Gendered inclusion in studies evaluating injectable HIV treatment and PrEP: a scoping review

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BACKGROUND

Globally, 54% of people living with HIV (PLWH) are female (UNAIDS).

Therapies containing LA-I agents are recommended in treatment guidelines and long-acting injectable (LA-I) Cabotegravir (CAB) is licensed for PrEP.

In female participants, LA-I CAB is superior to oral PrEP. However, cisgender and transgender women are historically underrepresented in wider HIV research.

We evaluated the extent to which women (cis/trans) and non-binary people (NBP) are included in studies evaluating long-acting injectable (LA-I) agents for HIV treatment and pre-exposure prophylaxis (PrEP).

METHODS

We performed a scoping review from January 1st 2020 to September 15th 2023 to evaluate inclusion of women (cis/trans) and NBP in Phase I-III clinical trials, implementation and real-world studies evaluating any LA-I agent for HIV treatment or PrEP.

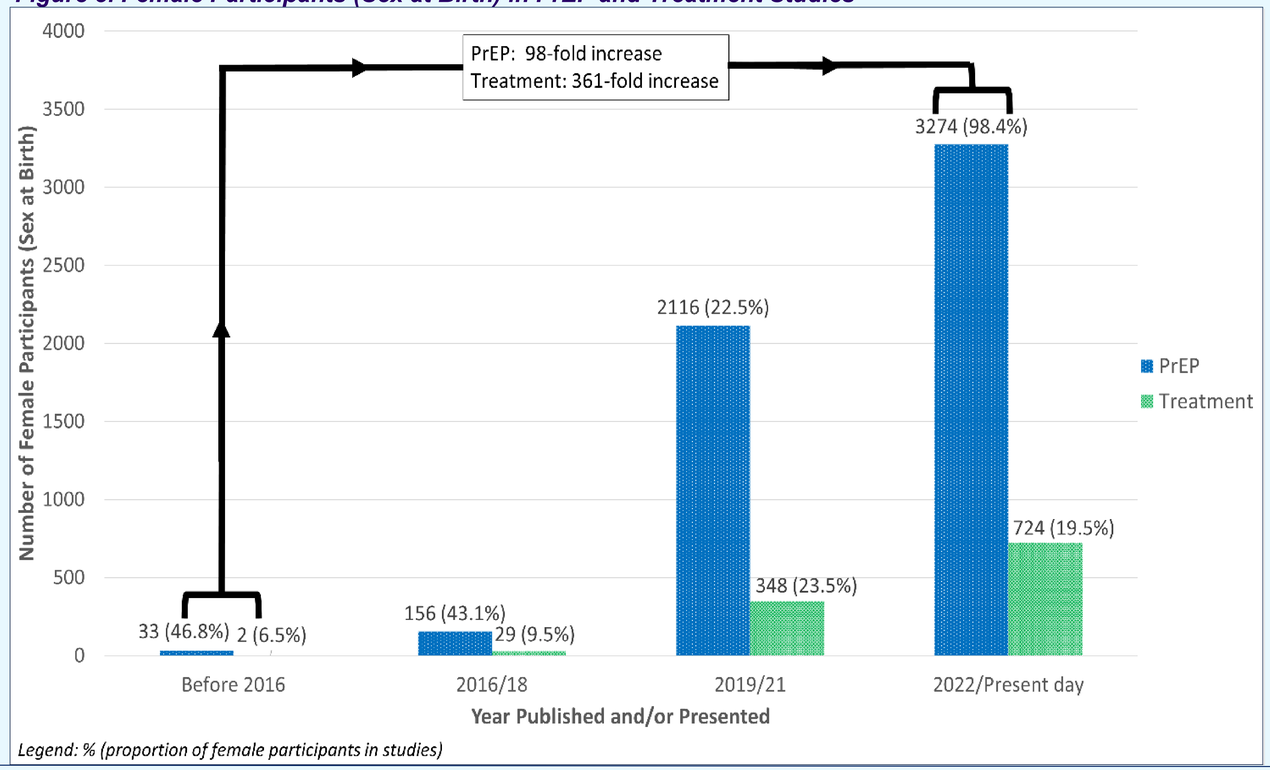
We searched electronic databases (PubMed, Medline, Embase) and peer reviewed abstracts excluding studies with no report of sex or gender. Statistics were descriptive.

