DIVISION OF HIV/AIDS PREVENTION
T.R.I.P. SERIES

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Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention

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

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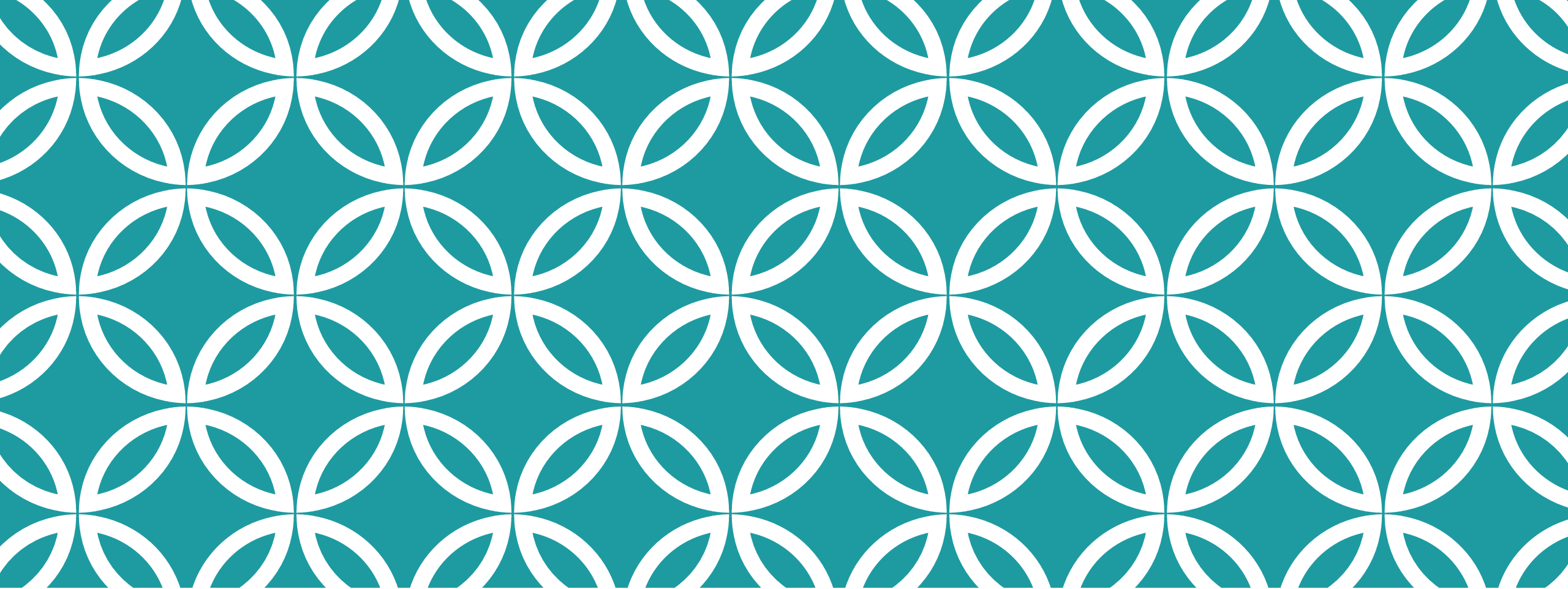   Email: Denis.Nash@sph.cuny.edu
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NYC Health

CHORDS
Cost, Health Outcomes & Real-world Determinants of Success in HIV Care Coordination

PROMISE
Program Refinements to Optimize Model Impact & Scalability based on Evidence

