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Durable Viral Suppression among HIV Care Coordination Participants and Non-participants

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Conflict of Interest Disclosure

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Has no real or apparent conflicts of interest to report.

HIV Care Coordination in NYC

- In 2009, with Ryan White Part A funding, NYC began implementing a comprehensive HIV care coordination program (CCP) at 28 HIV care provider agencies
 - Targets patients at high risk for suboptimal outcomes
- The CCP intervention combines various evidence-based programmatic elements*:
 - Case conferencing, patient navigation, adherence support including directly observed therapy (DOT), structured health promotion, and case conferencing
- Service delivery program no randomization
- CCP increases short-term (12 month) viral load suppression, beyond usual care, for
 - Persons newly diagnosed or
 - Persons with no evidence of viral suppression 12 months prior to enrollment



Objective

We aimed to compare durable viral suppression (DVS) of CCP enrollees with DVS in a matched group of HIV patients for 24 months, following an initial 12-month period for establishment in care and treatment.



Data Sources

- We retrospectively created an observational cohort of persons enrolled and not enrolled in the CCP by merging
 - Provider-reported programmatic data (CCP clients)
 - NYC HIV Surveillance Registry data (NYC residents with diagnosed HIV)
- Persons not enrolled in the CCP were identified after the merge and considered to be in the usual-care group
- For CCP and non-CCP persons, all outcome data (viral load) was taken from the Registry

Matched Usual-Care Comparison

- Randomly assigned a pseudo-enrollment date to usual-care
- Matched CCP enrollees to those in the usual-care group on
 - Propensity for CCP enrollment,
 - Pseudo-enrollment/enrollment dates and
 - Baseline treatment status

| Baseline Treatment | Definition |
|----------------------------|---|
| Newly diagnosed | Diagnosed ≤12 months prior to pseudo- enrollment/enrollment |
| Consistently suppressed | \geq 2 VLs \geq 90 days apart and all VLs \leq 200 copies/ μ L |
| No evidence of suppression | All VLs reported >200 copies/μL or no VL reported |
| Inconsistently suppressed | \geq 1 VL \leq 200 copies/ μ L but not all VLs \leq 200 copies/ μ L |

d Outcome

Statistical Analysis and Outcome Definitions

- Durable viral suppression (DVS):
 - Regular monitoring: ≥1 VL result in each 12-month period of follow-up
 - *All VLs* ≤200 copies/μL
 - From 13-36 months of follow-up
 - Also examined DVS using a ≤ 1500 copies/ μL threshold
- Ever achieved viral load suppression:
 - ≥1 VL was ≤200 copies/ μ L
 - From 0-36 months of follow-up
- To examine DVS, used log binomial regression

Characteristics of Matched CCP and Usual-Care Persons

CCP-Enrollees N = 7,058 12/09 to 3/13 Long-Term NYC Residents* N = 6.385 (90%)

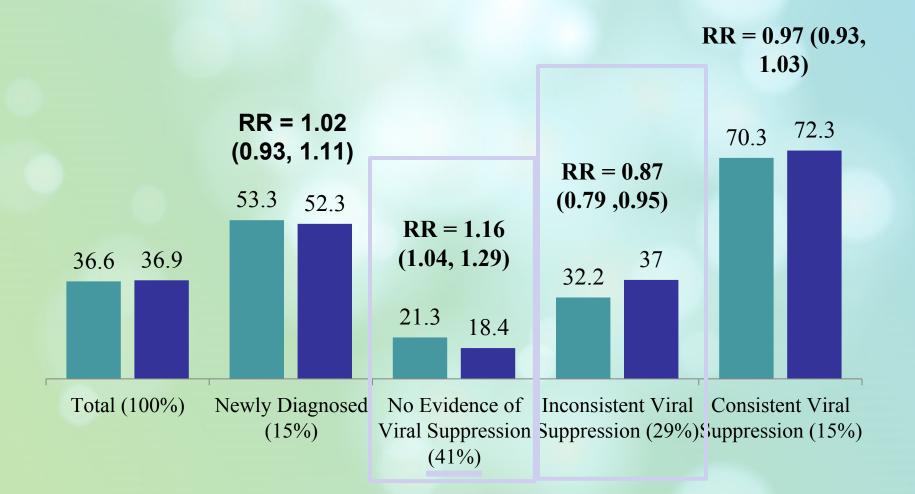
Matched CCP N = 6,284 (89%)

