



HPTN

HIV Prevention
Trials Network

Engaging a Hidden Population to Stop HIV

HPTN 078

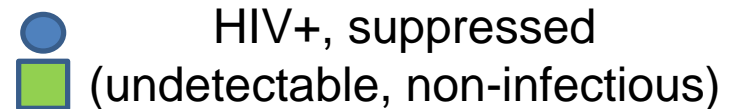
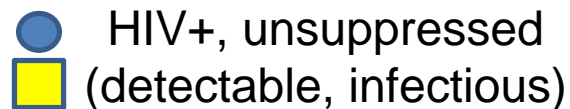
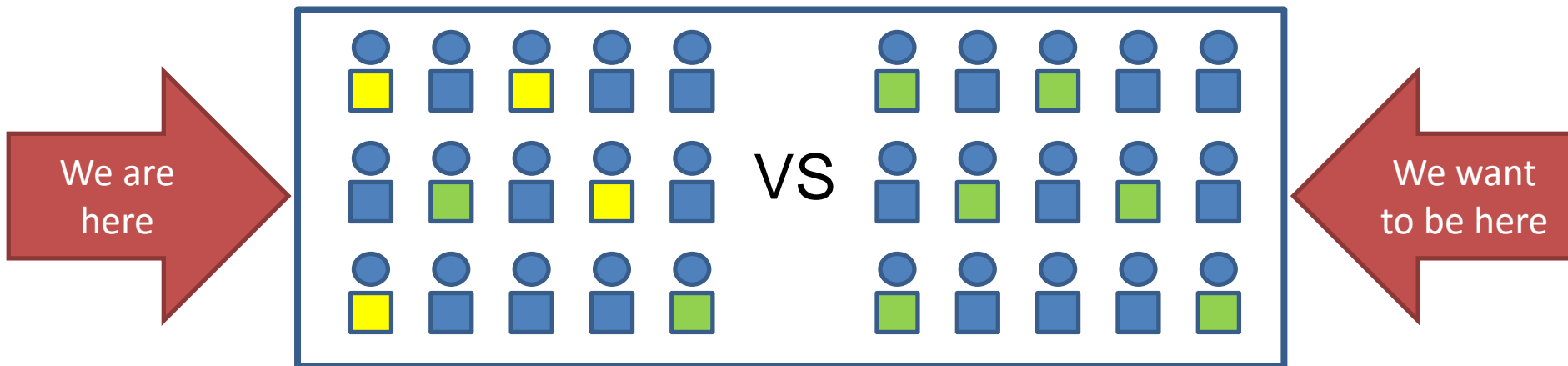
**Theresa Gamble, PhD
HPTN LOC, FHI 360
Durham, NC, USA
April 11, 2017**

Study Rationale

- In the US, MSM remain the most affected by HIV
 - 67% of new HIV diagnoses are MSM (2014)
- US MSM have low rates of viral suppression
 - 34% in White MSM, 16% in Black MSM

Study Rationale

- MSM who are HIV+ and virally unsuppressed serve as the reservoir for HIV and drive the epidemic
- If every one became virally suppressed, HIV transmission would stop



Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

**HIV+
Unaware
Of
Status**

**HIV+
Aware,
Not In
Care**

**HIV+
Aware,
In Care,
Not
Suppressed**

Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

EASY TO FIND



**HIV+
Aware,
In Care,
Not
Suppressed**

Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

**HIV+
Unaware
Of
Status**

**HIV+
Aware,
Not In
Care**

**HARD TO FIND
(HIDDEN POPULATION)**



Study Rationale

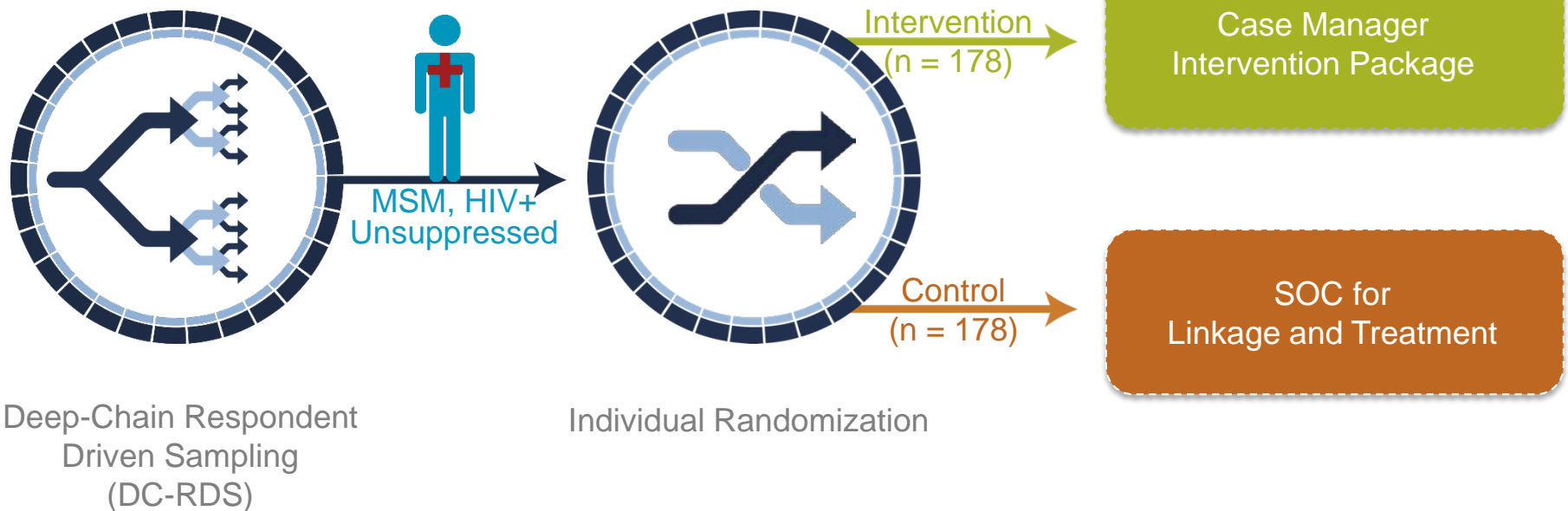
HPTN 078 tests two critical ideas

- How can we find MSM who are HIV+ and unsuppressed (detectable and infectious)
- When we find them, how can we help these MSM become suppressed (undetectable and non-infectious)

Study Design, Population and Duration

Screened population	Enrolled participants
2700	356
MSM \geq 16 yo	MSM HIV+, Unsuppressed
Study Duration: 24 M Follow-up	

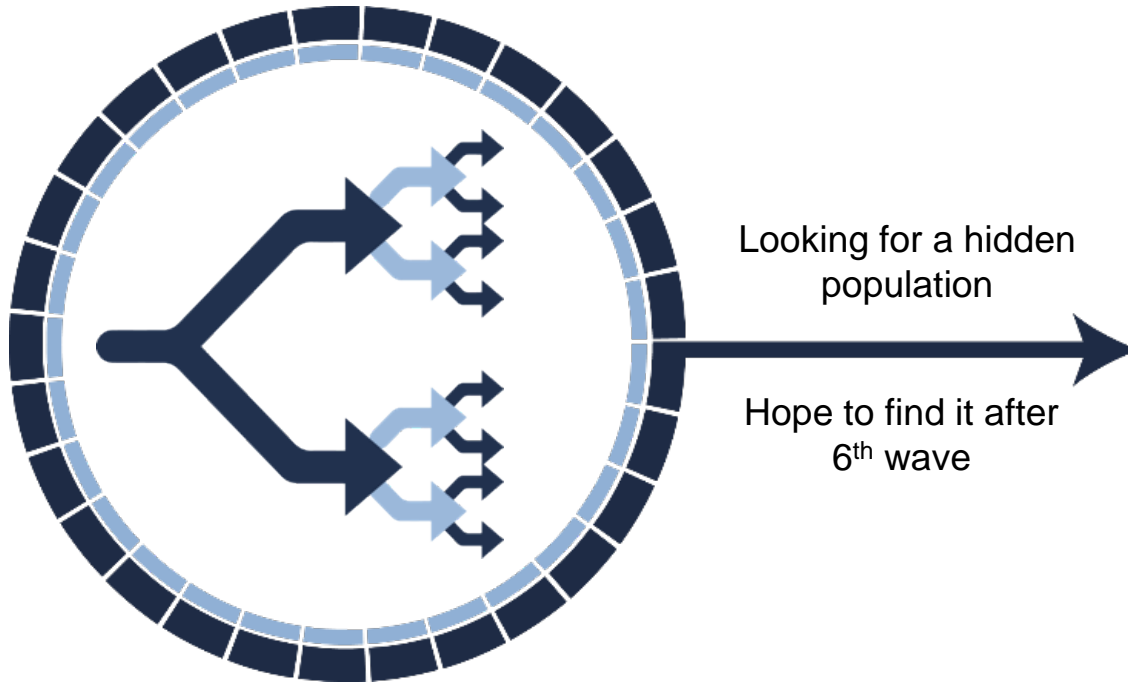
HPTN 078: Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States



Deep-Chain Respondent
Driven Sampling
(DC-RDS)

Individual Randomization

Deep-Chain Respondent Driven Sampling (DC-RDS)



MSM, HIV+
Unsuppressed

Example Coupons

TURN IT!

