HIV CARE COORDINATION PROGRAM (CCP)

Evidence-Based Structural Intervention
Evidence-Based for Viral Suppression

INTERVENTION DESCRIPTION

Goals of Intervention

- Improve time to viral suppression
- Improve time to immune recovery
- Facilitate re-engagement in HIV care among patients who have been out of care
- Increase retention in HIV care and treatment
- Maintain ART adherence and viral suppression

Intended Population

- Persons with HIV (PWH) who are:
  - Newly diagnosed,
  - New to HIV care,
  - Out of HIV care,
  - New to HIV treatment,
  - Undergoing a change in treatment regimen,
  - Virally unsuppressed at their most recent viral load test,
  - Experiencing co-occurring conditions, or
  - At high risk of being lost to care or not achieving viral suppression due to psychosocial or structural barriers to engagement in HIV care and treatment

Brief Description

The *New York City (NYC) Ryan White Part A HIV Care Coordination Program (CCP)* is an individual-level structural intervention that combines strategies such as case management provided by interdisciplinary care teams, patient navigation, and structured health education. The CCP applies a 'medical home' model for building HIV care continuum engagement for persons newly diagnosed with HIV or experiencing lapses in or barriers to HIV care and treatment. Through various collaborations across medical and social services, the CCP provides: (1) outreach for initial case finding and for re-engagement after any missed appointment; (2) case management services (e.g., social services and benefits eligibility assessment and linkages); (3) multidisciplinary care team communication and decision-making via case conferences and joint care planning; (4) patient navigation (e.g., appointment reminders, assistance with scheduling appointments, transportation assistance, and accompaniment to medical and supportive services); (5) anti-retroviral therapy (ART) adherence support (e.g., directly observed therapy for individuals with the greatest need); and (6) a structured health education curriculum delivered individually and in groups. Client engagement ranges from daily to quarterly contact with CCP staff depending upon the level of need.

Theoretical Basis
- Medical home model

Intervention Duration
- Ongoing, based on client's level of need

Intervention Setting(s)
- Hospitals, community health centers, and community-based organizations with medical partners
- Residential (client's home)
- Field-based locations (e. g., community centers, restaurants, and other public meeting areas)

Deliverer
- Interdisciplinary Care Team consisting of:
    - Care coordinator
    - Patient navigator
    - Primary medical care provider
    - Other providers of medical and supportive services (e.g., specialty medical providers, social workers, mental health providers, substance use counselors) who may be engaged as part of a given client's care team

Delivery Methods
- ART adherence support
- Case management services
- Case conferences
- Comprehensive care planning
- Outreach
- Patient navigation
- Structured health education curriculum

Structural Components
- Access
    - Increased access to HIV medical care, specialty care, mental health care, substance abuse services, diagnostic services, laboratory services, and supportive services
- Physical Structure – Services provided in non-traditional settings
    - Intervention components are offered in the clients' home or other field-based settings

INTERVENTION PACKAGE INFORMATION

Intervention materials are available in the form of an online toolkit at: https://www.cdc.gov/hiv/effective-interventions/treat/steps-to-care/index.html

Email: Gina Gambone (ggambone1@health.nyc.gov) and **Jennifer Carmona** (jcarmona@health.nyc.gov) for additional intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information
The original evaluation study was conducted in New York City, NY, with follow-up data covering the period between December 1, 2009 and March 31, 2017.

Key Intervention Effects
- Improved time to viral suppression

Recruitment Settings
Hospitals, community health centers, and community-based organizations with medical partners

Eligibility Criteria
HIV-infected adults or emancipated minors who were eligible for local Ryan White Part A services (based on residence within the New York eligible metropolitan area and household income < 435% of federal poverty level) and who were (1) newly diagnosed with HIV, (2) irregularly in care, (3) starting a new ART regimen, (4) experiencing ART adherence barriers, or (5) manifesting treatment failure or ART resistance.

