Strengthening the Evidence for HIV Care Continuum Interventions, Through Academic-Government Research Partnerships

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Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention
BACKGROUND: NEW YORK CITY (NYC) HIV CARE CONTINUUM, RYAN WHITE PART A & HIV CARE COORDINATION PROGRAM
HIV CARE CONTINUUM, FOR ALL PLWH AND NEWLY DIAGNOSED PLWH, NYC 2017

All PLWH

- People living with HIV: 100%
- HIV diagnosed: 95%
- In care: 89%
- Retained in continuous care: 85%
- Virologically suppressed: 75%

Newly diagnosed PLWH

- Newly Diagnosed: 100%
- Linked to care: 75% (2016)
- Virologically suppressed within 12m: 74% (2016)

Viral suppression: Percent of newly diagnosed people with any viral load measurement ≤ 200 copies/mL, within 12 months of diagnosis.

Virologically suppressed within 12m: 61% (2017)
NY RWPA: ~14,000 PLWH served annually in the New York Eligible Metropolitan Area (EMA)

- Local program predominantly focuses on providing supportive (vs. medical) services, including *but not limited to*:
  - Medical case management (including HIV Care Coordination)
  - Non-medical case management
  - Food/nutrition
  - Harm reduction
  - Mental Health
  - Health education/risk reduction
  - Housing
- Funds are contracted out to community based organizations, hospitals/health centers & other provider agencies
- ~90% of the local RWPA client population identifies as Black or Hispanic/Latino(a)
NYC HIV Care Coordination Program (CCP)

Launched in 2009 with Ryan White Part A funding at 28 agencies
Based in HIV clinics and in community-based organizations that have formal partnerships with HIV primary care providers
Provides comprehensive medical case management to PLWH who are:
  • newly diagnosed
  • lost to care or sporadically in care
  • new to care
  • new to treatment
  • struggling with ART adherence

Irvine et al. CID 2015; Nash et al. PLoS One 2018; Robertson MR et al. AJE 2018
THE CCP MODEL

What is it?

Who is it?
THE CHORDS STUDY (2013-19)

Costs, Health Outcomes and Real-world Determinants of Success in HIV Care Coordination (R01 MH101028, Principal Investigators: M. Irvine, D. Nash)
METHODS — DATA SOURCES

1. Provider reporting in eSHARE (local HIV services database)
   - Contains information on all CCP enrollees
   - CCP providers contractually required to submit programmatic data

2. NYC HIV surveillance registry
   - Contains information on all HIV diagnoses in NYC
   - Including comprehensive laboratory information (CD4 and VL data) for individuals who receive HIV medical care
**Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE) contains program reporting.**

**The NYC HIV Registry contains information on new HIV diagnoses, diagnosis date, demographics, risk factors, history of AIDS, longitudinal viral load and CD4 count results, and vital status.**
### ‘USUAL-CARE’ COMPARISON GROUP

**A.** Randomly assigned a pseudo-enrollment date to people who appeared eligible but not enrolled in CCP

**B.** Matched CCP enrollees to those in the usual-care group on

1. Propensity for CCP enrollment
2. Pseudo-enrollment/enrollment dates and
3. Treatment status at enrollment

### Variables in Propensity Score

<table>
<thead>
<tr>
<th>Category</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic variables</td>
<td>Sex, race/ethnicity, age, country of birth, HIV transmission risk</td>
</tr>
<tr>
<td>Clinical variables</td>
<td>Year of diagnosis, baseline VL, baseline CD4, linkage to care, concurrent AIDS and HIV diagnoses, number of VLs in 12 months prior to enrollment</td>
</tr>
<tr>
<td>Neighborhood variables</td>
<td>ZIP code at enrollment, HIV prevalence and poverty levels within ZIP code at enrollment</td>
</tr>
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</table>
## CCP VS. NON-CCP PLWH CHARACTERISTICS
### BEFORE & AFTER PROPENSITY MATCH

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Pre Match</th>
<th>Post Match</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Non-CCP N (%)</td>
<td>CCP N (%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>57,746 (100)</td>
<td>7,058 (100)</td>
</tr>
<tr>
<td>Male</td>
<td>42,067 (72.9)</td>
<td>4,525 (64.1)</td>
</tr>
<tr>
<td>Non-White</td>
<td>45,606 (79.0)</td>
<td>6,622 (93.8)</td>
</tr>
<tr>
<td>18-44</td>
<td>27,329 (47.2)</td>
<td>3,554 (50.4)</td>
</tr>
<tr>
<td>Foreign Born</td>
<td>10,463 (18.1)</td>
<td>1,629 (23.1)</td>
</tr>
<tr>
<td>Baseline Viral Load &gt;200*</td>
<td>37,271 (64.5)</td>
<td>4,862 (68.9)</td>
</tr>
<tr>
<td>Baseline CD4 &lt;200</td>
<td>6,999 (12.1)</td>
<td>2,303 (32.6)</td>
</tr>
<tr>
<td>Men who have Sex with Men</td>
<td>22,887 (38.6)</td>
<td>2,064 (29.2)</td>
</tr>
<tr>
<td>Injection Drug Use History</td>
<td>8,698 (15.1)</td>
<td>1,920 (21.1)</td>
</tr>
</tbody>
</table>

