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

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Youth Prevention Research Work Group (YPRWG) Webinar
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Study Design, Population and Duration

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

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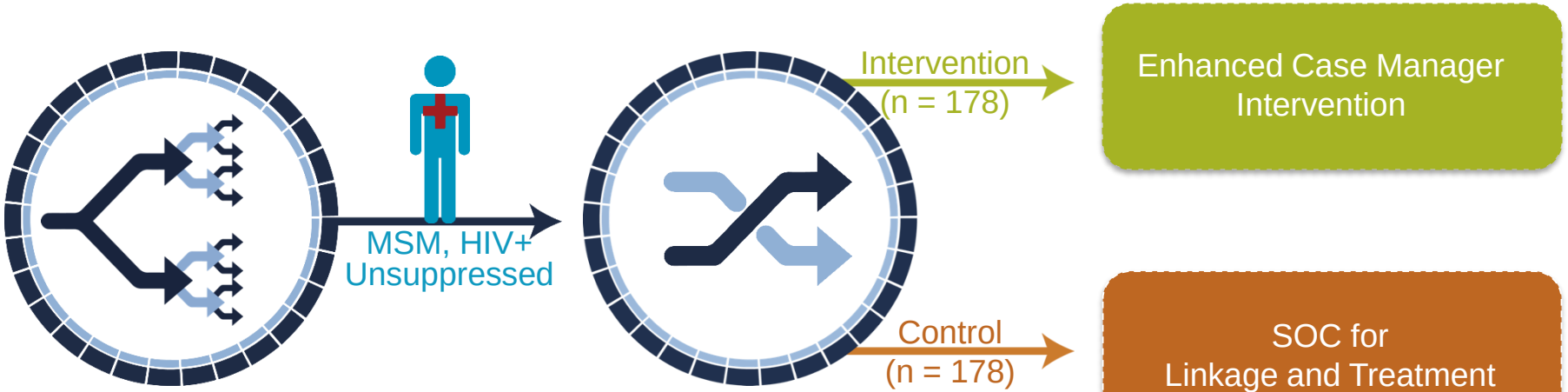

Deep-Chain Respondent Driven Sampling (DC-RDS)

Individual Randomization

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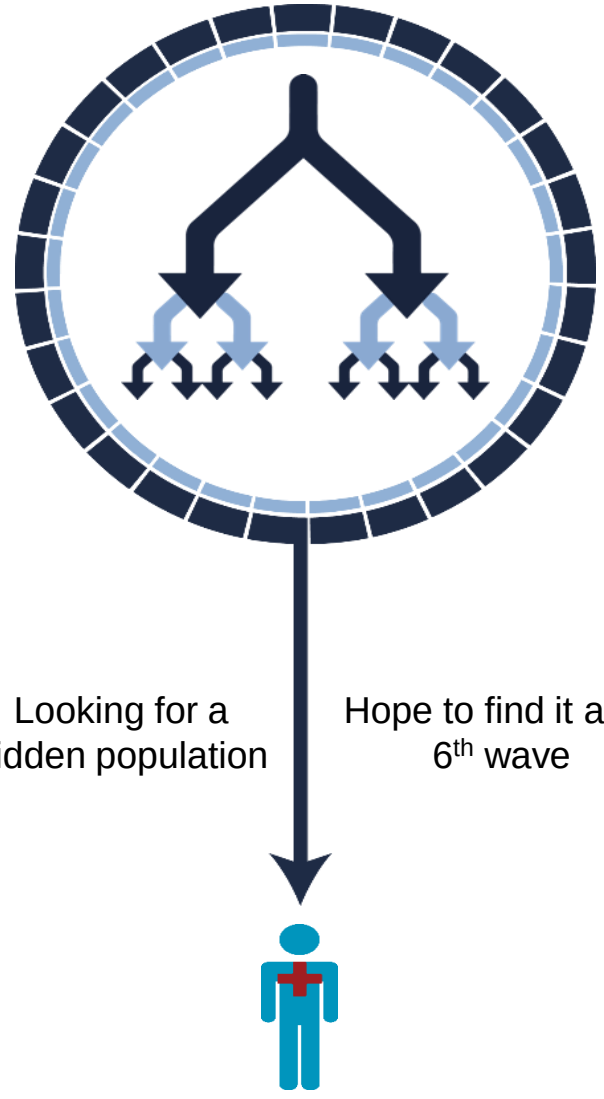
Deep-Chain Respondent Driven Sampling (DC-RDS)

