

Douglas Krakower^{1,2,3}, Adrianna Boulin², Alaina Dougherty⁴, DeMarcus Jones⁵, Alexander Limas⁴, Raymond McPherson^{6,7}, Matt Palmer², Ashley Ross⁵, Aditya Gaur⁵, Temitope Oyedele^{6,7}, Daniel Reirden⁴, erica I. hamilton^{8,9}, Sybil Hosek^{6,7}, Lynda Stranix-Chibanda¹⁰, HPTN 083-01 Protocol Team⁹

¹Beth Israel Deaconess Medical Center, Boston Massachusetts, United States; ²The Fenway Institute, Boston Massachusetts, United States; ³Harvard Medical School, Boston Massachusetts, United States; ⁴Children's Hospital Colorado, Denver Colorado, United States; ⁵St. Jude Children's Research Hospital, Memphis Tennessee, United States; ⁶Ruth M. Rothstein CORE Center, Adolescent & Young Adult Research, Chicago Illinois, United States; ⁷Cook County Health, Chicago Illinois, United States; ⁸Science Facilitation Dept., FHI 360, Durham North Carolina, United States; ⁹HIV Prevention Trials Network, Durham North Carolina, United States; ¹⁰University of Zimbabwe Faculty of Medicine and Health Sciences, Child and Adolescent Health Unit, Harare, Zimbabwe

1) BACKGROUND

HPTN 083-01 is a clinical trial examining whether injectable cabotegravir for pre-exposure prophylaxis (PrEP) is safe and acceptable for adolescent sexual and gender minority persons in the U.S. (NCT04692077). We report our experiences in recruiting for HPTN 083-01 (goal N = 50 youths).

2) METHODS

We recruited in **4 cities**:

- Chicago, IL – the CORE Center at AYAR (Adolescent & Young Adult Research)
- Memphis, TN – St. Jude Children's Research Hospital
- Boston, MA – The Fenway Institute
- Aurora (Denver metro area), CO – Children's Hospital Colorado

Recruitment began in February 2020, paused for 4 months due to the COVID-19 pandemic, and ended in January 2022. We recruited adolescents ≤17y (weighing ≥35kg) who identified as: men who have sex with men, trans-females, or gender nonconforming people (assigned male at birth).

3) RECRUITMENT OVERVIEW

Outreach included **relationship building and consistent engagement** with: 1) community members; 2) community-based organizations; 3) clinicians in practice at recruitment sites and at local clinics.

We had a strong **online presence and social media campaigns** on platforms such as Tik Tok, Facebook, and Instagram, with predominantly virtual efforts owing to COVID-19.



CONCLUSION

Recruiting adolescent sexual and gender minority persons for HPTN 083-01 was challenging, most likely due to general barriers to youth research during COVID-19, including a lack of in-person youth events.

Flexible, youth-centered strategies are critical to engage adolescents in trials of long-acting PrEP and could support interest, use, and impact of this modality in care settings.



4) RECRUITMENT STRATEGIES

A) Outreach to community members

- High School outreach, including school nurses
- Advisory Groups: Community Advisory Boards, Social Media Youth Advisors, Headliners Community Advisory Group
- Parent focused outreach
- Email to lists of people interested in being contacted about research
- Online virtual webinars, programs and discussions: Youth Empowerment Series, Facebook Live discussion on Injectable PrEP for Youth
- In-person events (e.g., Pride month; educational event with a food truck)
- Swag bags with study-labeled items

A) Outreach to community members

- Bus ads and radio ads
- Social Media posts on pages and in groups (Facebook, Instagram)
- Social media ads (Facebook, Instagram, Tik Tok, Snap Chat)
- Online ads (Reddit, Craigslist, YouTube, Grindr) and Pre-Screener
- Posting flyers where youth hang out (parks, coffee shops, etc.)
- Distributing print materials (palm cards, flyers)