ISPH CUNY
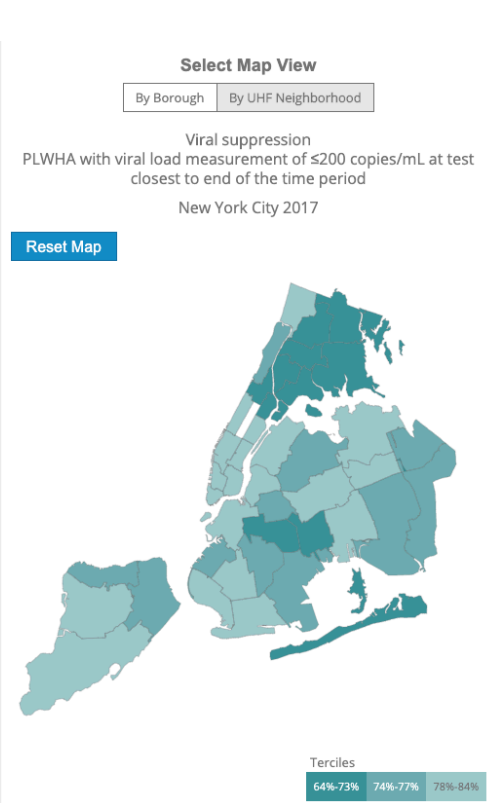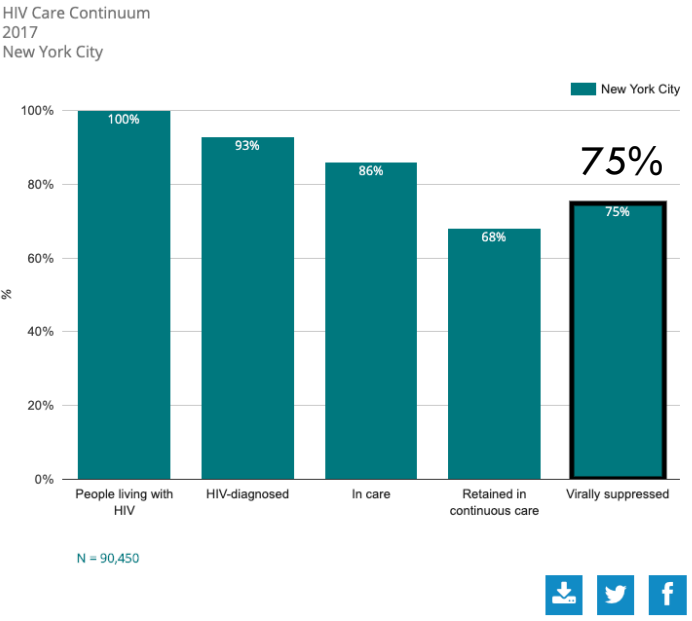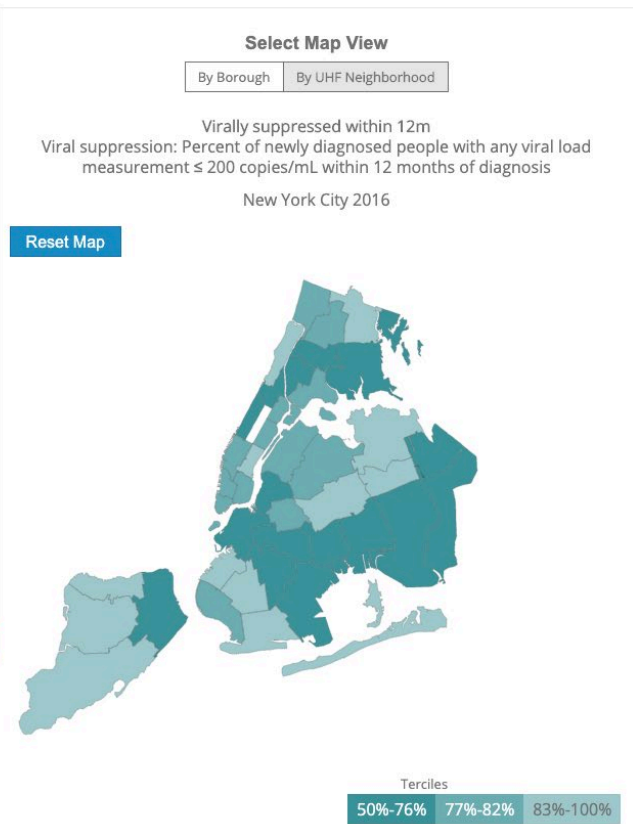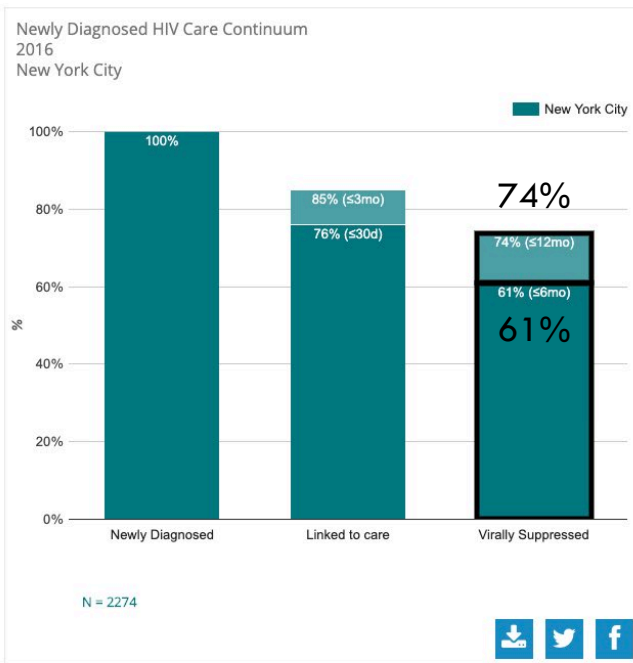Institute for Implementation Science in Population Health

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

HIV Care Continuum
2017
New York City

75%

N = 90,450

Select Map View

By Borough | By UHF Neighborhood

Viral suppression
PLWHA with viral load measurement of ≤200 copies/mL at test closest to end of the time period

New York City 2017

Reset Map

Terciles
64%-73% | 74%-77% | 78%-84%

Newly diagnosed PLWH

Newly Diagnosed HIV Care Continuum
2016
New York City

74%

61%

N = 2274

Select Map View

By Borough | By UHF Neighborhood

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

New York City 2016

Reset Map

Terciles
50%-76% | 77%-82% | 83%-100%

ETE DASHBOARD
Ending the HIV Epidemic
EtEdashboardny.org

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Ryan White HIV/AIDS Program Part A (RWPA) in New York

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:
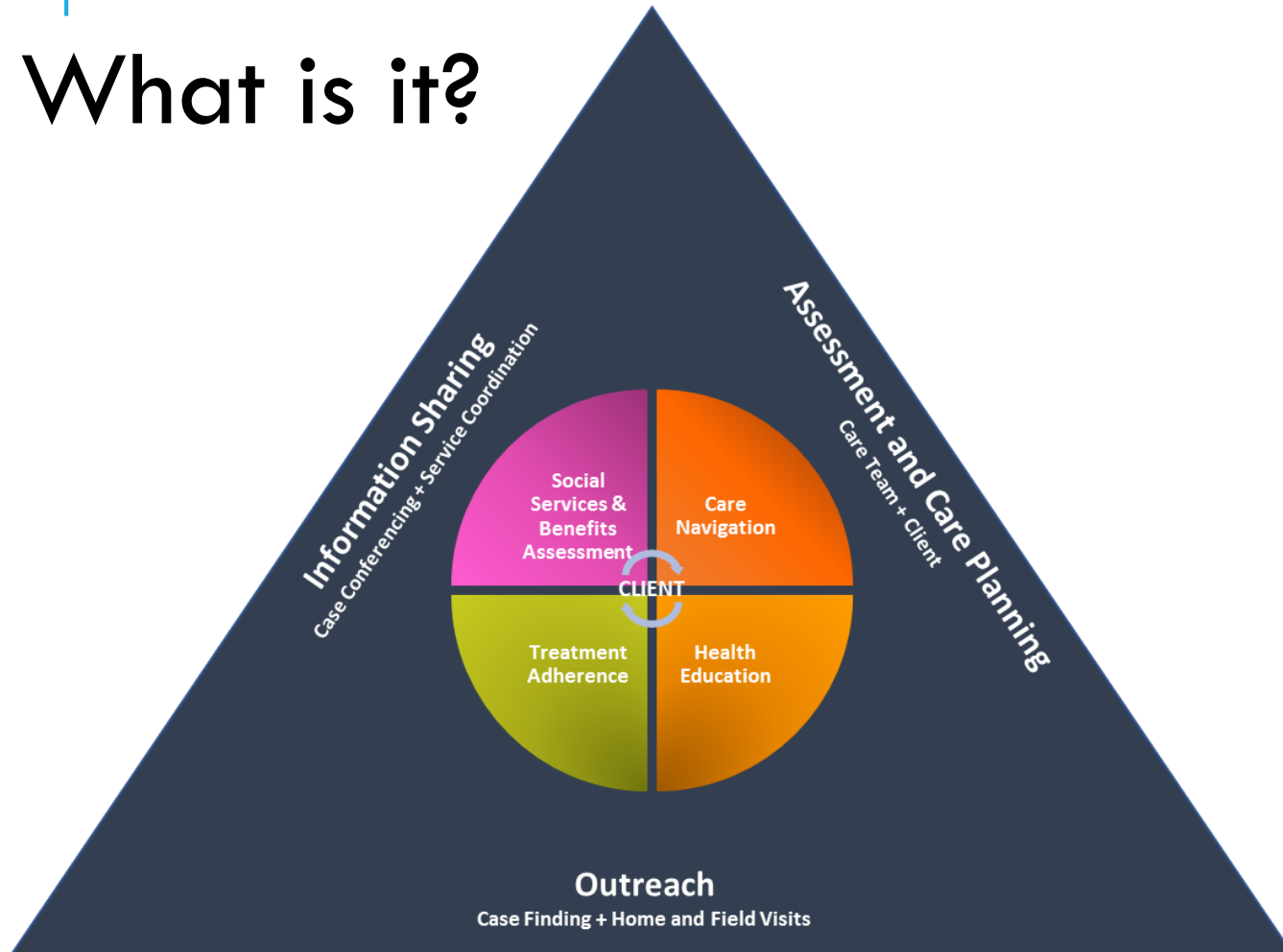
- newly diagnosed
- lost to care or sporadically in care
- new to care
- new to treatment
- struggling with ART adherence