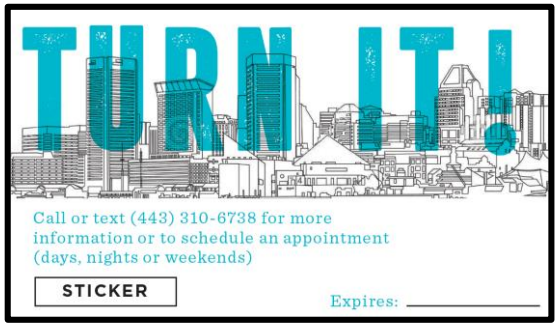


Looking for a hidden population

Hope to find it after 6th wave

MSM, HIV+
Unsuppressed

Site Coupons



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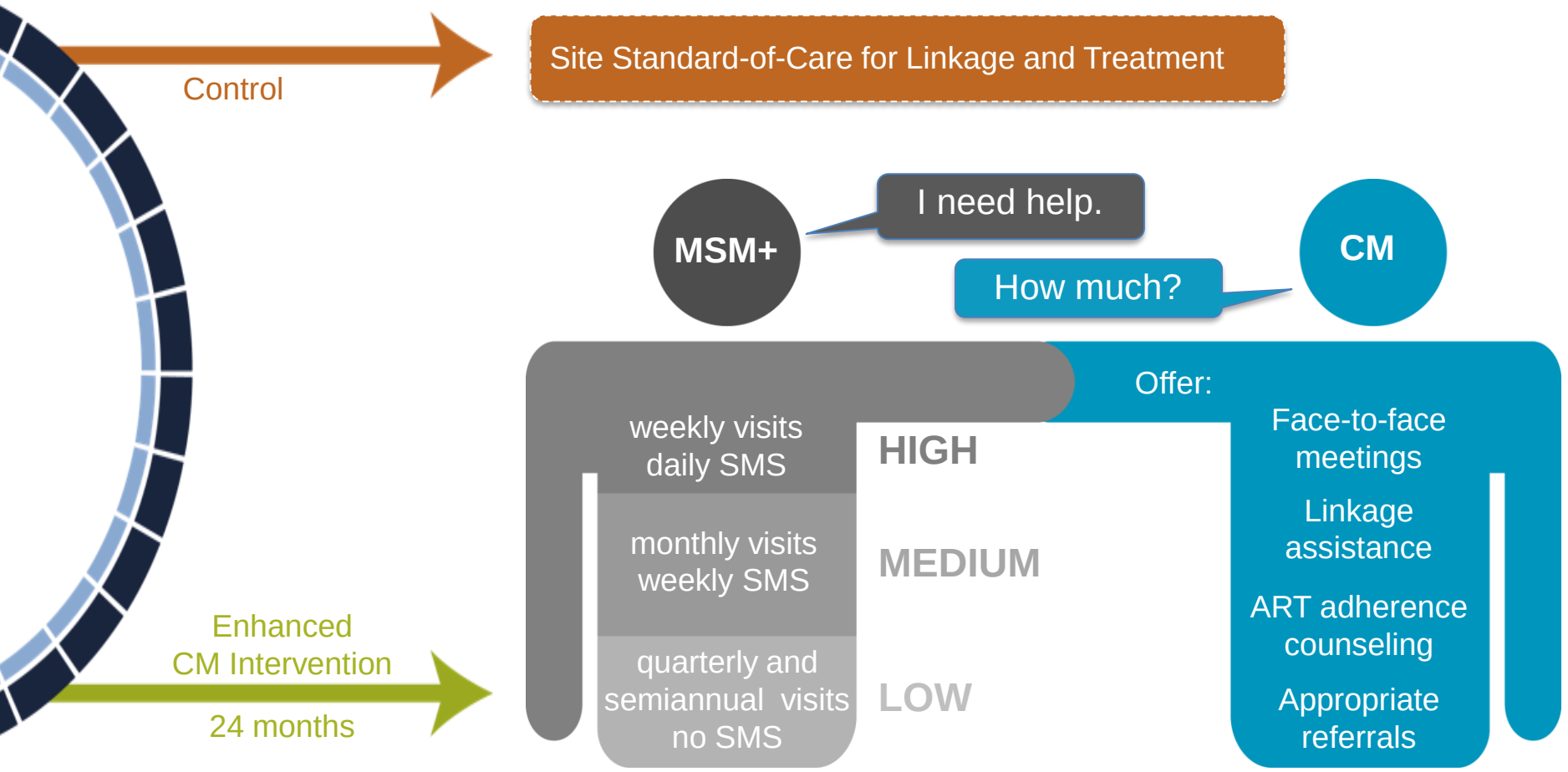
Enhanced Case Manager (CM) Intervention