B) Community-based organizations

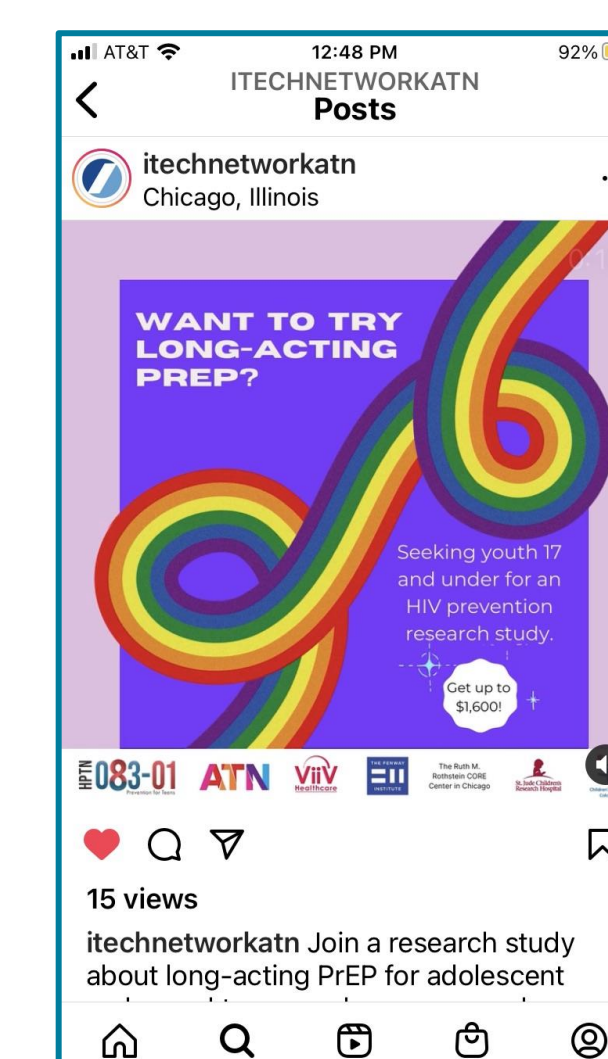
- PFLAG (Parent group for LGBTQIA+ youth)
- Rainbow Alley, Colorado Health Network (Aurora)

B) Community-based organizations

- BAGLY (Boston Alliance for GLBTQ+ Youth), NAGLY (the North Shore Alliance for GLBTQ+ Youth), Massachusetts Commission on LGBTQ+ Youth (Boston)
- Taskforce Prevention Community Services, Night Ministry, Brother's health collective (Chicago)
- The Benjamin L. Hooks Institute for Social Change at the University of Memphis (Memphis)