CCP team in case conference

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

THE CCP MODEL

What is it?

Information Sharing
Case Conferencing + Service Coordination

Assessment and Care Planning
Care Team + Client

Social Services & Benefits Assessment

Care Navigation

CLIENT

Treatment Adherence

Health Education

Outreach
Case Finding + Home and Field Visits

Who is it?

Care Coordinator

Program Director

Client

Patient Navigator

Primary Care Providers

THE CHORDS STUDY (2013-19)

Costs, **H**ealth **O**utcomes and **R**eal-world **D**eterminants of **S**uccess 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

METHODS – DESIGN
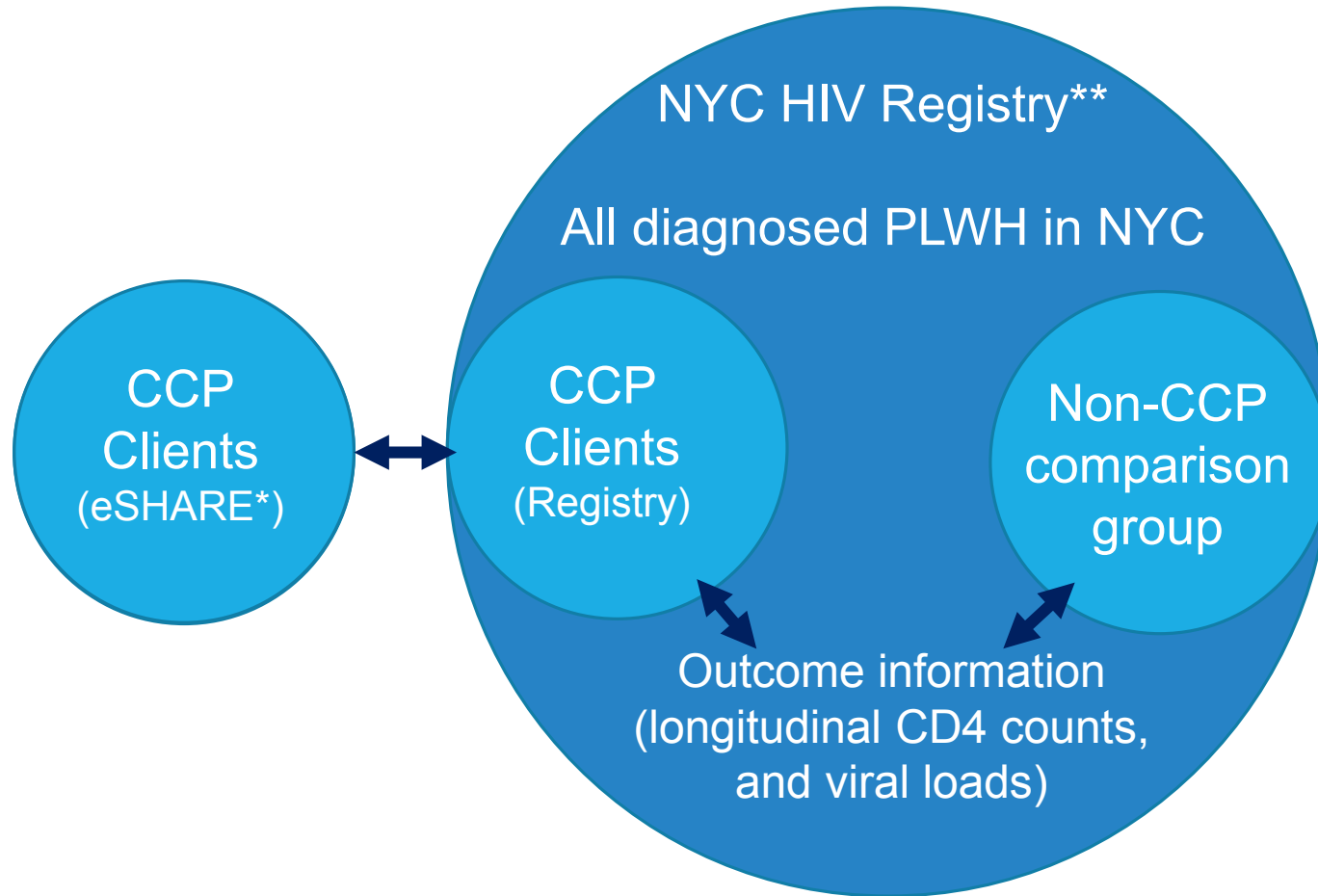
*Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE) contains program reporting.
**The NYC HIV Registry contains information on new HIV diagnoses, diagnosis date, demographics, risk factors, history of AIDS, longitudinal viral load and CD4 count results, and vital status.