Robertson MR et al. AJE 2018; Nash et al. PLoS One 2018
### RESULTS: VIRAL SUPPRESSION (VS, %) AT 12 MONTHS AFTER ENROLLMENT — CCP VERSUS USUAL CARE, BY BASELINE TREATMENT STATUS

<table>
<thead>
<tr>
<th>Baseline Treatment Status</th>
<th>Total</th>
<th>Newly Diagnosed</th>
<th>No Evidence of Viral Suppression</th>
<th>Inconsistent Viral Suppression</th>
<th>Consistent Viral Suppression</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCP</td>
<td>59.9</td>
<td>73.3</td>
<td>42.5</td>
<td>62.2</td>
<td>91.7</td>
</tr>
<tr>
<td>Usual Care</td>
<td>53.9</td>
<td>63.3</td>
<td>32.1</td>
<td>62.3</td>
<td>90.6</td>
</tr>
</tbody>
</table>

RR = 1.32 (1.23, 1.42)

RR = 1.15 (1.09, 1.23)

RR = 0.99 (0.95, 1.05)

RR = 1.01 (0.98, 1.04)

Viral Suppression: latest-dated VL within 12 months after enrollment/pseudo-enrollment ≤200 copies/µL

Nash et al. PLoS One 2018
RESULTS: DURABLE VIRAL SUPPRESSION (DVS, %) AT 13-36 MONTHS AFTER ENROLLMENT — CCP VERSUS USUAL CARE, BY BASELINE TREATMENT STATUS

Durable Viral Suppression: ≥1 VL in each 12-month period of follow-up and All VLs ≤200 copies/µL from 13-36 months

Robertson MR et al. JAIDS 2019
CHORDS CONCLUSIONS

The CCP has shown short- and long-term benefits (in terms of VS) among previously unsuppressed PLWH, as well as short-term benefits among newly diagnosed individuals.

However, there remains room for improvement.

- Over one-third of clients drop out of the program in the first year
- The proportion with DVS was very low (37%), despite 90% of the cohort (CCP and non-CCP) achieving VS at least once in months 13-36
- Among clients without evidence of VS in the year prior to enrollment, only 43% achieve VS at 12-month follow-up, and only 21% achieve DVS
- Findings suggest a substantial need for sustained, and perhaps more intensive, adherence support in this population

The potential for short- and long-term impact, and desirability of further scale-up, could be increased through some strategic changes to the CCP…
PROMISE (2018-23)

Program Refinements to Optimize Model Impact and Scalability based on Evidence (R01 MH117793, Principal Investigators: M. Irvine, D. Nash)
Context: In response to implementation experience/provider input and the literature—program revisions were integrated into the Health Department’s late-2017 request for proposals (RFP) initiating a competitive selection process for future CCP contracts.

- RFP outlined plan for randomization to early or delayed start of revised model

Objective: To study the impact and implementation of course corrections to an already evidence-informed intervention.

Premise: Revisions will minimize logistical and administrative barriers to service delivery and increase program engagement (among staff and clients), reach, fidelity and effectiveness.
**CHANGES: ORIGINAL VS. REVISED MODEL**

Added flexibility & tools to match services to current client needs

<table>
<thead>
<tr>
<th>Added Components</th>
<th>Changed</th>
<th>Removed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-management assessment</td>
<td>Use of video chat tools (optional)</td>
<td>iART (optional)</td>
</tr>
<tr>
<td>Uptake (provider)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fidelity (provider)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Engagement (client)</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Reach/impact</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Irvine et al. MedRxiv 2019
Figure 1. Implementation Science (IS) Conceptual Framework

IS-Informed Intervention Theory
1) Overall Revised CCP Implementation
Revisions informed by RE-AIM framework
2) Revision Component: Tailoring/Flexibility
Tailoring aligns with IS literature on matching interventions to patient and provider contexts
3) Revision Component: Payment Structure
Shift to fee-for-service payment with tiered rates addresses financial influences on service delivery