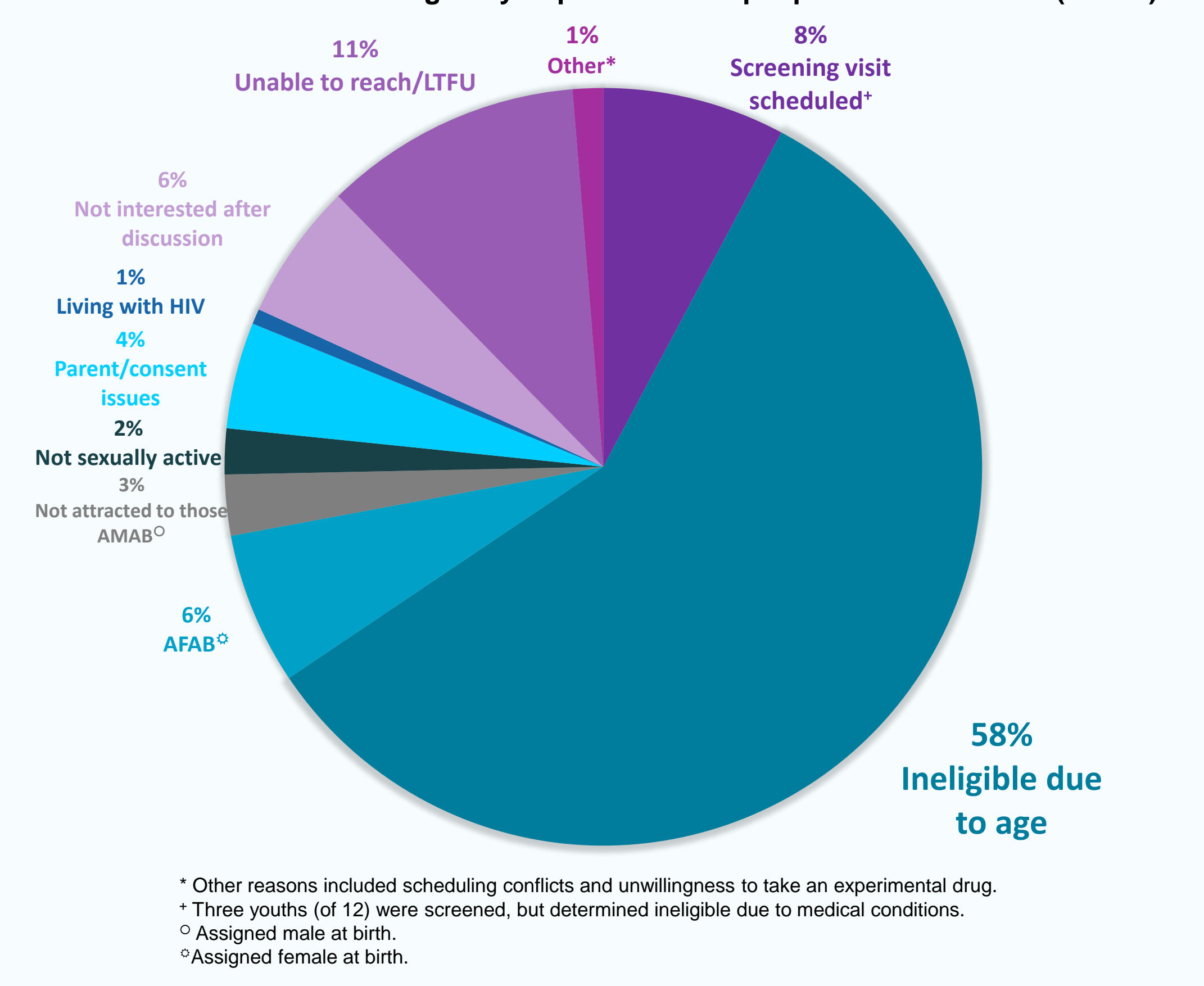
C) Provider and peer to peer staff outreach

- Study presentations for providers and staff via email, phone, in-person, at team meetings
- Flagging patients in EHR who may be eligible and interested in PrEP
- Receiving direct provider and peer referrals



5) REASONS FOR INELIGIBILITY

FIGURE 1. Reasons for ineligibility of pre-screened people in HPTN 083-01 (N=153)



6) ENROLLMENT / RETENTION

- Of 9 enrolled youths, 6 identified as male (3 in Chicago, 1 in Memphis, 1 in Boston, and 1 in Denver); 1 as trans-female (Boston); 1 as gender non-conforming (Boston); and 1 as other ("working on it", in Boston). One participant withdrew from the study after Week 9 (citing a desire not to take more medication), leaving N=8.
- Given enrollment was below our goal of 50 youths, we engaged in cross-site feedback to review "lessons learned" for future campaigns.

7) LESSONS LEARNED BASED ON CROSS-SITE FEEDBACK

CHALLENGES TO RECRUITMENT:

- youths' low HIV risk perception
- concerns about disclosing sexual orientation to parents when obtaining consent for participation
- concerns about the safety of experimental medications
- fear of injections, and
- scheduling conflicts with school-based activities

COVID-19 EFFECTS ON RECRUITMENT:

- exacerbated challenges by decreasing referrals from overburdened clinicians
- limited recruitment opportunities in traditional settings, such as community events and youth drop-in sites
- necessitated recruitment at virtual events with lower attendance

ADDITIONAL BARRIERS:

- parental hesitancy to enroll youths,
- restrictions on recruiting adolescents on dating apps and social media

FACILITATORS OF YOUTH ENGAGEMENT:

- social media campaigns
- waiving parental consent requirements (when consistent with local laws) to mitigate youths' concerns about disclosure
- emphasizing the convenience of long-acting PrEP
- flexible scheduling of study visits, and
- text-based communication

The 9 youths who enrolled were recruited from social media ads (3), provider referral (1), in-person tabling event (1), staff referral (1), flyer posted at recruitment site (1), bus ad (1), and referral from CBO (1). **EVEN STRATEGIES THAT DID NOT RESULT IN ENROLLMENTS WERE FELT TO BUILD TRUST WITH COMMUNITY.**

ACKNOWLEDGMENTS

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