# Introducing experimental design into real-world practice settings: Protocol for a cross-sectional stepped-wedge effectiveness trial of the New York City HIV Care Coordination Redesign

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## Purpose

- The overall goal of the **health department-university collaborative study** known as Program Refinements to Optimize Model Impact and Scalability based on Evidence (PROMISE) is **to investigate the impact and implementation of empirically driven course corrections to an *already effective intervention model*.**
- PROMISE Aim 1: **Test the effect of program revisions in a cluster-randomized controlled trial** applying a cross-sectional, stepped-wedge design to the rollout of the revisions.

## Hypothesis

- Drawing upon an implementation science framework, we posit that model revisions will minimize logistical and administrative barriers to service delivery, increasing reach, engagement, fidelity and effectiveness.
- Specifically, **we hypothesize that a higher proportion of clients enrolled in the Care Coordination revised (CCR) program with unsuppressed HIV viral load (VL) will achieve timely viral suppression (VS), as compared with their counterparts enrolled in the original Care Coordination Program.**

## Background

- In New York City (NYC), a multi-component Ryan White Part A–funded medical case management intervention known as **the Care Coordination Program (CCP) was launched in 2009 to meet the needs of persons with HIV (PWH) with suboptimal care outcomes or a recent diagnosis.**[1]
- In its first 8 years, **the CCP showed significant benefits for care retention and VS**,[2,3,4] particularly for the most vulnerable clients. **Yet room for improvement remained**, and some CCP design features curbed client and provider engagement.[5]
- In response to identified implementation barriers and the evolving intervention literature, **CCP model revisions were integrated into the Health Department's 2017 request for proposals (RFP) initiating a competitive selection process for Care Coordination service delivery contracts.**
- Based on preliminary health department-university discussions, the RFP outlined plans for agency randomization to an early or delayed start of the revised model, for an experimental evaluation of effectiveness.

## Participants, Intervention & Outcomes

***Intervention (CCR) & Control (CCP) Conditions***

- The control condition is the site-level continuation of CCP delivery; the intervention condition is a site-level change to deliver the CCR. *(See Table 1 for key differences.)*

*Table 1: CCR features expected to boost uptake, fidelity, engagement, effectiveness, reach*

| | Added Components | | | Changed | | Removed |
|---|---|---|---|---|---|---|
| | Self-management assessment | Use of video chat tools (optional) | iART (optional) | Eligibility criteria | Payment structure | Rigid program tracks |
| **Uptake (provider)** | | | | | | X |
| **Fidelity (provider)** | | X | | | X | X |
| **Engagement (client)** | X | X | | | | X |
| **Intervention effectiveness** | X | X | X | | X | X |
| **Population reach/impact** | X | X | X | X | X | X |

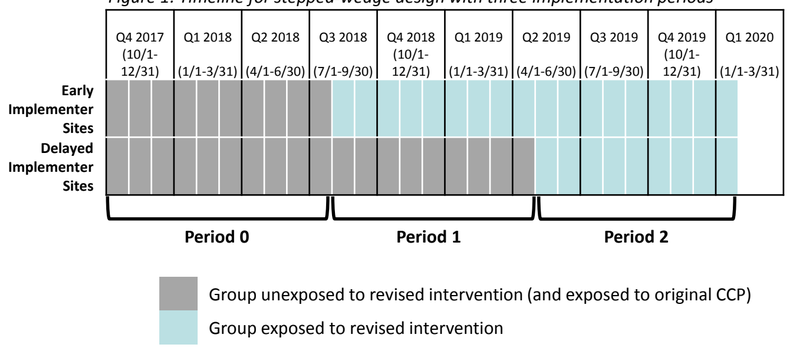
***Outcome Measurement***

- **Timely VS (TVS)**: VL <200 on last VL test reported to the HIV surveillance registry in the four months following enrollment (TVS=1).
  - Missing VL is classified as TVS=0, given a lack of monitoring since the last unsuppressed VL.

***Eligibility Criteria for Trial***

- **Clients:** newly enrolled in the CCP/CCR with unsuppressed VL (≥200) at their last test in the year prior to enrollment or with no VL test result in that year.
- **Agencies:** 17 previously funded/re-awarded agencies (that could be assigned to continue CCP delivery uninterrupted or begin CCR delivery in the initial implementation phase).

*Figure 1: Timeline for stepped-wedge design with three implementation periods*




## Assignment of Interventions

***Randomization***

- The unit of randomization is the Care Coordination provider agency (i.e., cluster).
- The 17 agencies were matched and randomized within pairs (including one case in which two smaller agencies were matched to a larger one). Matching accounted for attributes plausibly related to the outcome: agency type, primary location and program size (*Table 2*).