Call or text (443) 310-6738 for more information or to schedule an appointment (days, nights or weekends)

STICKER Expires: _____

The sticker features a blue city skyline illustration and the text 'TURN IT!' in large, bold, blue letters.

YOU HAVE JUST RECEIVED A

Golden Ticket

TICKET EXPIRES: _____

The coupon is yellow with black text and features several starburst patterns around the central text.

We have an IDEA...

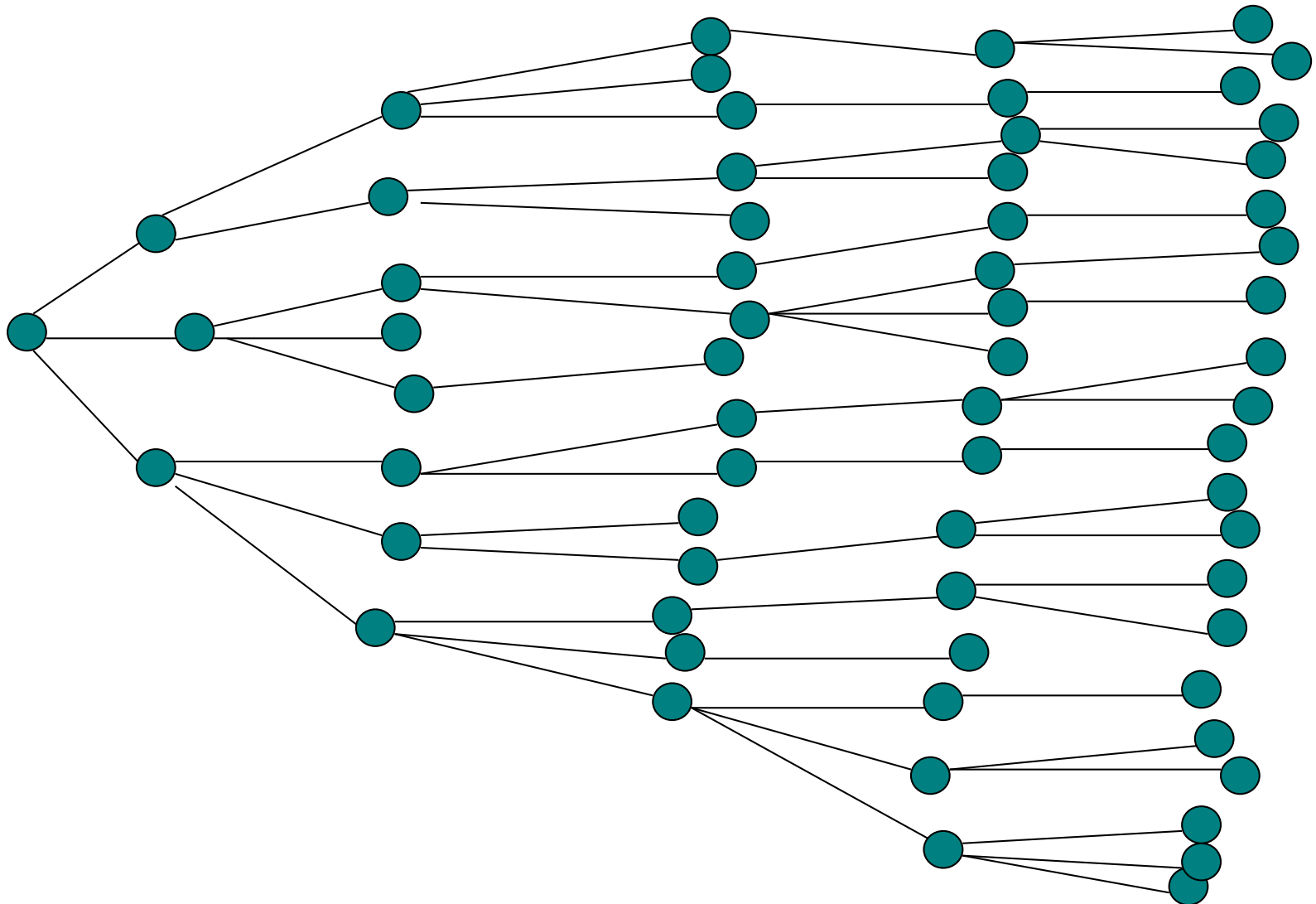
Contact Us Now:

(857) 206-5178 call or text
(617) 927-6440 call only

The coupon is black with green and white text. It features a white lightbulb icon on the right side.