'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
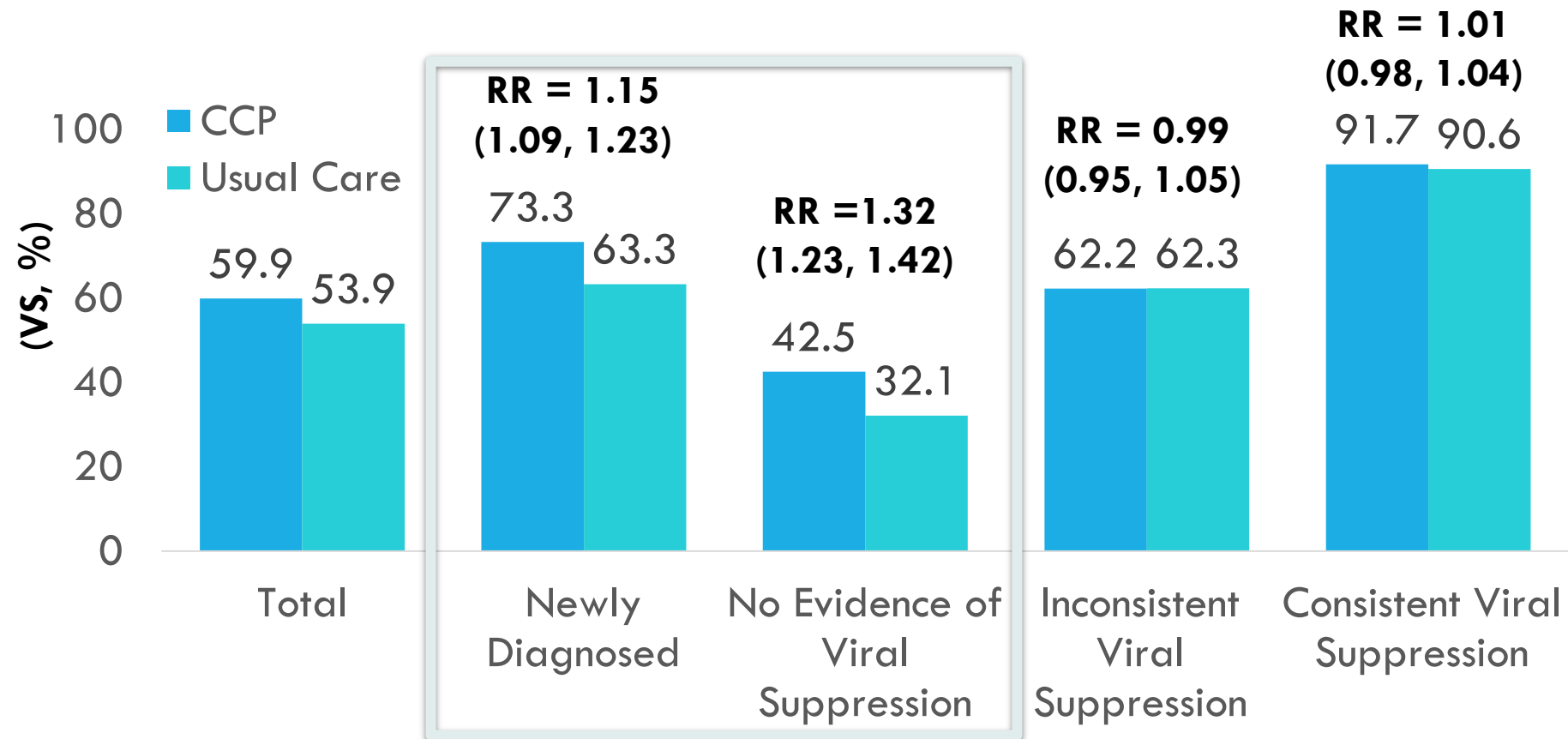   2. Pseudo-enrollment/enrollment dates and
   3. Treatment status at enrollment

Variables in Propensity Score	
Demographic variables	Sex, race/ethnicity, age, country of birth, HIV transmission risk
Clinical variables	Year of diagnosis, baseline VL, baseline CD4, linkage to care, concurrent AIDS and HIV diagnoses, number of VLs in 12 months prior to enrollment
Neighborhood variables	ZIP code at enrollment, HIV prevalence and poverty levels within ZIP code at enrollment

Robertson MR et al. AJE 2018; Nash et al. PLoS One 2018

CCP VS. NON-CCP PLWH CHARACTERISTICS BEFORE & AFTER PROPENSITY MATCH

Baseline Characteristics	Pre Match		Post Match	
	Non-CCP N (%)	CCP N (%)	Non-CCP N (%)	CCP N (%)
Total	57,746 (100)	7,058 (100)	7,030 (100)	7,030 (100)
Male	42,067 (72.9)	4,525 (64.1)	4,508 (64.1)	4,513 (64.1)
Non-White	45,606 (79.0)	6,622 (93.8)	6,627 (94.3)	6,594 (93.8)
18-44	27,329 (47.2)	3,554 (50.4)	3,427 (48.7)	3,537 (50.3)
Foreign Born	10,463 (18.1)	1,629 (23.1)	1,508 (21.5)	1,608 (22.8)
Baseline Viral Load >200*	37,271 (64.5)	4,862 (68.9)	4,756 (67.7)	4,834 (68.8)
Baseline CD4 <200	6,999 (12.1)	2,303 (32.6)	2,227 (31.7)	2,275 (32.4)
Men who have Sex with Men	22,887 (38.6)	2,064 (29.2)	2,031 (28.9)	2,059 (29.3)
Injection Drug Use History	8,698 (15.1)	1,920 (21.1)	1,545 (22.0)	1,905 (21.1)