| Characteristic | CCP N (%) | Usual Care N (%) |
|---------------------------|--------------|---------------------|
| Total ($N = 12,414$) | 6,207 (100) | 6,207 (100) |
| Male | 3,955 (64) | 3,951 (64%) |
| Black | 3,322 (54) | 3,414 (55) |
| 25-44 | 2,596 (42) | 2,576 (42) |
| Men who have sex with men | 1,788 (29) | 1,810 (29) |
| Baseline CD4 <200 | 1.995 (32) | 1.934 (31) |

* 1 VL in first 12 months and ≥2 VL in months 13-36 of enrollment

Durable Viral Suppression (%) – CCP versus Usual Care, by Baseline Treatment Status

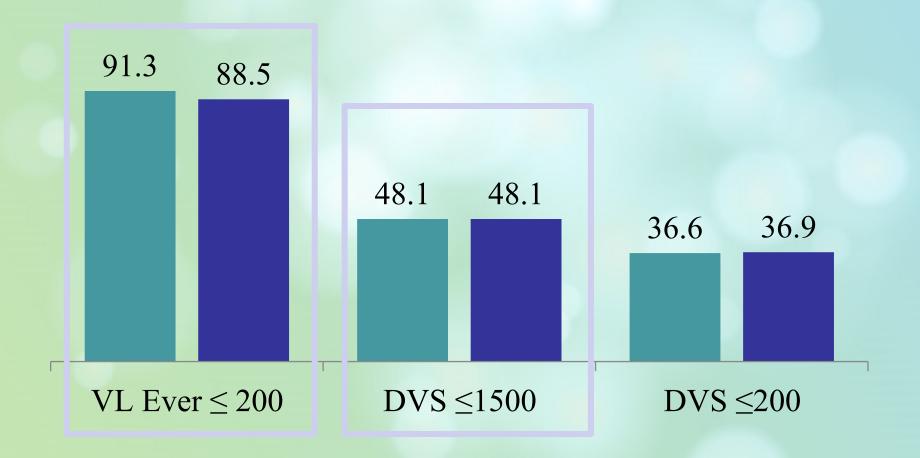
■ CCP ■ Usual Care

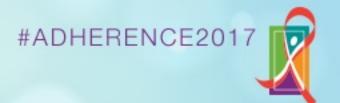


Viral Load Ever ≤200 or DVS at 1500 and 200 Copies/µL Thresholds (%) – CCP versus Usual Care

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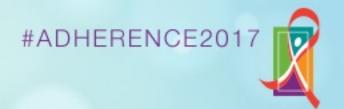
■ CCP ■ Usual Care





Strengths

- Outcome data for CCP and usual-care group was longitudinal and came from the same source, and available regardless of care location or duration of enrollment
 - ≥ 3 years of follow-up
 - Ability to examine different viral load outcome definitions
- Population-based comparison group
- Our method of creating a comparison group (i.e., matching on pseudo-enrollment/enrollment date) ensured a CCP effect was not the result of secular improvements in VLS



Limitations

- Observational study
 - Possibility of uncontrolled confounding remains
 - However, we controlled for numerous demographic and clinical confounders, in addition to secular trends in VLS

 Change in treatment guidelines may affect outcomes of persons with high pre-treatment CD4 counts (>500 cells)

Discussion (1)