RESULTS

- We included 41 studies, 14 evaluated PrEP (34%) and 27 (66%) evaluated treatment. We included 27 clinical trials [Phase I (n=8); Phase II (n=12); Phase III (n=7)], 6 implementation and 8 real-world studies. 38 studies included sites in high-income countries and 13 included sites in low and middle-income countries.
- PrEP studies evaluated CAB 8 (57%), rilpivirine (RPV) 2 (14%) and mono-clonal antibodies (mAb) 4 (29%). Treatment studies evaluated CAB+RPV, lenacapavir (LEN), albuvirtide (ABT) and mAb, [18 (67%), 5 (18%), 3 (11%), 1 (4%) respectively].
- The number of female participants increased 98-fold in PrEP studies (2014-present), and 361-fold in treatment studies (2010-present). However, the percentage of female participants in LA-I treatment studies during 2022/3 remains disappointing [724/3709 (20%)]. From 2020, gender-targeted PrEP studies were established to ensure inclusive recruitment. Between 2019-2023, 42% of participants in PrEP studies were female (n=5390).
- Only 13/41(32%) studies reported on self-identified gender. The number and percentage of transgender women, transgender men, and NBP included in treatment and PrEP studies was 728 (4%), 28 (0.2%), 58 (0.3%) respectively.

> The number of female participants increased 98-fold in PrEP studies (2014-present), and 361-fold in treatment studies (2010-present). However, the percentage of female participants in LA-I treatment studies during 2022/3 **remains low** (20%) and **does not reflect the global population of people living with HIV.**

Figure 3. Female Participants (Sex at Birth) in PrEP and Treatment Studies



Legend: % (proportion of female participants in studies)

Figure 1. Study Selection

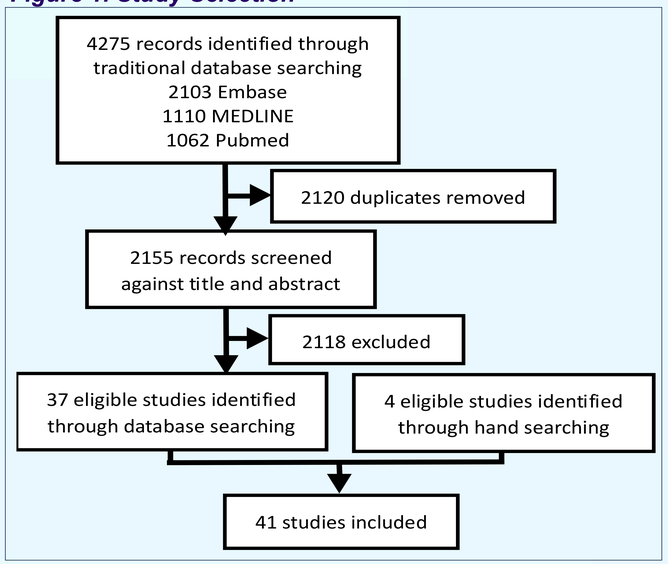
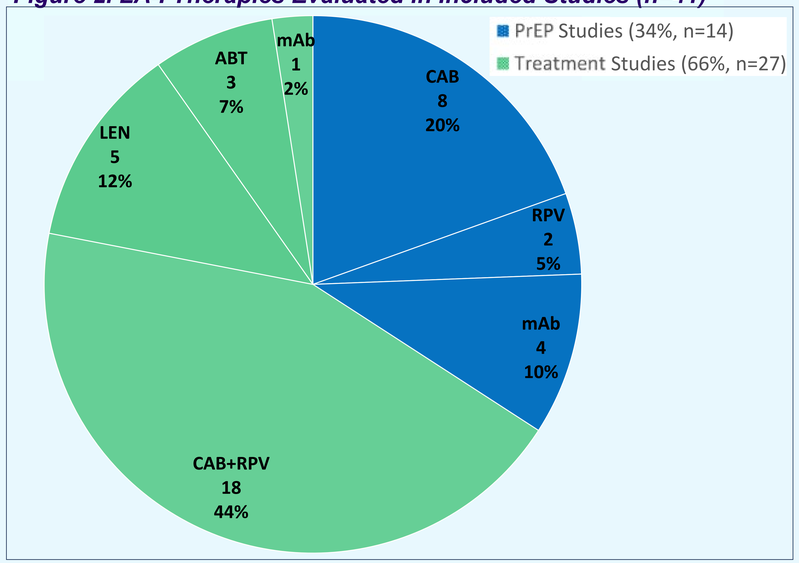


Figure 2. LA-I Therapies Evaluated in Included Studies (n=41)



CONCLUSIONS

The number of female participants in studies of LA-I treatment have significantly increased but remains unacceptably low at 20% (2022/3) and does not reflect the global population. Gender-targeted PrEP studies have been effective at increasing numbers of females recruited. Transgender and NBP remain very poorly represented. A gender-targeted approach to inclusion in treatment studies is urgently needed and long overdue.

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