Deep-Chain Respondent Driven Sampling (DC-RDS)

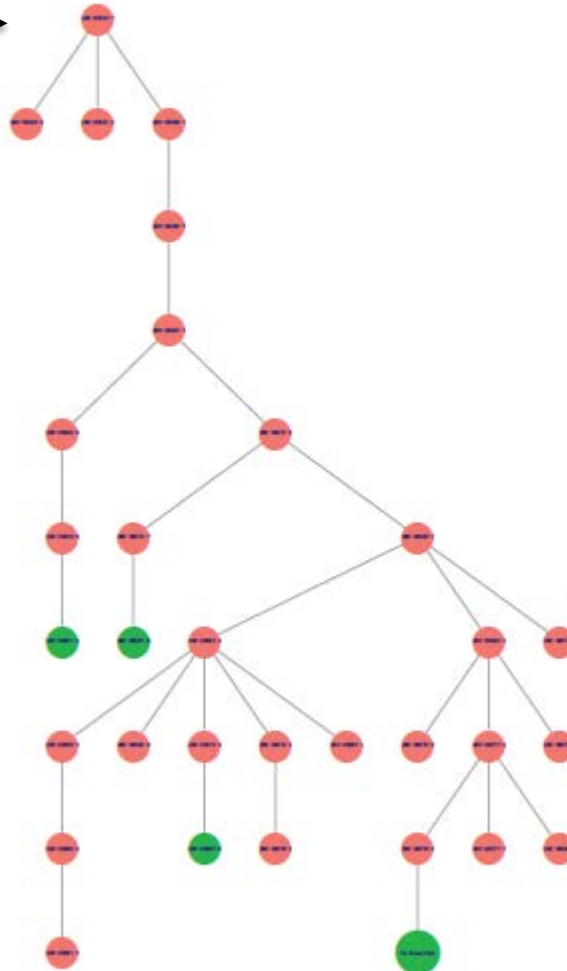
Seed **Wave 1** **Wave 2** **Wave 3** **Wave 4** **Wave 5**



Deep-Chain Respondent Driven Sampling (DC-RDS)