- Consistent with our short-term outcomes, CCP effect among persons with no evidence of viral suppression, the largest group of enrollees by baseline status
 - New York has many care and treatment services available to PLWH
 - People in usual-care group may be receiving similar services as CCP-enrollees
 - CCP effect may look better in jurisdictions with fewer resources
- No CCP effect for newly diagnosed
 - Newly diagnosed are entering a more favorable treatment landscape (e.g., reduced toxicity) with fewer negative experiences around ART and more services available than previous generations
 - As a result, newly diagnosed persons may have an easier time achieving DVS

Discussion (2)

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- CCP enrollees have more observation time and VL events reported during follow-up than the usual-care group
 - As a result, CCP group had more opportunities to fail on our measure of DVS than the usual-care group
 - Most problematic for outcomes measured among CCPenrollees in the inconsistently suppressed group
 - Because the inconsistently suppressed group is, by definition, moving above and below the 200 copies/ul threshold
- Proportion achieving DVS is very low (36%)
 - Almost everyone had access to ART (90% ever suppressed).
 - Implies the barrier to achieving DVS is ART adherence over time, and not access to care





Acknowledgements

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- Care Coordination Program Service Providers and Clients
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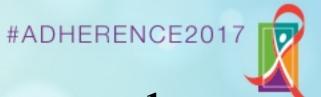








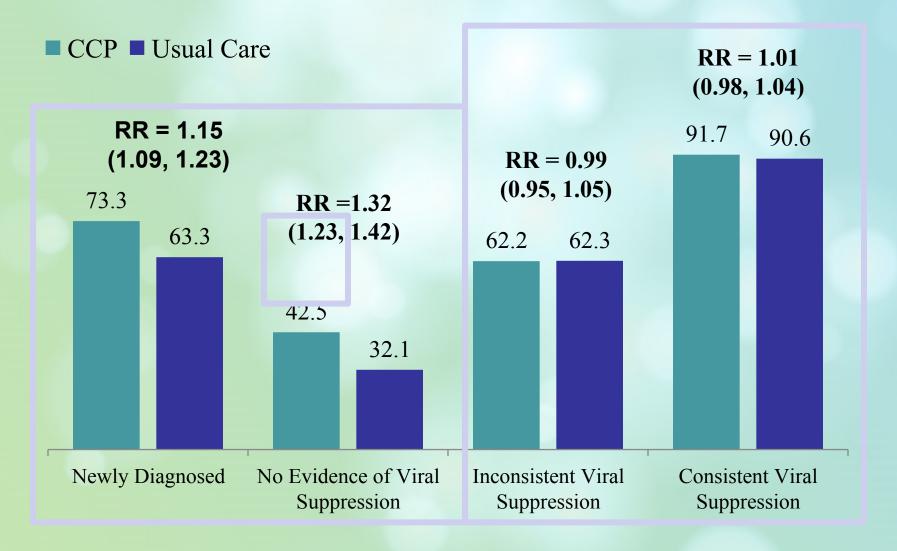
Supplemental Slides



Supplemental Background

Short Term - Viral Suppression (%) at 12 Months after Enrollment – CCP versus Usual Care, by Baseline Treatment Status

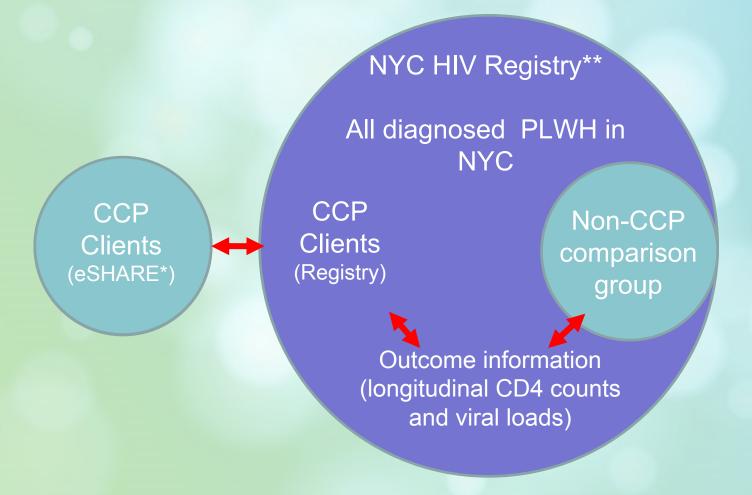
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Supplemental Methods

Data Sources



*<u>Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE)</u>

**The NYC HIV Registry contains information on HIV diagnoses and longitudinal viral load results for all diagnosed persons living with HIV.