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

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
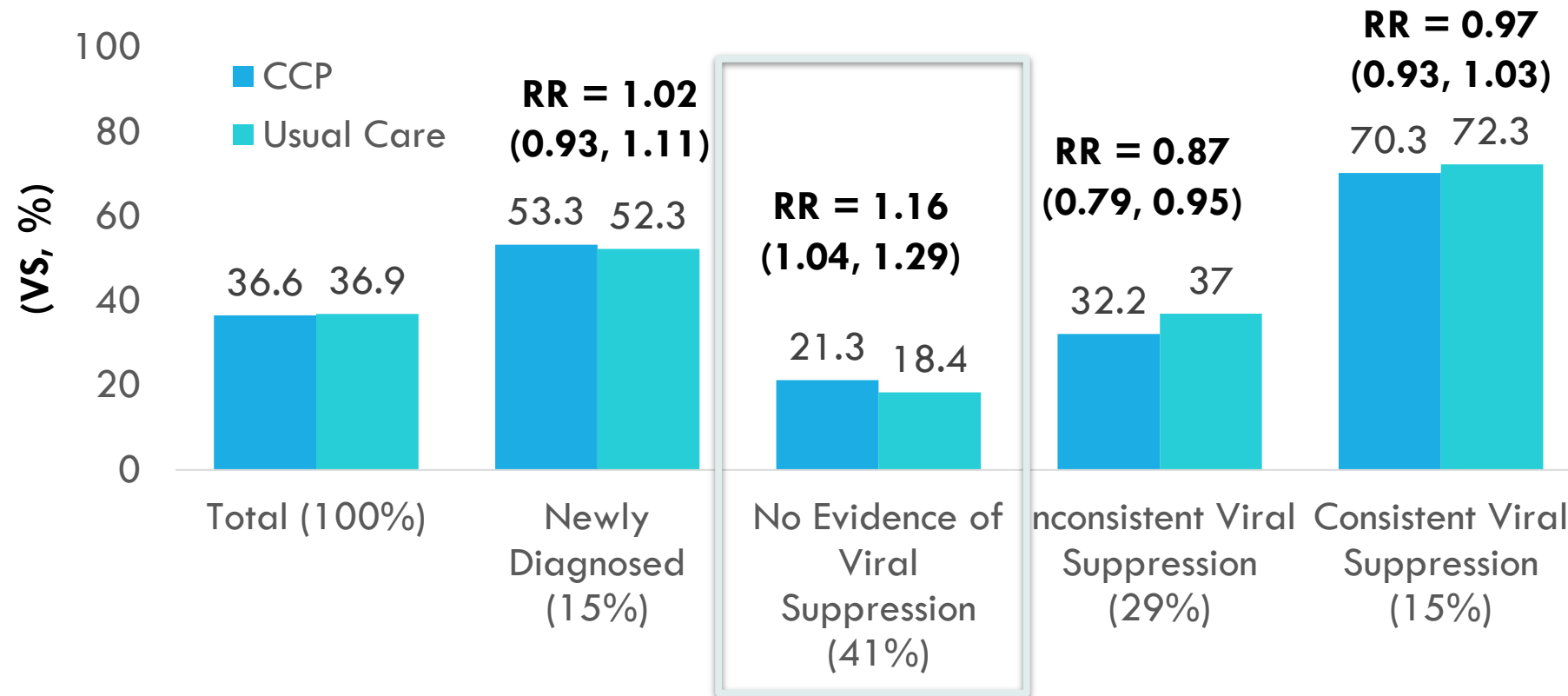
Durable Viral Suppression: ≥1 VL in each 12-month period of follow-up and *All VLs ≤200 copies/μL* from 13-36 months
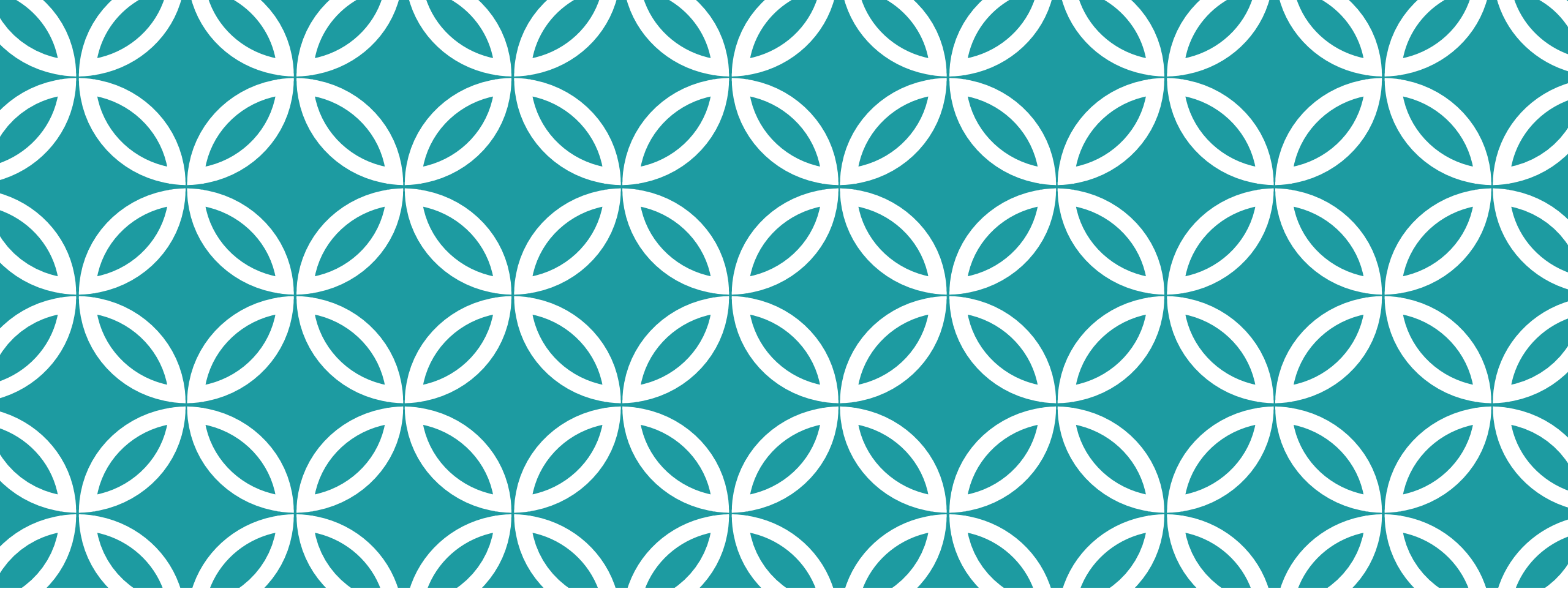
Robertson MR et al. JAIDS 2019