## Assignment of Interventions (continued)

*Table 2: Agency characteristics, pairings and study arm assignments*

| Agency ID | Typical (prior) Caseload | Award increased >20% from prior year? | Borough | Type of Site | Phase (study arm) |
|---|---|---|---|---|---|
| 21 | 84 | Yes | Bronx | CBO/no clinical services | 1 |
| 1 | 101 | No | Bronx | CBO/no clinical services | 2 |
| 20 | 109 | Yes | Brooklyn | Public Hospital | 1 |
| 14 | 151 | No | Brooklyn | Public Hospital | 2 |
| 28 | 87 | Yes | Brooklyn | Private Hospital | 1 |
| 24 | 96 | No | Brooklyn | Community Health Center | 2 |
| 25 | 62 | No | Manhattan | Community Health Center | 1 |
| 9 | 78 | No | Manhattan | Community Health Center | 2 |
| 23 | 228 | No | Manhattan | Private Hospital | 1 |
| 18 | 220 | No | Manhattan | Private Hospital | 2 |
| 13 | 82 | Yes | Bronx | Public Hospital | 1 |
| 11 | 82 | Yes | Queens | Public Hospital | 2 |
| 5 | 202 | No | Bronx | Private Hospital | 1 |
| 4 | 181 | No | Manhattan | Private Hospital | 2 |
| 8 | 77 | Yes | Staten Island | CBO/no clinical services | 1 |
| 16 | 63 | No | Brooklyn | Community Health Center | 1 |
| 2 | 184 | No | Manhattan | Community Health Center | 2 |

## Statistical Analysis, Sample Size & Power

***Analysis Approach***

- The analysis plan is based on the exact, conditional distribution theory of non-central multiple hypergeometric distributions and their convolutions, which will enable us to estimate and test the effect of the revised intervention as a single parameter (having conditioned out nuisance site and period effects).[6]
- Table 3 provides the detectable effect size and power values given actual, post-randomization numbers of eligible clients for Periods 0 (N=169) and 1 (N=389), a conservative estimate of eligible clients for Period 2 (N=266), and TVS proportions for Period 0.
- The detectable effect size (80% power with exact Type I error rate ≤0.05 two-tailed) is currently an OR of 2.90, corresponding to RRs between 1.49 and 1.74. Power estimates range between ~76% and 83% for true ORs between 2.75 and 3.00, respectively.

*Table 3: Power calculations for the CCR effect on TVS*

| Reference P [TVS] | Detectable P [TVS] | Risk ratio at Detectable P [TVS] for True OR=2.90 | True OR | Power (%) |
|---|---|---|---|---|
| 0.35 | 0.610 | 1.74 | 3.00 | 82.8 |
| 0.40 | 0.659 | 1.65 | 2.95 | 81.1 |
| 0.45 | 0.704 | 1.56 | 2.90 | 80.6 |
| 0.50 | 0.744 | 1.49 | 2.85 | 78.7 |
| | | | 2.80 | 77.8 |
| | | | 2.75 | 75.8 |

Note: Average P[TVS] among all sites in base period = 0.465.
Monte Carlo standard error for power values is less than 0.5%.

## Discussion

- The PROMISE trial, conducted in real-world service settings, uses secondary analyses of merged surveillance and program data to assess the effects of a revised (CCR) vs. original Care Coordination intervention on VS.
- **To meet stakeholder expectations for rapid CCR rollout, the study applies a stepped-wedge design with a nine-month gap between implementation phases**, prompting use of a short-term (4-month) outcome and a brief (5-month) lead-in time for client enrollment accumulation.
- **Randomization at the agency level minimizes crossover** between intervention conditions; providers would otherwise struggle logistically/ethically with simultaneously delivering two intervention models based on random client assignment.
- **Randomization within matched pairs** offers advantages akin to those of stratified random assignment: raising power when the number of units of randomization is small, by maximizing equivalency between the intervention and control groups.

## Conclusions

- **'Phasing in' an intervention with random assignment to early or delayed implementation offers a means of rigorously evaluating a set of changes to a major public-services program, while ensuring fair, uninterrupted access** to its benefits in the eligible population.
- **Through robust health department-university partnerships that include joint planning of research in advance of key policy or practice initiatives, locally important research questions can be answered without substantially slowing the pace of desired change, and with methods that support knowledge generation and generalizability**.

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