Seed →

Recruitment Tree



**Early waves
(1 - 6)**

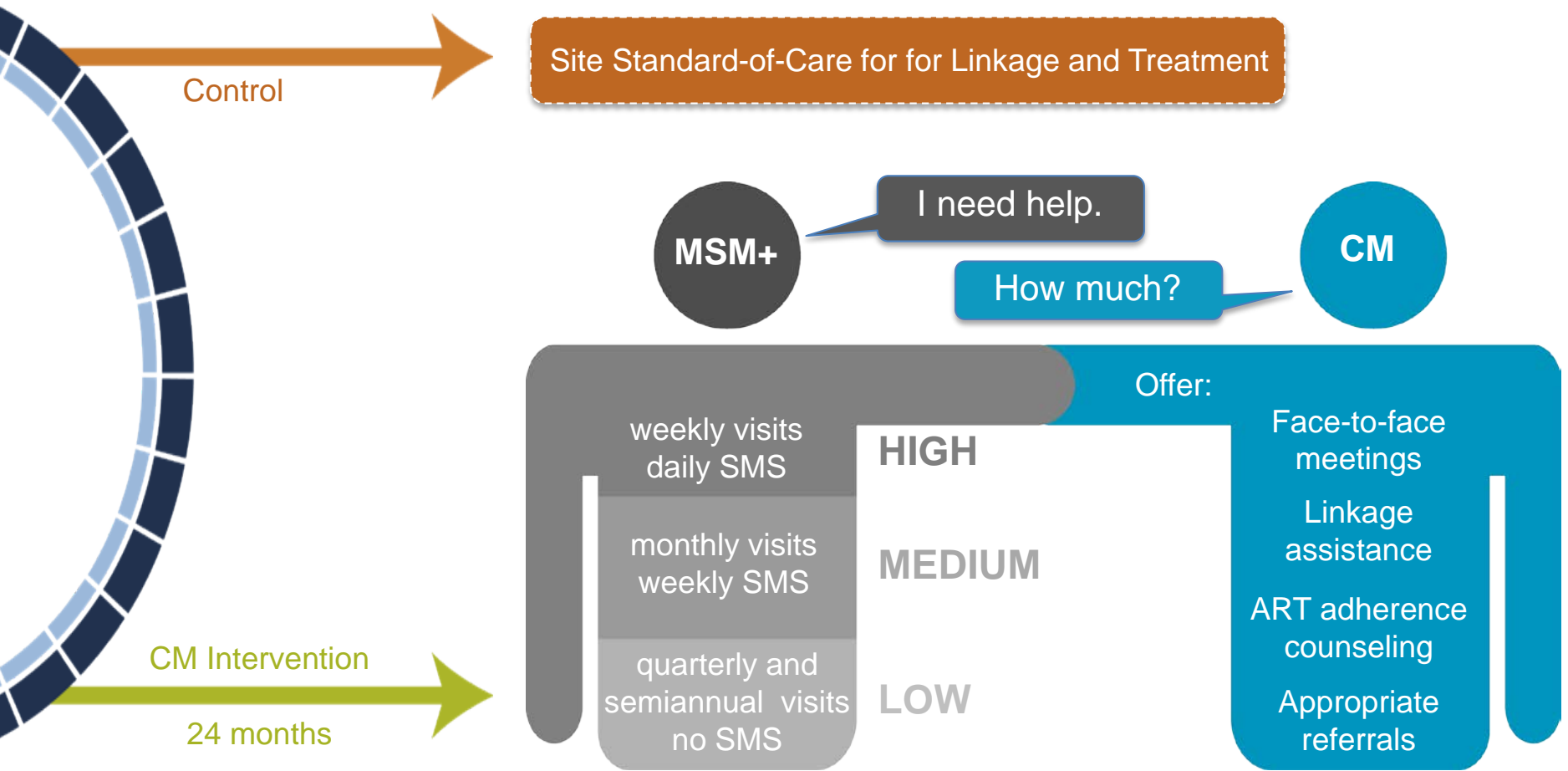
Wave 6 →

*In DC-RDS, things get
interesting past wave 6*

**Late waves
(7 - 9)**

● A - before Feb ● B - February

Case Manager (CM) Intervention



The CM intervention includes patient choice, motivational interviewing and automated phone/email/text messages

Study Objectives

- Assess the ability of DC-RDS to identify and recruit HIV-infected MSM in the US who are unsuppressed.
- Compare the efficacy of the two study arms (CM intervention vs. SOC control) in achieving durable viral suppression 24 months after enrollment.

Sites



- Alabama CRS
(Birmingham, AL)
- Fenway Health CRS
(Boston, MA)
- Johns Hopkins University CRS
(Baltimore, MD)
- Ponce de Leon Center CRS
(Atlanta, GA)

Current Study Status

- DC-RDS is working – all sites have recruitment trees that have reached waves 10 - 12
- In order to fully enroll, we have added direct recruitment activities in parallel to DC-RDS
 - Clinic/hospital referrals
 - Support group referrals
 - Alliances with testing programs
 - Study advertisements (flyers, social media posts)
 - Limited venue-based recruitment

Current Study Status

	S1 DC-RDS Visits	S1 Direct Recruitment Visits	Total Screened
Fenway	156	17	173
JHU	108	40	148
Ponce	78	52	130
Alabama	103	61	164
Total	445 (72%)	170 (28%)	615

	Enrolled via DC-RDS	Enrolled via Direct Recruitment	Total Enrolled	Randomized to CM Arm	Randomized to SOC Arm
Fenway	12	5	17	8	9
JHU	7	3	10	5	5
Ponce	21	6	27	14	13
Alabama	2	8	10	6	4
Total	42 (66%)	22 (34%)	64	33	31

Community Engagement

- DC-RDS did not require special community engagement
- Direct recruitment does – sites have worked to form alliances for referrals and are starting to conduct venue-based activities.

ACKNOWLEDGEMENTS

The HIV Prevention Trials Network is sponsored by the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health, and the National Institute on Drug Abuse, all components of the U.S. National Institutes of Health.

Special thanks to:

Dr. Chris Beyrer (Chair)

Dr. Bob Remien (Co-chair)

HPTN LOC Staff (Jill Stanton, Anna LeViere, Marcus Bolton)

HPTN SDMC Staff (Laura McKinstry, Ethan Wilson, Dr. Jim Hughes)

HPTN LC Staff (Vanessa Cummings, Paul Richardson, Dr. Sue Eshleman)

DC-RDS Expert: Dr. Stef Baral

MI Expert: Dr. Ivan Balan

Site IoRs, Site Staff and Participants

Question and Answer Session