IS-Informed Study Design
1) RE-AIM Framework
Offers measures for key implementation processes and links those to effectiveness
2) CFIR Framework
Supports RE-AIM by identifying influences on the RE-AIM outcomes and testing intervention/implementation theory

Cumulative Outcomes Analysis
Implementation Outcomes
• Program reach
• Quality of care
• Sustainability
Intermediate outcomes:
• Program access
• Service utilization
Clinical outcomes:
• Timely VS (TVS)
• 12-month VS
• Durable VS (DVS)

1) Discrete Choice Experiments
Inform future model revisions, through assessment of implementation preferences
2) Statistical Outcomes Analysis
IS supports outcomes explanations
**PROMISE AIMS**

**Aim 1:** Stepped-wedge Design to Compare Original vs. Revised Model Effects on Timely VS

- Focuses on 17 re-awarded ("experienced") CCP sites
- Agencies matched based on type, borough & program size
  - Due to odd #, two smaller programs matched to one larger one
  - Matching was finalized with programmatic leads at BHIV
- Random number generator used to assign each site in matched pair to Phase 1 or Phase 2 (starting 9 mos. apart)
- Phase 2 sites provide original model until their assigned start date

ClinicalTrials.gov Identifier: NCT03628287
METHODS

Aim 1: Paired Stepped-wedge Design

The 9-month gap in contract starts allows side-by-side assessment of the short-term VS effect of the revised model vs. the original

ClinicalTrials.gov Identifier: NCT03628287
PROMISE AIMS (CONTINUED)

**Aim 2: Assess Longer-term Effects on VS**
- Apply CHORDS comparison-group methods

**Aim 3: Study Implementation Experiences**
- Mixed-methods study of factors shaping implementation & preferences for model features, via agency partnerships
  - Discrete choice experiments (DCEs) elicit preferences for practice (N=150 staff) and receipt (N=200 clients)
  - Qualitative interviews with ~25 providers and ~30 clients will cover 1st-hand implementation experiences
Imagine that you had to choose between two programs with the features below. Select the one you would prefer.

(5 of 10)

**Option A**
- Help with Taking Medication
  - You receive reminders by phone or text to take your medication

**Option B**
- Help with Primary Care Appointments
  - You don’t receive medication reminders, but a staff member works with you on sticking to a medication schedule

- Help with Issues other than Primary Care
  - A staff member only reminds you about primary care appointments
  - Staff help with medical care from specialists (cardiologists, oncologists, neurologists, ear-nose-throat doctors, etc.)

- Where Program Visits Happen
  - A staff member meets you in person at your home

- Staff help with securing housing and food assistance

Select

Select
Experimental design can be implemented in the ‘real world’: service delivery settings and government agency administration of contracts.

Phasing in an intervention with random assignment to early or delayed implementation permits evaluation of changes to a major public-services program, while ensuring uninterrupted access to it.

Challenges:

- This is not “business as usual” for a health department.
- Acceptability of randomization (even at the agency level) is low.
- Timing is everything.
DATA TO SUPPRESSION (D2S) — A NEW APPLICATION OF DATA TO CARE

Leveraging Ryan White Part A support services programs and HIV surveillance data to address gaps in the HIV care continuum
NYC surveillance data on PLWH with any evidence of care in 2011-15 show greater RWPA vs. non-RWPA retention in care in 2016 (89% vs. 80%), but, among those retained in care:

- lower VS on last VL test in 2016 (80% vs. 89%) and
- lower durable VS (DVS) on all VL tests in the 24-mo. period from 2016-17 (57% versus 75%).

Controlling for gender, age, years since Dx, and race/ethnicity, RWPA clients have greater risk for non-VS (aRR=1.61; 95% CI, 1.55-1.67) and non-DVS (aRR=1.53; 95% CI, 1.49-1.56).

NYC care continuum shows consistent VS gains (RWPA & non-RWPA) over time, without concurrent gains in retention, suggesting VS trends relate more to ART use/adherence.

Among PLWH in care with ART Rx in 2017, VS was 81% in RWPA, 93% in NYC overall.

- Intervention is needed to address the retention-suppression drop-off, and to reduce the NYC RWPA disparity in HIV treatment outcomes!
A 2014 amendment to NYS Public Health Law 27-F opened the door to enhanced data sharing for care engagement.