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 **R**efinements to **O**ptimize **M**odel **I**mpact and **S**calability based on **E**vidence (R01 MH117793, Principal Investigators: M. Irvine, D. Nash)

PROMISE BACKGROUND

<u>Context:</u> 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

<u>Objective:</u> *To study the impact and implementation of course corrections to an already evidence-informed intervention.*

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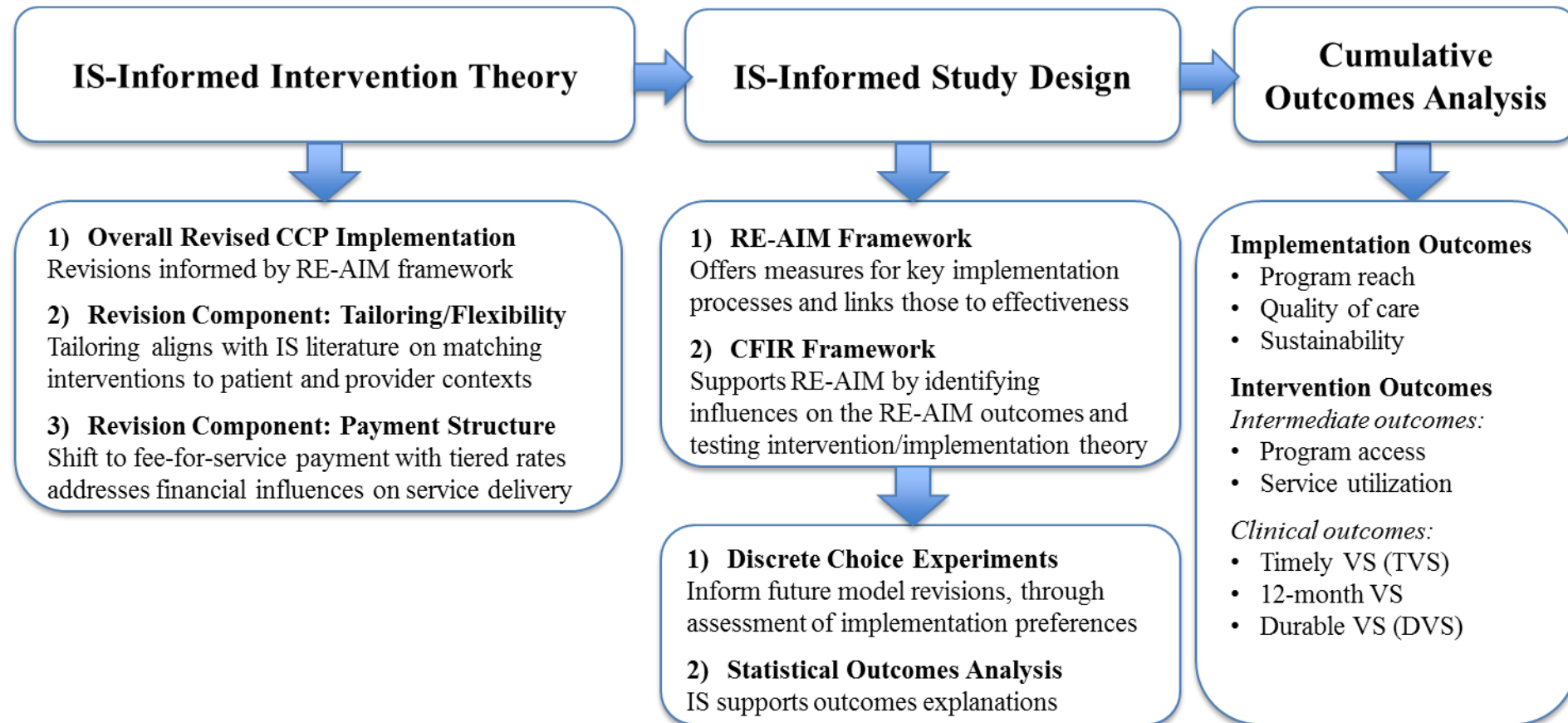
CHANGES: ORIGINAL VS. REVISED MODEL

Added flexibility & tools to match services to current client needs

	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
Effectiveness	X	X	X		X	X
Reach/impact	X	X	X	X	X	X

Irvine et al. MedRxiv 2019

CONCEPTUAL FRAMEWORK FOR PROMISE

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

1) **Discrete Choice Experiments**
Inform future model revisions, through assessment of implementation preferences

2) **Statistical Outcomes Analysis**
IS supports outcomes explanations

Cumulative Outcomes Analysis

Implementation Outcomes
- Program reach
- Quality of care
- Sustainability

Intervention Outcomes
Intermediate outcomes:
- Program access
- Service utilization

