

Preliminary Efficacy for HPTN 094: 26-week RCT of Integrated Strategies for People Who Inject Drugs

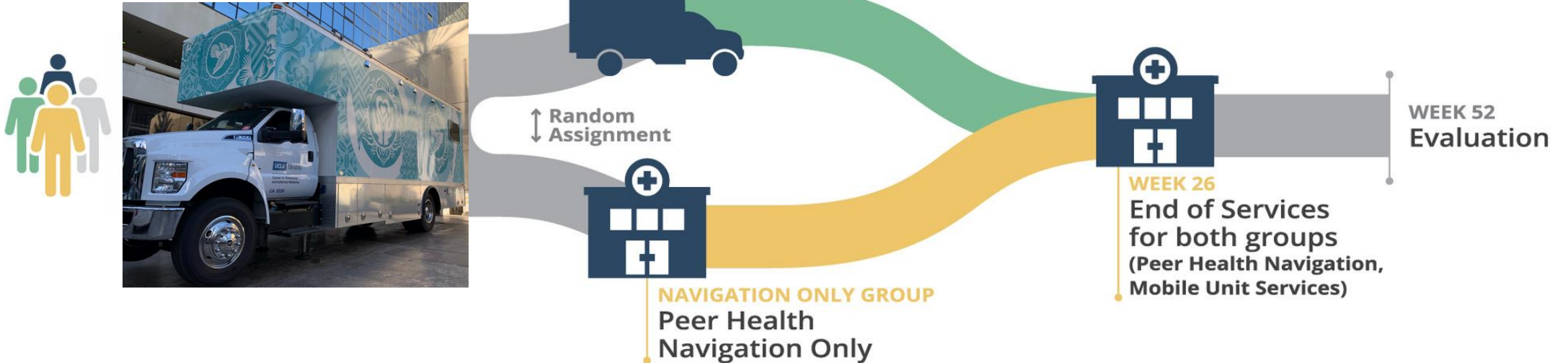
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* Co-Chair

Study Design

Consent, Screening, & Enrollment in Mobile Units



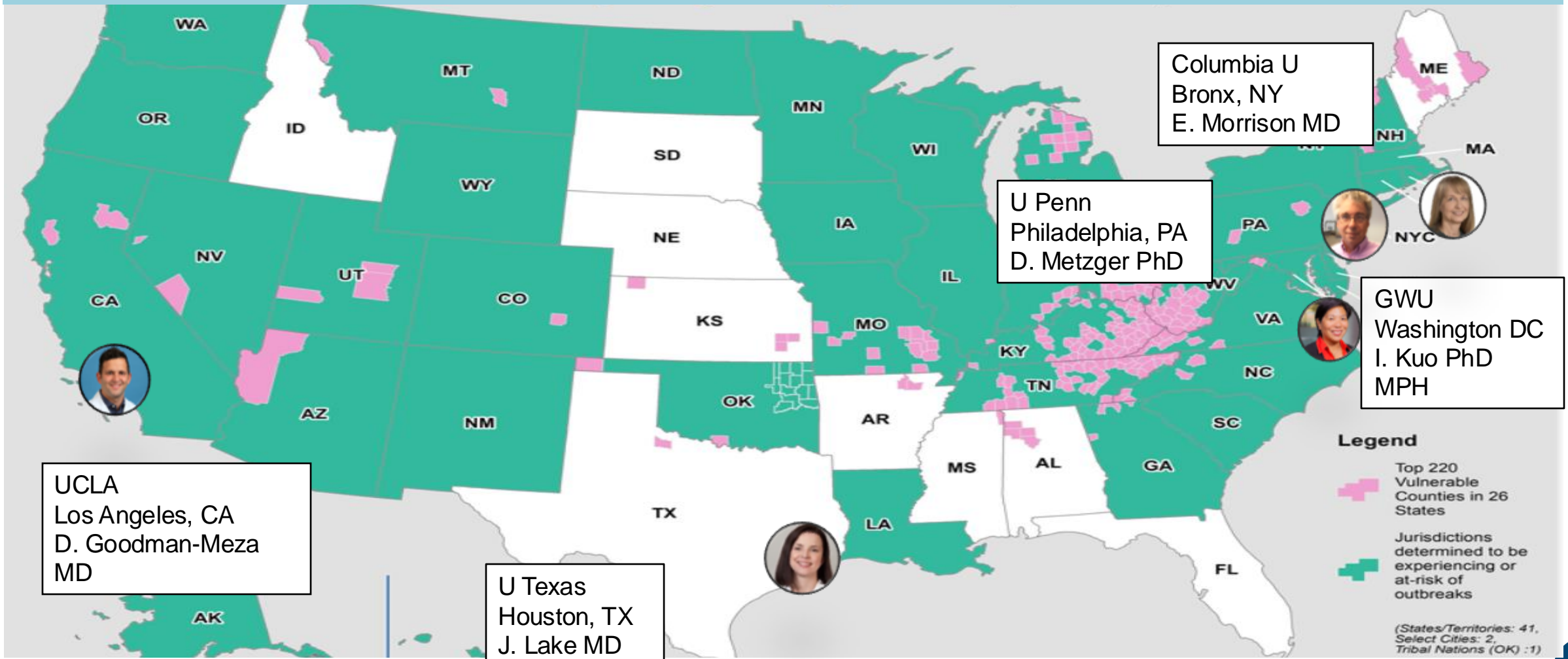
To evaluate if 26 weeks of “one stop” integrated health services supported by peer navigation delivered in a mobile unit is superior to peer navigation alone to “brick and mortar” agencies is superior along **three primary outcomes**