Study Sample
The analytic study sample of [N = 1,836] people newly diagnosed with HIV is characterized by the following:
- *47% Black or African American; 41% Hispanic, Latino or Latina; 8% White*
- *74% male, 26% female*
- *51% men who have sex with men (MSM), 29% heterosexual, 16% other or unknown transmission risk category, 4% injection drug use history*
- *Median age of 34 years (interquartile range [IQR] 26-44)*
- *Viral load at enrollment/pseudo-enrollment (see "Comparison" below for description): 68% >1500 copies/mL, 10% between 201 and 1499 copies/mL, 14% ≤200 copies/mL (viral suppression), 8% no VL measurements available*
- *Median CD4 count at enrollment/pseudo-enrollment: 352 (IQR 202–551), with 23% CD4 count < 200 cells/µL and 29% CD4 count > 500 cells/µL*

Assignment Method
PWH who were enrolled in CCP and who were newly diagnosed (n = 918) were matched to PWH who were not CCP enrollees but who also were newly diagnosed (n = 918), [N = 1,836].

Comparison
The authors retrospectively created an observational cohort of PWH not enrolled in the CCP by merging longitudinal population-based surveillance and programmatic data sources. The NYC HIV Surveillance Registry contains demographic and clinical information on all diagnoses of HIV reported in NYC and comprehensive HIV-related laboratory reporting (including all CD4 and VL results for individuals who have received HIV medical care in NYC). Vital status information is updated through regular matches with death data. CCP programmatic data were drawn from the NYC Department of Health and Mental Hygiene's Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE). Programmatic data were merged with surveillance registry data to identify newly diagnosed PWH who were CCP enrollees and PWH who were not CCP enrollees who were potentially eligible for the inclusion in the comparison group. Potentially eligible PWH who were not CCP enrollees, who had to be alive for at least 12 months after diagnosis for comparability, were randomly assigned pseudo-enrollment dates with a probability such that the distribution of pseudo-enrollment dates in the comparison group replicated the distribution of enrollment dates of the CCP participants. Newly

diagnosed PWH who were not CCP enrollees from the registry were then matched to newly diagnosed CCP clients on propensity for CCP enrollment and specific enrollment or pseudo-enrollment date (+/- 3 months).

Relevant Outcomes Measured

- Time to viral suppression was measured as the time from the date of enrollment/pseudo-enrollment to the date of viral suppression (viral load ≤200 copies/mL) or censored at either end of follow-up (March 31, 2017) or death, whichever was earlier.
- Time to immune recovery was measured as time from the date of enrollment/pseudo-enrollment to the date of the first two successive CD4 counts >500 cells/mm^3 or censored at either end of follow-up (March 31, 2017) or death, whichever was earlier.

Participant Retention

- Participant retention was not reported. Because participant retention is not a criterion for the Structural Interventions chapter, the Prevention Research Synthesis project does not evaluate that information.

Significant Findings on Relevant Outcomes

- Time to viral suppression was significantly shorter (i.e., viral suppression was more rapid) among CCP enrollees than non-CCP enrollees (adjusted Hazards ratio: 1.17 [95% CI 1.02-1.34]) out to 48 months of follow-up. *

*Adjusted for matched-pair design and the time from diagnosis to enrollment.

Considerations

- This study was also determined to be evidence-based for the Linkage to, Retention in, and Re-engagement in HIV Care (LRC) Chapter.
- A previous study evaluating the CCP using a pre-post design was determined to be evidence-informed for the Linkage to, Retention in, and Re-engagement in HIV Care Chapter and Structural Interventions Chapter.

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

- There were no significant intervention effects for time to immune recovery out to 48 months of follow-up.

Negative findings

- None reported

Other related findings

- None reported

Implementation research-related findings

- None reported

Process/study execution findings

- None reported

Adverse events

- None reported

Findings from Previous Studies

Robertson et al. (2019). Study period 2009-2013.