Clinical outcomes:
- Timely VS (TVS)
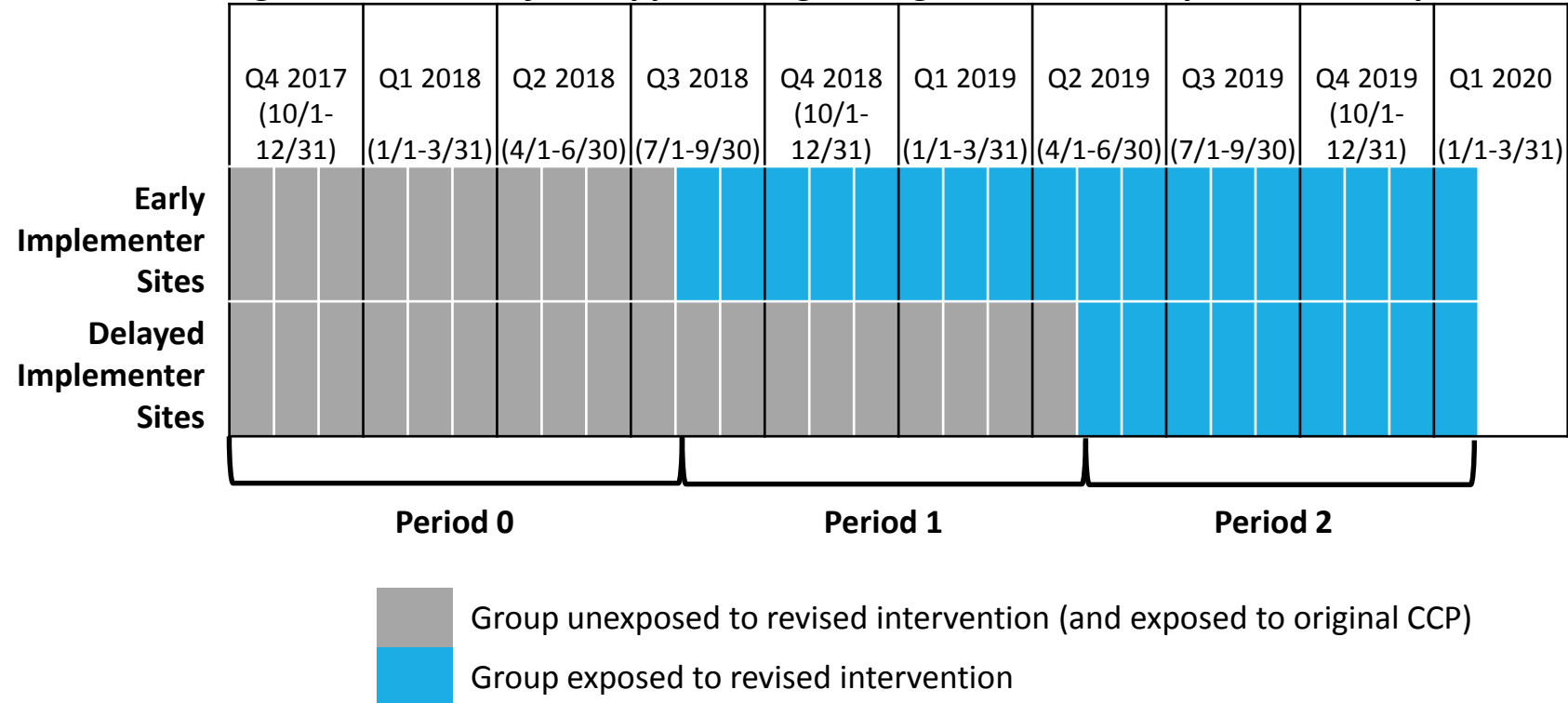- 12-month VS
- Durable VS (DVS)

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

Irvine et al. MedRxiv 2019

ClinicalTrials.gov Identifier: NCT03628287

METHODS

<u>Aim 1:</u> Paired Stepped-wedge Design

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

	Q4 2017 (10/1-12/31)	Q1 2018 (1/1-3/31)	Q2 2018 (4/1-6/30)	Q3 2018 (7/1-9/30)	Q4 2018 (10/1-12/31)	Q1 2019 (1/1-3/31)	Q2 2019 (4/1-6/30)	Q3 2019 (7/1-9/30)	Q4 2019 (10/1-12/31)	Q1 2020 (1/1-3/31)

Early Implementer Sites

Delayed Implementer Sites

Period 0   Period 1   Period 2

Group unexposed to revised intervention (and exposed to original CCP)

Group exposed to revised intervention

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

Irvine et al. MedRxiv 2019

ClinicalTrials.gov Identifier: NCT03628287

PROMISE AIMS (CONTINUED)

<u>Aim 2</u>: Assess Longer-term Effects on VS

- Apply CHORDS comparison-group methods

<u>Aim 3:</u> 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

PROMISE DCE EXAMPLE QUESTION

PROMISE: EARLY LESSONS

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.

Irvine et al. MedRxiv 2019
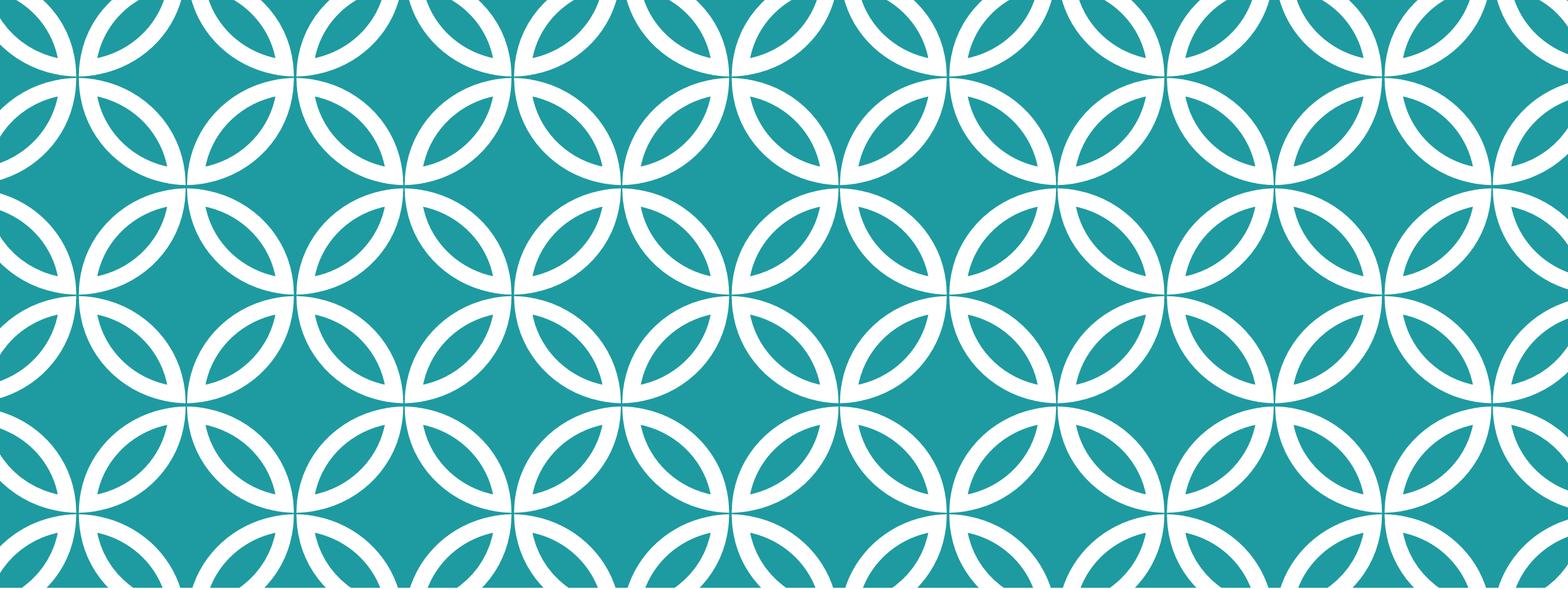
DATA TO SUPPRESSION (D2S) — A NEW APPLICATION OF DATA TO CARE