PRIMARY OUTCOMES at 26 Weeks

1. On MOUD
2. ↑ rate of viral suppression for PWH
3. ↑ PrEP among PWhoH

Participating Sites

Plotted onto spatial map of IDU-HIV risk



Study Population

- 18 and older
- Have opioid use disorder (OUD) and be injecting drugs
- Willing to start OUD treatment, but not currently in treatment
- At risk for transmitting or acquiring HIV
- Living with or without HIV



Peer Navigation

HPTN 094 peer navigation model draws upon systems theory, self-determination theory, empowerment theory, shared decision-making theory and social support theory to:

- **Facilitate Identification and Prioritization** of needs and use motivational interviewing techniques to reinforce linkages to appropriate services through 26 weeks
- **Facilitate Retention** in MOUD and harm reduction, HIV care and PrEP through 26 weeks.
- **Facilitate Receipt** of housing and food support, transportation assistance, other social services at available community resources through 26 weeks







Navigation materials available at: www.hptn.org



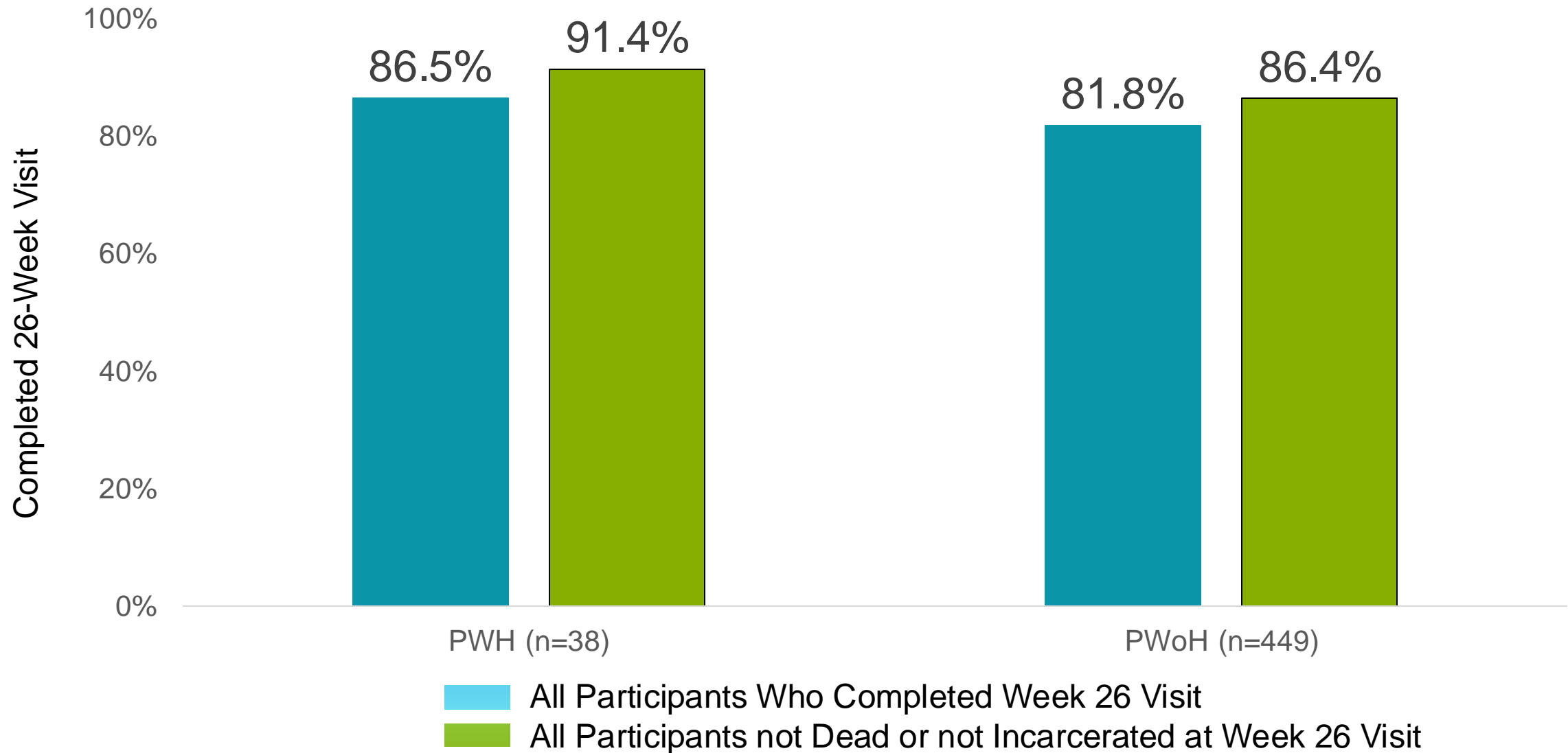
HPTN 094 PEER NAVIGATION MANUAL

*A research guide for peer-navigators
conducting the navigation for the HIV
Prevention Trials Network 094 study*

Demographics at Enrollment

| | PWH n=38 | PWoH n=409 |
|-------------------------------------|--|---|
| Females |  8 (21.1%) |  134 (32.8%) |
| Age (years) < 30 |  3 (7.9%) |  46 (11.2%) |
| Race | | |
| - American Ind/Alaska Native | 4 (10.5%) | 18 (4.4%) |
| - Black/African American | 11 (28.9%) | 84 (20.5%) |
| - White | 15 (39.5%) | 226 (55.3%) |
| Hispanic or Latino Ethnicity | 13 (34.2%) | 133 (32.5%) |
| Current Housing | | |
| - Residence of any kind | 7 (18.4%) | 127 (31.1%) |
| - Park/sidewalk | 15 (39.4%) | 115 (28.1%) |
| - Tiny home/trans house |  11 (28.9%) |  103 (25.2%) |
| - Unspecified or missing | 5 (13.1%) | 64 (15.6%) |

