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 (PROMISE) is to investigate the impact and implementation of empirically driven core correction strategies in 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 (TVS) 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 care 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.
- In its first 8 years, the CCP showed significant benefits for care retention and VL suppression, particularly for the most vulnerable clients. Yet, room for improvement remained, and some CCP design features curbed client and provider engagement.
- 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 application process for Care Coordination service delivery contracts.
- Based on preliminary health department-university discussions, the RFP outlined criteria for agency randomization to an early or delayed start of the revised model, for an experimental evaluation of effectiveness.

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

<table>
<thead>
<tr>
<th>Feature</th>
<th>CCP</th>
<th>CCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uptake (provider)</td>
<td>N/A</td>
<td>X</td>
</tr>
<tr>
<td>Fidelity (provider)</td>
<td>N/A</td>
<td>X</td>
</tr>
<tr>
<td>Engagement (client)</td>
<td>N/A</td>
<td>X</td>
</tr>
<tr>
<td>Intervention effect (hospital)</td>
<td>N/A</td>
<td>X</td>
</tr>
<tr>
<td>Population reach/impact</td>
<td>N/A</td>
<td>X</td>
</tr>
</tbody>
</table>

Outcome Measure

- 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 CCR/CCP 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 CCR delivery uninterrupted or begin CCR delivery in the initial implementation phase).

statistical analysis, sample size & power

- 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).
- Table 3 provides the detectable effect size and power values given actual, post-randomization numbers of eligible clients for Periods 2 (N=149) 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 1.74.

randomization

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