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RCT of Mobile Health Unit Versus Patient Navigation to Increase PrEP in Criminal Legal-Involved PWUD

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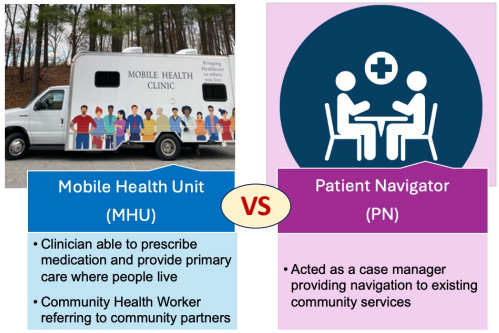
BACKGROUND

- Persons who use drug (PWUD) who are involved in the criminal legal system (CLS) are at high risk for HIV [1]
- CLS PWUD are less likely to initiate pre-exposure prophylaxis (PrEP) [2, 3]

DESIGN

- **Design**: 5-Year Hybrid Type 1 Effectiveness-Implementation Randomized Controlled Trial that compared two models of care: 1) Patient Navigation (PN) and 2) Mobile Health Units (MHU) service delivery for HIV and substance use disorder prevention/treatment[4]
- **Primary Outcome**: Initiation of PrEP (prevention) or ART (treatment) medication within a 6-month intervention window over 6 months

Figure 1. Intervention Description



METHODS

- Four sites (2 in Texas and 2 in Connecticut).
- 6-month intervention period with an additional 6 month follow up period.
- **Eligibility criteria for this analysis**:
  - 18+ years of age,
  - Recent criminal legal involvement
  - Met CDC PrEP eligibility
  - Opioid and/or stimulant use in the past 12 months
- **Sub-analysis**: Survival analysis and Cox regression were conducted to estimate the time to PrEP initiation for persons who were PrEP eligible.

Mobile Health Unit participants were 3X more likely to start PrEP than those assigned a Patient Navigator.

Of PrEP initiators: 45% on the Mobile Health Unit started **LAI PrEP** vs 0% in the Patient Navigator group

RESULTS

Of the randomized participants without HIV:

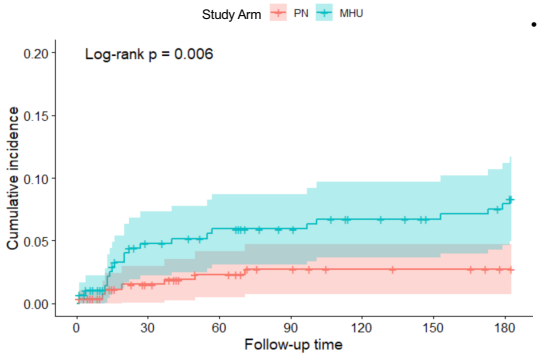
N=568 (N=280 PN and N=288 MHU) from 2022 to 2024 (Figure 1, Table 1)

Table 1. Baseline Participant Characteristics

Characteristic	Overall N=568 (%)	PN N=280 (%)	MHU N=288 (%)
State			
Texas	301 (53)	148 (53)	153 (53)
Connecticut	267 (47)	132 (47)	135 (47)
Age (Mean, SD)	41.9 (10.3)	41.8 (10.4)	41.9 (10.2)
Male at Birth	428 (75)	213 (77)	213 (74)
Unstable housing/Unhoused	422 (75)	214 (76)	209 (73)
Hispanic	142 (25)	70 (25)	72 (25)
Black/African American	143 (25)	74 (26)	69 (24)
No Health Insurance Coverage	199 (35)	100 (36)	99 (34)
HCV diagnosis in past 12 months	24 (4.2)	11 (3.9)	13 (4.5)
Opioid Use Disorder	268 (47)	128 (46)	140 (49)
Stimulant Use Disorder	349 (61)	175 (63)	174 (60)
Alcohol Use Disorder	109 (19)	58 (21)	51 (18)

Primary Outcome

Figure 2. Kaplan Meier Curve and Log-rank Test results comparing PrEP initiation by study arm



- **The MHU arm was statistically more likely to initiate PrEP at a faster rate than the PN arm**
- The MHU arm initiated PrEP throughout the 180-day intervention period while the PN arm stopped at day 70
- **Cox regression analysis: Hazard Ratio of 3.09 (95% CI 1.32-7.23; p=0.009),** thus persons in the MHU arm were 3 times more likely to initiate PrEP than those in the PN arm.

Table 2. Month 6 Secondary Outcomes for those at risk for HIV

Month 6 Outcome	Overall N=568 (%)	PN N=280 (%)	MHU N=288 (%)
Participants initiating PrEP	**29* (5.1)**	**7 (2.5)**	**22 (7.6)**
Of those who initiated PrEP:			
Prescribed long-acting injectable (LAI) PrEP	**10 (34.5)**	**0 (0)**	**10 (45.5)**
Persons retained on PrEP of those who initiated PrEP	**19* (65.5)**	**4 (57.1)**	**15 (68.2)**
HIV seroconversion	1 (0.2)	1 (0.4)	0 (0)

* p<0.05

CONCLUSIONS

- **MHU provision of 'one-stop' care led to 3x greater initiation of PrEP and at a faster rate over the 6-month intervention compared to the PN arm.**
- **Bringing services to where people are might lead to increases in PrEP initiation and a reduction in HIV incidence.**
- **Persons receiving care from a MHU may be an effective model for HIV prevention in hard-to-reach communities.**

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