-Care

Constructing a Usual-Care Comparison (1)

- 1. Identified persons who met clinical criteria for CCP enrollment, but were not enrolled
 - 1. Newly diagnosed
 - 2. Out of medical care
 - 3. Treatment naïve
 - 4. Exhibiting poor ART adherence
 - 5. Experiencing a viral rebound
 - 6. Experiencing a high viral load

N = 62,828 Eligible Persons

Constructing a Usual-Care

Comparison (2)

- 2. Randomly assigned a pseudoenrollment date to eligible persons and restricted to persons residing in NYC
 - Assigned with probabilities such that the temporal distribution of dates matched the distribution of enrollment dates among CCP enrollees
 - Pseudo-enrollment date = time zero
 - Required persons to have ≥1 VL in months 0-12 after pseudo-enrollment/enrollment and ≥ 2 VLs in months 13-36 (evidence of NYC residence and HIV care)

N = 62,828 **Eligible Persons**

N = 37,108
Assigned pseudo
-enrollment date
and residing in
NYC

Constructing a Usual-Care Comparison (3)

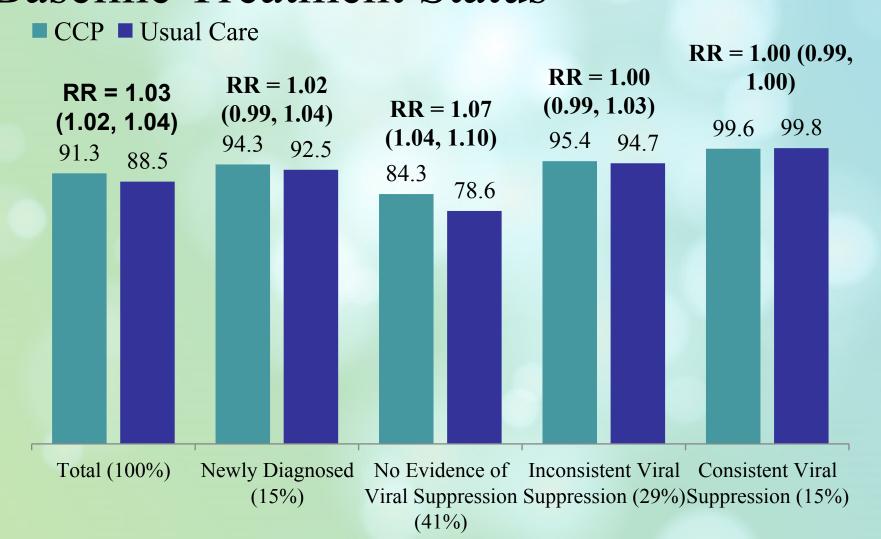
- 3. Matched CCP enrollees to those in the usual-care group on
 - a) Propensity for CCP enrollment
 - b) Pseudo-enrollment/enrollment dates
 - c) Baseline treatment status