Robertson et al. (2019) assessed the impact of the CCP on durable viral suppression (DVS) among PWH who had suboptimal care outcomes. The study authors merged programmatic data on CCP clients with surveillance data on all adults diagnosed with HIV to create a contemporaneous, non-CCP-exposed comparison group. DVS was defined as regular VL monitoring and all VLs ≤ 200 copies per milliliter in months 13-36 of follow-up and was measured in three ways: at 200 copies/mL threshold, using all VLs; at 1500 copies/mL threshold, using all VLs; and at 200 copies/mL threshold, using the first and last VLs. The study authors also examined ever having viral suppression (ever ≤ 200 copies/mL). Within each DVS threshold and for the outcome of ever having viral suppression, participants were analyzed overall and by baseline treatment subgroup: newly diagnosed, consistently suppressed, no evidence of suppression, and inconsistently suppressed.

- There were no differences between CCP participants and non-CCP enrollees (overall) for all DVS thresholds.
    - For participants with no evidence of suppression in the 12 months prior to enrollment, CCP enrollees were significantly more likely to have DVS for all DVS thresholds and to have ever achieved viral suppression, compared to non-CCP enrollees.
        - DVS at 200 copies/mL threshold, using all VLs: relative risk (RR)= 1.16; 95% CI 1.04 - 1.29; $p < 0.05$
        - DVS at 1500 copies/mL threshold, using all VLs: relative risk (RR)=1.12; 95% CI 1.03 - 1.23; $p < 0.05$
        - DVS at 200 copies/mL threshold, using the first and last: relative risk (RR)=1.17; 95% CI 1.07 - 1.27; $p < 0.05$
        - VL ever ≤200 copies/mL: relative risk (RR)=1.07; 95% CI 1.04 – 1.10; $p < 0.05$
    - For participants who were inconsistently suppressed in the 12 months prior to enrollment, CCP enrollees were significantly less likely to have DVS for DVS at 200 copies/mL threshold and at 1500 copies/mL threshold using all viral loads compared to non-CCP enrollees.
        - DVS at 200 copies/mL threshold, using all VLs: relative risk (RR)=0.87; 95% CI 0.79 – 0.95; $p < 0.05$
        - DVS at 1500 copies/mL threshold, using all VLs: relative risk (RR)=0.87; 95% CI 0.83 – 0.93; $p < 0.05$
    - For participants who were newly diagnosed within 12 months of enrollment or consistently suppressed in the 12 months prior to enrollment, there were no CCP versus non-CCP differences for any DVS threshold or for ever being virally suppressed.
- Overall, CCP enrollees were significantly more likely to have ever been virally suppressed (≤200 copies/ mL) compared to non-CCP enrollees. Relative risk (RR)=1.03; 95% CI 1.02 – 1.04; $p < 0.05$.

Nash et al., 2018. Study period 2009-2013.

An earlier study (Nash et al., 2018) using the same dataset of CCP enrollees and non-CCP participants compared the two groups for viral suppression at 12 months of follow-up. Viral suppression was measured as ≤ 200 copies/mL threshold. Participants were analyzed overall and by baseline treatment subgroup: newly diagnosed, consistently suppressed, consistently unsuppressed, and inconsistently suppressed.

- Overall, CCP enrollees were more likely to be virally suppressed at 12-month follow-up compared to non-CCP enrollees. Relative Risk (RR)=1.11; 95% CI 1.08 – 1.14; $p < 0.001$.
    - CCP enrollees who were newly diagnosed and consistently unsuppressed at baseline were more likely to be virally suppressed at follow-up compared to non-CCP enrollees in the same baseline treatment subgroups.
        - Newly diagnosed: Relative Risk (RR)=1.15; 95% CI 1.09 – 1.23; $p < 0.001$
        - Consistently unsuppressed: Relative Risk (RR)=1.32; 95% CI 1.23 – 1.42; $p < 0.001$
    - Among those who were consistently suppressed or inconsistently suppressed at baseline, there were no significant differences in 12-month viral suppression between CCP enrollees and non-CCP enrollees.

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