Retention at 26 weeks



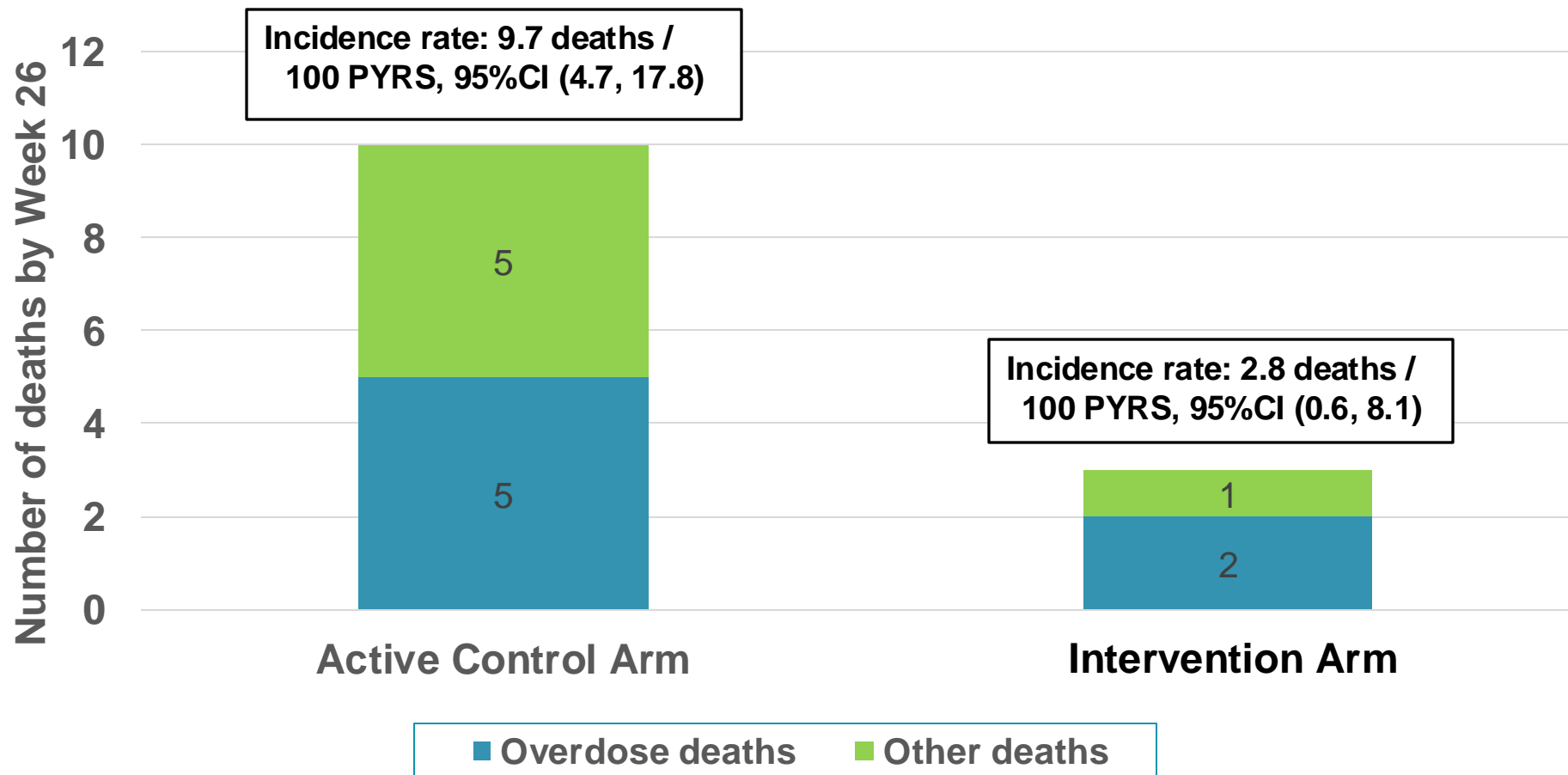
Primary Outcomes at 26-Weeks

| | PWH (N=38) | | PWoH (N=409) | |
|--|--------------------|------------------|--------------------|------------------|
| | Active Control Arm | Intervention Arm | Active Control Arm | Intervention Arm |
| | n = 17 | n = 21 | n = 206 | n = 203 |
| MOUD using biomarker and prescription | 1 (5.9%) | 3 (14.3%) | 16 (7.8%) | 15 (7.4%) |
| Self-Reported Taking MOUD | 5 (29.4%) | 7 (33.3%) | 37 (18%) | 51 (25.1%) |
| HIV suppression using biomarker | 7 (41.2%) | 8 (38.1%) | --- | --- |
| PrEP detected using biomarkers | --- | --- | 6 (2.9%) | 11 (5.4%) |

2 incident HIV acquisitions, one in each arm. Incidence rate = 1.03 per 100 PY, 95% CI: 0.13, 3.73

All Cause Mortality

Six-month mortality

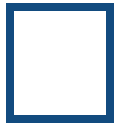


Estimated Hazard Ratio (95% CI): 0.30 (0.08, 1.08), p=0.0661

A Priori Ambitious Goals

Yes

No



- 50% of participants in the intervention arm are on MOUD at 26 week



- Death rate in the intervention arm is reduced by half, compared to the active control arm



- Twice as many participants in the intervention arm are virally suppressed or on PrEP compared to the active control arm

Conclusions on Integrated Care for Addictions and HIV Prevention for PWID

- ✓ ~7-8% PWID started MOUD and continued at 26 weeks. This is significant.
- ✓ Intervention showed 70% reduction of all cause mortality for intervention compared to active control arm, non-statistically significant signal
- ✓ A “one stop shop” using a mobile unit to treat PWID at risk for HIV where they are at represents a unique solution for people facing multiple health threats
- ✓ Findings provide evidence to support implementation science follow-on study

Thank you



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