- NYS 2017 regulations added a provision authorizing health departments to share line-level HIV surveillance data with entities engaged in care coordination with primary care providers and mental health service providers (Title 10, Part 63, §63.4c)

- Can now report individuals’ surveillance-based data to their HIV support-service providers
Launched in mid-2018 with RWPA CCP agencies

- Shows clients’ VS status based on labs reported to Registry (past year)
- Includes program’s active caseload (past year)
- Not real-time (data are 2-3 mos. old by release date)
- 79% of surveyed recipients indicated value of continuing reports
### CPR SAMPLE REPORT ( MOCK DATA )

<table>
<thead>
<tr>
<th>eSHARE ID</th>
<th>Agency</th>
<th>Contract</th>
<th>Last Service Date</th>
<th>Client Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AAAAAAAA</td>
<td>Y</td>
<td>00-MCM-000</td>
<td>Needs follow-up for care and viral suppression ¹</td>
</tr>
<tr>
<td>2</td>
<td>BBBBBBBBBB</td>
<td>Y</td>
<td>00-MCM-000</td>
<td>Needs follow-up for viral suppression ²</td>
</tr>
<tr>
<td>3</td>
<td>CCCCCCCCCC</td>
<td>Y</td>
<td>00-MCM-000</td>
<td>Shows some evidence of viral suppression ³</td>
</tr>
<tr>
<td>4</td>
<td>DDDDDDDDDD</td>
<td>Y</td>
<td>00-MCM-000</td>
<td>Should be closed due to death ⁴</td>
</tr>
<tr>
<td>5</td>
<td>EEEEEEEEE</td>
<td>Y</td>
<td>00-MCM-000</td>
<td>Shows stable viral suppression ⁵</td>
</tr>
</tbody>
</table>

¹ Client had no VL test reported to the NYC HIV surveillance registry during the report year
² Client had at least one VL test reported in the year and was unsuppressed as of the latest available VL in the year
³ Client had at least one VL test reported in the year and was suppressed as of the latest available VL in the year
⁴ Based on death information in the NYC HIV surveillance registry, the client appears to have died
⁵ Client had at least two VL tests reported (≥3 months apart) in the year and was suppressed on all tests that year
Starting with behavioral health and non-medical case management
- CPR users recommended these programs as being able to benefit
- All have *patient navigators* on staff, for client outreach/follow-up
- Often lack other reliable means of accessing clients’ laboratory test data

Focusing reports on clients *without* current VS
- Will still include out of care and deceased clients, based on provider feedback

Accompanying reports with capacity-building technical assistance (TA)
- Some programs may have less experience directly addressing ART adherence
Strengthening the safety net: Testing a novel data-to-suppression (D2S) intervention strategy in the Ryan White HIV/AIDS Program

**Purpose:** to test and refine an agency-level D2S intervention in 24 RWPA-funded support-service agencies, to close the retention-suppression gap.

**3 AIMS:**

1. **Assess D2S intervention effects** on timely VS and time to VS, in a stepped-wedge hybrid Type 1 trial.
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.
3. **Identify preferences and priorities for D2S implementation**, to inform future refinements, in eight (client and provider) focus groups and in Discrete Choice Experiments (DCEs) with RWPA site staff (n=150).
WHAT’S NEW?

1. Application of D2C strategies to target VS
2. Increased likelihood that clients flagged can be reached
   a. reports restricted to those served in past year
   b. reports go to staff with connections to clients around their nonmedical needs
3. Leveraging of RWPA support-service programs to do outreach and tackle the very barriers that may have precipitated ART non-adherence
4. Use of hybrid trial design to assess clinical and implementation outcomes
   a. engaging front-line providers in real-world service settings, from the outset
5. Ongoing academic-govt. partnership to speed translation to practice

If D2S proves effective, we will have identified a structural intervention capable of reducing VS disparities in NYC & beyond.
CONCLUSIONS

Academic-government partnerships that include joint planning of research in advance of key policy or practice initiatives can produce answers to locally important public health research questions

- without substantially slowing the pace of desired change
- with methods that support knowledge generation and generalizability

Inclusion of service providers in these partnerships is critical

- to understanding on-the-ground implementation and the factors that shape it
- to planning study design and data collection
- to ensuring that findings will be relevant to future intervention delivery

Evidence-based programs may continue to evolve

- and studying that evolution and its effects can inform adoption and scale-up
REFERENCES

Original HIV Care Coordination Program Tools: https://www1.nyc.gov/site/doh/health/health-topics/aids-hiv-care-coord-tools.page

STEPS to Care online toolkit: https://effectiveinterventions.cdc.gov/en/care-medication-adherence/group-4/steps-to-care


PROMISE study protocol on Clinical Trials Registry: https://clinicaltrials.gov/ct2/show/NCT03628287
ACKNOWLEDGMENTS

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- Care Coordination Quality Management & TA team (Health Department)
- CHORDS & PROMISE study teams
- Bruce Levin, PhD (Columbia University)