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

Sites

Recruiting ≥ 16

- Alabama CRS (Birmingham, AL)
- Fenway Health CRS (Boston, MA)

Recruiting ≥ 18

- Johns Hopkins University CRS (Baltimore, MD)
- Ponce de Leon Center CRS (Atlanta, GA)

Primary Objectives

- Assess the ability of DC-RDS to identify and recruit HIV-infected MSM in the US who are not VS.
- Compare the efficacy of the CM intervention vs. SOC in achieving durable VS (defined as HIV VL < 200 copies/ml) 24 months after enrollment.

Original Study Duration

48 months

- 12 months for DC-RDS recruitment and enrollment
- 24 months of follow-up for participants randomized to CM and SOC arms
- ~12 months after completion of study visits for data analyses, phylogenetic assessments and modeling.

Informed Consent

Written informed consent obtained from each study participant prior to conducting study-related procedures.

Each study site responsible for developing a study informed consent form for local use…which describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations.

Based on local IRB approval and state law, sites may seek a waiver of parental consent for either the DC-RDS activities alone or both the DC-RDS and CM activities.

Only sites that are granted a waiver of parental consent for the DC-RDS activities allowed to screen minors (16 and 17 year olds).

Screening and Enrolling under 18: Site Diversity

- **UAB** is screening <18 w/o parental consent – but if eligible, parental consent needs to be obtained in order to enroll the participant (this was an IRB decision, not related to state laws)
- **Fenway** can screen and enroll <18 w/o parental consent
- **Emory** IRB: "After extensive research and phone consultation with the lead site's legal representative, the GA department of health, and Emory OGC, our team has come to the conclusion that the plan for screening minors for HIV prior to obtaining parental permission is not consistent with GA state law."
- **JHU** – IRB decided not to grant waivers for screening or enrollment—not a state determination

Outcomes of IRB Determinations

UAB	**Waiver of parental consent granted for screening (DC-RDS) only.**
Emory	Waiver of parental consent NOT granted, will only enroll 18 and over
JHU	Waiver of parental consent NOT granted, will only enroll 18 and over
Fenway	Waiver of parental consent granted for screening and enrollment

Current Study Status

- 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

Primary Study Objectives:

- Assess the ability of DC-RDS to identify and recruit HIV-infected MSM in the US who are not virally suppressed.
- **Compare the efficacy of the two study arms (intervention vs. SOC) in achieving durable viral suppression (defined as HIV VL < 200 copies/ml) 24 months after enrollment**

