METHODS
In January 2020, we initiated a prospective qualitative sub-study with a maximum of 104 women from 4 sites [Lilongwe, Malawi; Johannesburg, South Africa; Kampala, Uganda; Harare, Zimbabwe]. Up to 3 in-depth interviews were conducted with each participant, the initial interviews and subsequent follow-up interviews were planned based on the participant’s availability and comfort. Interviews were audio-recorded, translated to English, and transcribed. Two coders conducted open coding and generating themes. Analyses were planned to assess the acceptability of and preferences for various PrEP options, as well as PrEP access challenges of particular relevance to women.

FINDINGS
Sub-study participants’ risks contexts varied across sites, and their motivations to join HPTN 084 were multiple. Over a third of women reported being monogamous, and marry, cohabiting or committed relationships. Others described multiple, sequential, or concurrent partners – some relationships were more transactional, and about 1/5 described themselves as sex workers (Table 1). Across contexts, women wanted to gain access to HIV prevention products, either due to concern about their own risk behaviors or because they suspected their partner’s behaviors. Women also sought access to free long-acting contraception, HIV testing or new experiences.

To varying degrees, participants’ perceptions of injectable and oral PrEP options, and their thoughts about PrEP use and use post-trial differed by risk category.

Injectable PrEP
By far, participants liked the ease and convenience of a long-acting formulation. Injectable PrEP did not require daily remembering and fit better into women’s lifestyles, especially for women who had trouble or had overwhelmed adherence. 64 (62% of all participants) said they would receive injectable CAB.

"I joined this study because when my marriage ended, I was promiscuous and when I heard that there is a study where there is a pill and then after you receive pain in the injection site you receive a pill, I thought I would be protected because I was going to be protected from HIV, not just from my partner but also from multiple sexual partners. So, here we are a bit similar... (Malawi, 26-year-old divorcee, sex worker)"

Regardless of risk category, women liked the injectable’s privacy from husbands, boyfriends, sexual clients or just “noisy people.” Of note, few women in any category reported disclosing study participation to partners, but were more likely to have disclosed to family members or friends. Disclosure was always at times necessary when a household member found a woman’s study pill.

The potential effectiveness of injectable PrEP was mentioned by some women, more often among women in higher risk categories.

The main disadvantage of injectable PrEP was pain. Almost all women described some level of pain, but descriptions varied widely. For the initial injection was painful, but they got used to it over time. Others attributed the level of pain to the skill of the clinic staff, while for some pain continued to be intense with each injection.

"That one... it’s painful. It’s better here when you go home. The doctor is very kind and even when the partner touches you on the injection site you feel more pain, but in the hospital it is painful. It is painful. They really feel numbness on the leg... It is painful. (Malawi, 30-year-old monogamous participant)"

"The Depo injection is more painful... I am not a fan. It’s not painful. I didn’t feel like it was a painful injection... (Uganda, 22-year-old single participant, transactional sex)"

A small number of women complained of other side effects from injectable PrEP, including injection site swelling and itching, or post-injection dizziness. Some worried about potential longer-term health effects, especially on the adolescent body.

Oral PrEP
Almost 1/3 of participants found oral PrEP easy to take and mentioned few side effects. But, more than half worried about forgetting to take oral pills. Some referenced prior mistakes, including unintended pregnancies, while taking oral contraceptive pills. PrEP attributes – size, taste and smell were disliked by some.

"How often do you feel that you forget to take your pills? I would not be able to say how many times. It is not a problem. I have always taken it well... (Uganda, 22-year-old single participant, monogamous)"

"I think that I can take it more than once. (Malawi, 26-year-old non-transactional monogamous partner, participant)"

Injectable PrEP compared favorably in terms of overall pain, and 50% of women said they preferred injectable PrEP. Injectable PrEP may be a preferred option for women who experience difficulty tolerating oral PrEP due to its side effects.

BACKGROUND
HPTN 084, a multisite, double-blind, randomized Phase 3 trial, compared the safety and efficacy of injectable cabotegravir (CAB) administered 8-weekly to daily oral TDF/FTC for prevention of HIV-1 in uninfected African women. Initiated in November 2017, the study enrolled >3,200 sexually active women aged 18-45 who were randomized to receive one active (CAB or TDF/FTC) and one placebo product and participated in a 5-week oral run-in before moving into an injection phase.

Like a similar trial in men-who-have-sex-with-men and transgender persons (HPTN 083), the trial was stopped early for demonstrating superiority of CAB over TDF/FTC in preventing HIV. Participants in both trials have been “unblinded” (e.g., informed about which active product they were using), and women have been learning to apply the product on their thighs (or no product!). The shortened timeline of these two trials has expedited the need to consider introduction strategies for different populations.

We examine qualitative data from the initial phase of a four-country sub-study nested within HPTN 084 to better understand the acceptability of these two PrEP methods and considerations for CAB access among African women at risk of HIV.

Take home message: Women’s desire for privacy and ease of use outweighed other injectable concerns, resulting in a strong preference for Injectable PrEP. Concerns about cost and accessibility will need to be addressed by implementation programs.

Table 1 provides an overview of sub-study participants, by country.

<table>
<thead>
<tr>
<th>Country</th>
<th>Age (mean)</th>
<th>HIV status</th>
<th>South Africa</th>
<th>Uganda</th>
<th>Zambia</th>
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<tr>
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<tr>
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<td>Female</td>
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</table>

PRPP Preferences
Most women preferred injections to daily pills, with strongest preferences appearing to be related to risk category.

1. "The injection is painful. I will not choose it. MAY I TELL YOU WHY? Because it is a very tiring thing. Yes, I just have to remember the date, but after that is over... AND MAYBE WE FIND THAT THE PILLS WORKING BETTER. WOULD YOU STILL USE IT? OF COURSE NOT! No, I will not use it. I will make a decision. (Malawi, 26-year-old monogamous participant who preferred pills)"

Access PrEP Beyond the Trial
Only a third of women said they knew of ways to access PrEP in our communities. Most referred generically to clinics, several specifically mentioned clinics for sex workers. A few participants believed that PrEP might be available in pharmacies or the hospital, although few women had previously sought PrEP or knew someone who had. Was often mentioned as a potential barrier to PrEP access. Other barriers included eligibility (e.g., not high-risk), poor services or being lazy.

DISCUSSION
Our qualitative data support the hypothesis that injectables are preferred over pills because they are discover, and easier to adhere to – particularly for women with busy lives. However, no data exist yet to indicate how well women will adhere to and/or persist on CAB outside the trial setting. For example, the degree to which pain will be a determinant to persist on PrEP is unknown. This analysis includes women on CAB or a placebo (Intralipid 2%) injection; shown to have different pain profiles to indicate how well women will adhere to and/or persist on CAB outside the trial setting. For example, the degree to which pain will be a determinant to persist on PrEP is unknown. This analysis includes women on CAB or a placebo (Intralipid 2%) injection; shown to have different pain profiles to indicate how well women will adhere to and/or persist on CAB outside the trial setting. For example, the degree to which pain will be a determinant to persist on PrEP is unknown. This analysis includes women on CAB or a placebo (Intralipid 2%) injection; shown to have different pain profiles to indicate how well women will adhere to and/or persist on CAB outside the trial setting. For example, the degree to which pain will be a determinant to persist on PrEP is unknown. This analysis includes women on CAB or a placebo (Intralipid 2%) injection; shown to have different pain profiles to indicate how well women will adhere to and/or persist on CAB outside the trial setting.