| Baseline Treatment Status | Definition |
|----------------------------|--|
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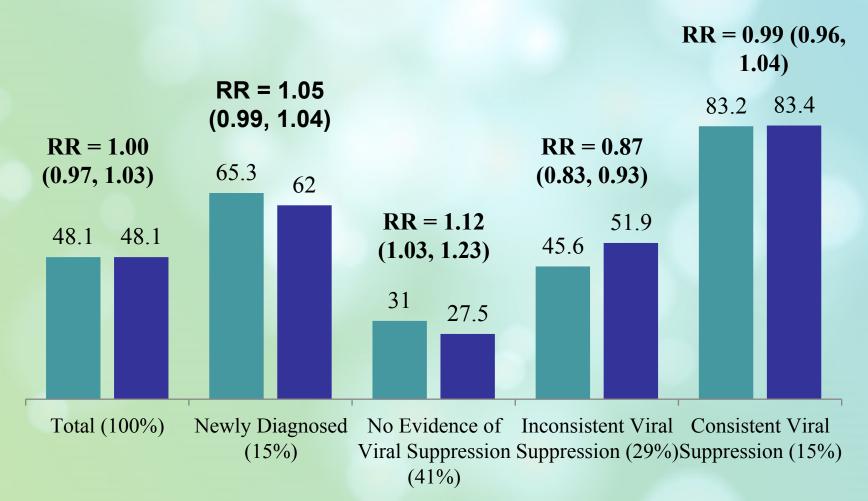
Supplemental Results

Viral Load Ever ≤200 (%) — #ADHERENCE2017 CCP versus Usual Care, by Baseline Treatment Status



Long Term – Durable Viral Suppression at 1500 copies/µL threshold (%) – CCP versus Usual Care, by Baseline Treatment Status

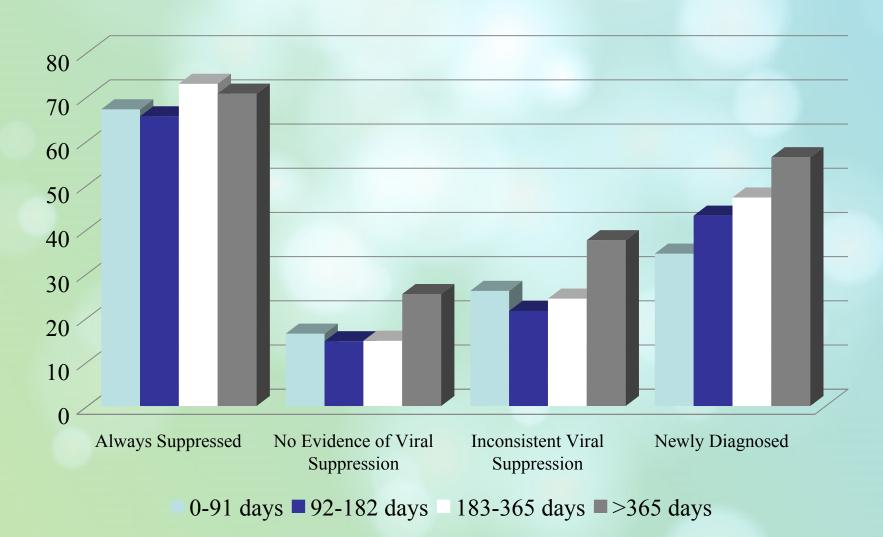
■ CCP ■ Usual Care



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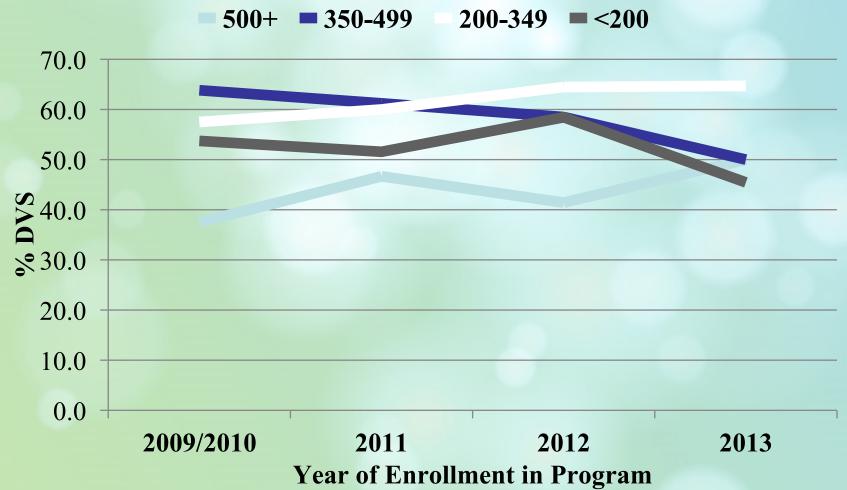
Proportion with Durable Viral Suppression at 200 copies/µL threshold (%), by Length of Enrollment - Among CCP Enrollees