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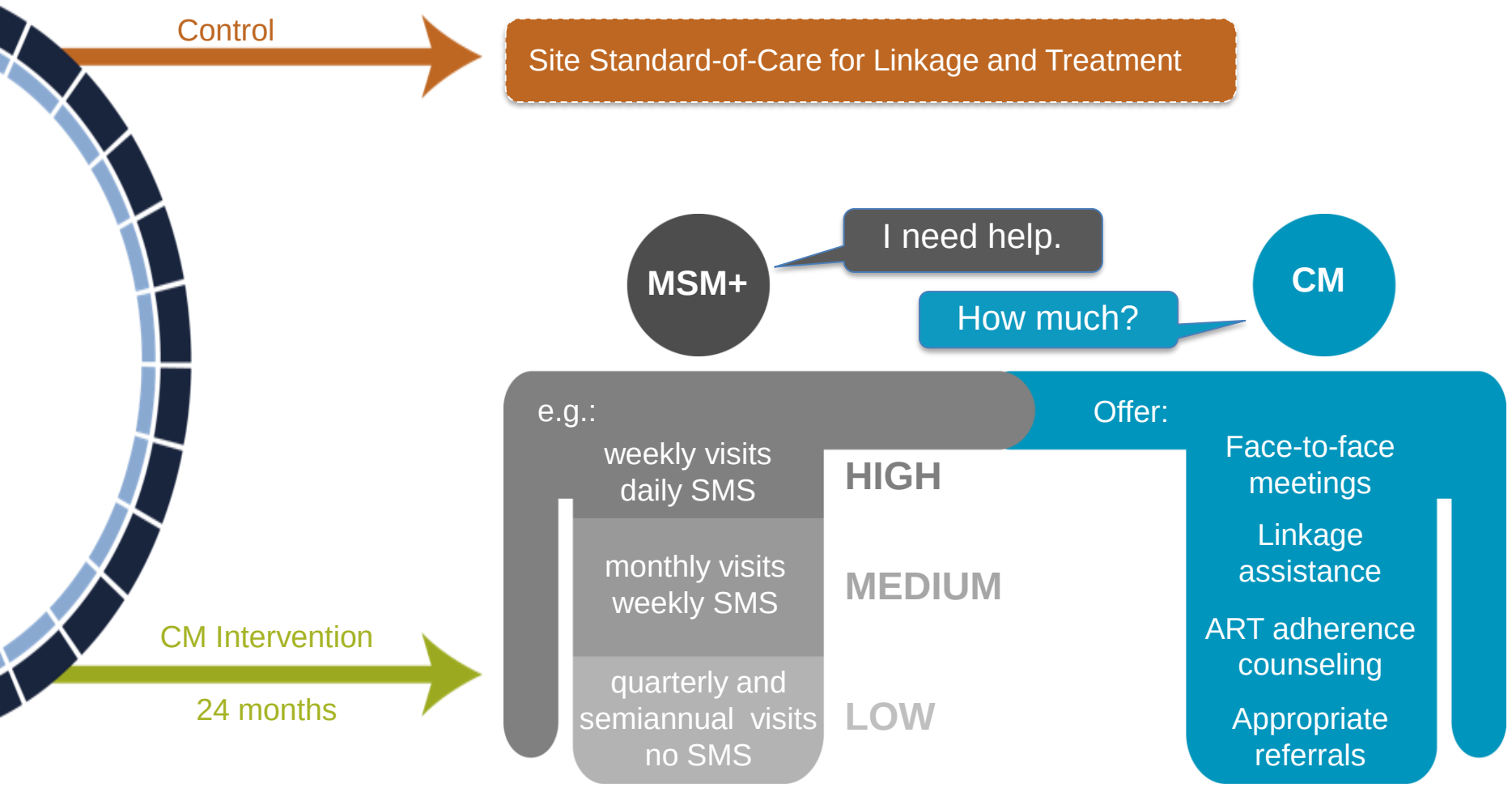
HPTN 078 Intervention



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What have we learned and where do we go from here?

What have we learned?

- Significant diversity across sites, IRBs, States, in screening and enrolling under age 18 year olds
- Study design limits adolescent/young adult participation
- Majority of men enrolled are not newly diagnosed but men with HIV who have fallen out of care continuum

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Special Thanks To

Protocol Chair and Co-Chair: Chris Beyrer and Bob Remien

DC-RDS Expert: Stef Baral; **MI Expert:** Ivan Balan; **Questionnaires:** Risha Irvin

Site IoRs: Ken Mayer, Michael Mugavero/Scott Batey, Jason Farley, Carlos del Rio

Site Staff: Oscar Perez, Julian Dormitzer, Josh Bruce, Neil Rafferty, Chastity McDavid, Heath Shirkey, Adam Bocek, Kelly Lowensen, Ron Gaston, Michael Heard, Diego Schaps, Darian West, Derek Jobe, Edwin Blount, Chris Root, Chris Foster, Sally Shurbaj, Kiko King, Ty Wilson, William Graves and many others

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HPTN LC Staff: Vanessa Cummings, Paul Richardson, Sue Eshleman

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