide documentation to other sites.

Other participating study sites will provide necessary information and assurances to the DOHMH for submission to the IRB. For example, all City University of New York (CUNY) Institute of Implementation Science in Population Health (ISPH) study team members and ISPH-hired consultants will be listed on the DOHMH IRB application, and their CVs and HSR certifications (CITI) will also be maintained up to date and filed with the DOHMH IRB. The DOHMH IRB will communicate directly with the study team as a proxy for all relying sites (e.g., CUNY ISPH).

Individual Authorization Agreement: All participating sites shall enter into and sign an institutional authorization agreement (IAA) prior to the initiation of the study, as has been done in our previous studies.

Recordkeeping: As the lead institution under the grant, ISPH will be responsible for maintaining records related to the fully executed IAA. ISPH will also be responsible for maintaining records related to the Communication Plan.

T. FUTURE RESEARCH ☒ N/A

Please indicate if there are plans to retain, maintain, use or share the information collected from this research study for future research. If applicable, please include a description of the types of research, period of time, and whether sharing or plans to make information publically available.

We expect to disseminate findings from this study through public meetings, scientific conferences and publications. If the D2S intervention proves effective and feasible to implement, we expect to integrate it into broader practice with HIV-related health and human services contracts. We do not at present have any commitment to or funding for future research.

U. ATTESTATION

By submitting this form to the IRB, the Principal Investigator (PI) and study team members completing this form **attest** that the information provided on this form is correct and complete. The PI and study team members pledge to not change, modify, or revise any of the procedures, forms, or protocols used in this study without first seeking review and approval from the Institutional Review Board.

This form was completed on behalf of the Principal Investigator by*: Mary K. Irvine (PI) Date: May 13, 2021

The Principal Investigator (PI) may designate an individual on the research team to complete regulatory documents. The PI must review all information and agree to the statement above. Please cc the PI on all electronic communications