Proportion with Durable Viral Suppression at 200 copies/µL threshold (%), by Year of Enrollment and CD4 count at enrollment - Among Newly Diagnosed CCP Enrollees





Differences in Person-Time and Number of Laboratory Results – CCP Versus Usual Care

| | Mean (STD) | Mean (STD) Total PT Non- | P-value paired t- | Mean (STD) Total | Mean (STD) Total Labs | P-value paired t- |
|-------------------|---------------|-----------------------------|----------------------|------------------------|--------------------------|----------------------|
| | Total PT CCP | ССР | test | Labs CCP | Non-CCP | test |
| | | | | | | |
| Baseline - Match | | | | | | |
| Groups | | | | | | |
| Newly Diagnosed | 556.1 (127.8) | 534.2 (146.3) | 0.0008 | 6.3 (2.3) | 5.7 (2.1) | < 0.0001 |
| Always Suppressed | 574.7 (112.5) | 543.6 (134.5) | < 0.0001 | 6.7 (2.1) | 5.7 (2.2) | < 0.0001 |
| Never Suppressed | 547.8 (147.5) | 521.3 (160.6) | < 0.0001 | 7.1 (3.1) | 6.3 (2.9) | < 0.0001 |
| Inconsistently | | | | | | |
| Suppressed | 561.6 (138.5) | 537.8 (146.2) | 0.0003 | 7.3 (3.0) | 6.3 (2.7) | < 0.0001 |

Person-time: number of days from first to last laboratory even reported in months 13-36 of follow-up Total labs: number of CD4 or VL laboratory results reported to surveillance in months 13-36 of follow-up

Time above 1500 copies/µL (days) – CCP versus Usual Care, by Baseline Treatment Status

| | Mean (STD) Days | Mean (STD) | P-value paired t- |
|---------------------------|-----------------|---------------|-------------------|
| | ССР | Days Non-CCP | test |
| | | | |
| Baseline - Match Groups | | | |
| Newly Diagnosed | 92.1 (175.7) | 96.4 (173.2) | 0.59 |
| Always Suppressed | 33.2 (103.0) | 28.5 (92.4) | 0.3 |
| Never Suppressed | 233.5 (226.4) | 242.6 (227.3) | 0.15 |
| Inconsistently Suppressed | 151.8 (200.7) | 129.8 (190.3) | 0.0003 |

Time above 1500 copies/ul: Marks, Gary, et al. "Time above 1500 copies: a viral load measure for assessing transmission risk of HIV-positive patients in care." *AIDS (London, England)* 29.8 (2015): 947.

Year of Diagnosis (%) by Baseline Treatment Status among Matched Population Diagnosed >1 Year before PseudoEnrollment/Enrollment

| | No Evidence of Viral Suppression | Inconsistent Viral Suppression | Consistent Viral Suppression |
|--------------------------|--|--------------------------------|------------------------------|
| Year of HIV Diagnosis | N = 5,084 | N = 3,644 | N = 1,850 |
| Prior 1995 | 19.2 | 24.8 | 24.6 |
| 1995-1999 | 19.7 | 21.8 | 22.1 |
| 2000-2004 | 32.3 | 31.3 | 32.4 |
| 2005-2009 | 25.2 | 19.6 | 19.8 |
| 2010-2013 | 3.6 | 2.5 | 1.0 |