Leveraging Ryan White Part A support services programs and HIV surveillance data to address gaps in the HIV care continuum

LOCAL PROBLEM: CARE CONTINUUM GAPS IN NYC

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!*

LOCAL OPPORTUNITY: CHANGE IN NYS HIV LAW

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*

RWPA D2S PILOT: CLIENT PROGRESS REPORT (CPR)

➢ 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)

	eSHARE ID	Agency	Contract	Last Service Date	Client Status
1	AAAAAAAAAA	Y	00-MCM-000	12/18 /2017	Needs follow-up for care and viral suppression [1]
2	BBBBBBBBBB	Y	00-MCM-000	04/01/2018	Needs follow-up for viral suppression [2]
3	CCCCCCCCCC	Y	00-MCM-000	03/15/2018	Shows some evidence of viral suppression [3]
4	DDDDDDDDD	Y	00-MCM-000	12/04/2017	Should be closed due to death [4]
5	EEEEEEEEEE	Y	00-MCM-000	02/19/2018	Shows stable viral suppression [5]

[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

NEXT STEPS: EXPANDING D2S WITHIN RWPA

Navigator on home visit

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

2019 R01 PROPOSAL

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, <u>to close the retention-suppression gap.</u>

3 AIMS:

1. <u>Assess D2S intervention effects</u> on timely VS and time to VS, in a stepped-wedge hybrid Type 1 trial.

2. <u>Identify modifiable determinants of D2S response</u>, by comparing characteristics of D2S-exposed clients who do and do not achieve VS, to recognize opportunities to tailor and strengthen the intervention.

3. <u>Identify preferences and priorities for D2S implementation</u>, 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
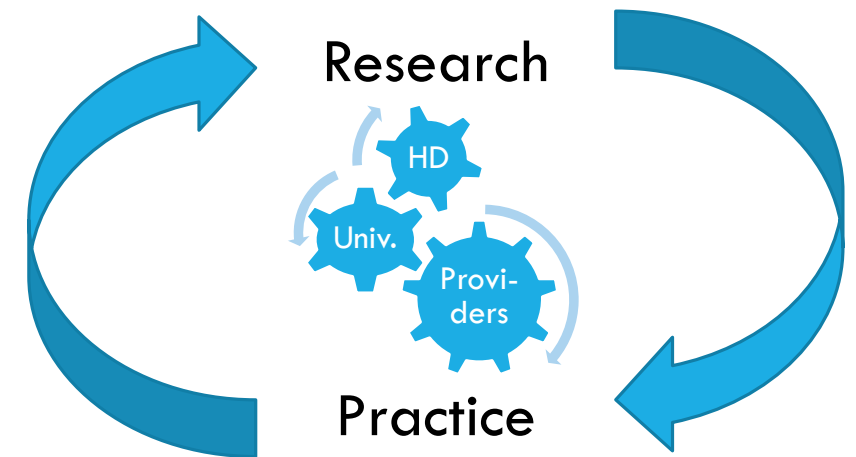
Academic-government partnerships that include joint planning of research in advance of key policy or practice initiatives can produce answers to locally important public health research questions

- 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*

RESOURCES

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

CCP Page on CDC Compendium Site: http://www.cdc.gov/hiv/pdf/prevention/research/compendium/cdc-hiv-HIVCCP_EI_Retention.pdf

Irvine MK, Chamberlin SA, Robbins RS, et al. Improvements in HIV care engagement and viral load suppression following enrollment in a comprehensive HIV care coordination program. Clinical Infectious Diseases 2015;60:298-310.

Irvine MK, Chamberlin SA, Robbins RS, Kulkarni SG, Robertson MM, Nash D. Come as you are: Improving care engagement and viral load suppression among HIV care coordination clients with lower mental health functioning, unstable housing, and hard drug use. AIDS and Behavior 2017;21:1572-9.

Robertson MM, Waldron L, Robbins RS, et al. Using Registry Data to Construct a Comparison Group for Programmatic Effectiveness Evaluation: the New York City HIV Care Coordination Program. American Journal of Epidemiology 2018;187:1980–9.

Nash D, Robertson MM, Penrose K, et al. Short-term effectiveness of HIV care coordination among persons with recent HIV diagnosis or history of poor HIV outcomes. PLoS One 2018;13:e0204017.

Robertson MM, Penrose K, Irvine MK, et al. Impact of an HIV Care Coordination Program on Durable Viral Suppression. JAIDS Journal of Acquired Immune Deficiency Syndromes 2019;80:46–55.

Robertson MM, Penrose K, Nash D, et al. Impact of an HIV Care Coordination Program on the Timeliness of Viral Suppression and Immune Recovery Among Clients Newly Diagnosed with HIV. AIDS and Behavior 2019; https://doi.org/10.1007/s10461-019-02732-0

Irvine MK, Levin B, Robertson M, et al. PROMISE (Program Refinements to Optimize Model Impact and Scalability based on Evidence): A cluster-randomized, stepped-wedge trial assessing effectiveness of the revised versus original Ryan White Part A HIV Care Coordination Program for patients with barriers to treatment. medRxiv 2019:19012427; doi: https://doi.org/10.1101/19012427

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

ACKNOWLEDGMENTS