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BACKGROUND

- The COVID-19 pandemic has had a serious impact on health systems, and socio-economic activities globally. Countries developed policies and guidelines to reduce spread of the virus and manage the emerging disease, resulting in socioeconomic burden (WHO, 2021).
- Few studies have explored women's experiences in HIV prevention clinical trials during the COVID-19 pandemic.
- This analysis seeks to assess how COVID-19 affected participants' experiences within HPTN 084, a multisite, double-blind, randomized Phase 3 trial that compared the safety and efficacy of injectable Cabotegravir (CAB LA) administered 8-weekly to daily oral TDF/FTC for prevention of HIV-1 in uninfected African women.
- HPTN 084 demonstrated that CAB LA was superior to daily oral TDF/FTC for HIV prevention in women.

METHODS

- Between August 2020-December 2022, 76 HPTN 084 participants were enrolled in a qualitative sub-study conducted in Malawi, South Africa, Uganda, and Zimbabwe.
- 76 participants were interviewed at multiple time points using semi-structured guides where participants described their experiences using oral and injectable PrEP and the impact of COVID-19 within and outside of the trial.
- Interviews were conducted in the local language of each country, audio-recorded, transcribed, and translated into English.
- Qualitative thematic analysis was used to analyze the data.

Participants feared being infected with COVID-19 more than with HIV as they perceived poorer prognosis with COVID-19. Most participants reduced sexual partners due to this perceived risk and restrictions on travel. Although the pandemic brought significant disruptions to participants' daily life, almost all participants reported that adherence to the study product was not affected.

RESULTS

Socio-Demographic Characteristics

- The mean age of participants was 24.6 years, and the participants were slightly older in Zimbabwe (mean age of 27.0 years) while Uganda, Malawi and South Africa enrolled younger participants with mean ages of 24.7, 23.9 and 23.1 years respectively.
- Many participants were not employed (77%). 41% reported ever been paid for sex and 25% of all participants identify themselves as female sex workers.

Effect of COVID-19 pandemic on daily life and work

Participants in all countries reported significant effects that COVID-19 brought to their daily life and income, as well as that of their partners (Table 1).

Table 1: Effects of the COVID-19 pandemic on daily life that participants in all countries reported

- Travel restrictions during lockdowns and curfews. This also led to a reduction in public transportation and increases in transport fares.
- Income was affected as participants and/or their partners had reduced or no income.
- Did not have enough food for the family as participants:
 - Had only a little, or no, income
 - Food prices increased
 - Could not leave their homes to buy food
 - Could not travel to shops where prices of food were cheaper
- Schools were closed and students could not go back to school for a long period of time which affected their education

You could want to eat meat or fish, but we could no longer afford it and we had to boil beans every day, every day like that. Instead of taking milk, you could take dry tea, and sugar itself is not there. We used to buy a bar of soap but could only afford a piece. Everything was moving backwards. (Participant from Uganda)

More Feared COVID-19 than HIV

During participants' first interviews, most participants viewed COVID-19 as highly contagious and a potential “death warrant” compared to HIV where someone can take ARVs.

COVID-19 worries me more because currently it has no cure. And when it infects you sometimes it doesn't give you a chance to get treated. (Participant from Zimbabwe)

Fear of COVID-19 versus HIV over time

- Despite the fear of Covid-19, most women reported not receiving the Covid-19 vaccine due to uncertainty of its effectiveness and misconceptions.
- During follow-up interviews, the majority accepted that “the virus is here to stay” and that they needed to live a normal life with COVID-19 and HIV. Participants eventually balanced their fear of COVID-19 with a fear of HIV, which requires lifelong treatment.
- Most women reduced sexual partners due to COVID-19 restrictions on mobility, closure of entertainment hubs, and fear of COVID-19 spread, leading to a potential reduction in risk of HIV.

Maybe your partner has called you and then you also consider that “Should I have my nose close to his, I will not go.” This is because in the room where you have met coming from different directions, you cannot wear masks. (Participant from Malawi)

Effect of COVID-19 restrictions on study product adherence

Almost all participants said they were not affected and were able to get their injections and study pills at the clinic:

- During travel restrictions in their locality, the study clinic will either provide participants with a travel authorization letter or arrange transportation for them to be picked up and dropped off.
- A few (from Uganda and Zimbabwe) said that it was easier to take their daily study pills during lockdown or curfew as they had no choice but to be at home and could easily take their pills on time.

No, it (COVID-19 restrictions) did not affect me, they picked us up. The health visitors used to pick us and bring us to the clinic. (Participant from Uganda)

CONCLUSIONS

- Emerging infectious diseases, such as COVID-19, and public health responses to such outbreaks, can affect the economic, social, sexual and health-seeking behaviors or community members in multiple ways.
- Clinical trials, which are nested within these communities, must be dynamic in their responses to social change that may pose a public health risk to participants and staff.
- The effects of COVID-19 and other emerging diseases should be taken into consideration when designing HIV prevention clinical trials for easy access to study products among high-risk participants in an African context.