

**Responses provided to SpotlightNSP by Jeremy Nuttall on 30 October 2024**

- 1. Was any safety data collected around the use of the 3 month ring in pregnant or breast feeding women and in younger women? And if so, is any of that data available to the public yet?**

Only two trials have been conducted with the 3-month ring: MTN-036/IPM 047, which included women aged 18 to 45 years, and the IPM 054 trial, which was conducted in women aged 19 to 45 years. None of the women in either trial were pregnant or breastfeeding.

- 2. Also then I'm just curious if there's a plan to submit data on the use of ring (either the one month or the three month) in pregnant or breast feeding women and in younger women since some African countries have restrictions on the use of the dapivirine ring in these populations.**

Although studies in these populations have not been conducted with the 3-month ring, they have been performed with the 1-month ring:

The REACH (MTN-034) study was a randomized Phase IIa crossover trial among adolescent girls and young women (AGYW) aged 16-21 years in South Africa, Uganda, and Zimbabwe. From February 2019 to September 2021, 247 girls were enrolled and each participant used the dapivirine vaginal ring (DVR) and oral PrEP for six months, after which they could choose to use either the DVR or oral PrEP, or neither, for a third six month period. Adherence was moderately high and similar between oral PrEP and the DVR with favorable safety and tolerability. Almost all (95%) participants chose to use either the dapivirine ring or oral PrEP during the third six month period, and of these two-thirds chose the DVR. These results highlight that AGYW can have high adherence and persistence with oral PrEP and the DVR for up to 18 months, with client-centered, non-judgmental, flexible adherence support strategies and monthly visits. Results from this study were published in the Lancet HIV. On the basis of these results, the Population Council has submitted a request to the EMA to expand the label for the 1-month DVR to include AGYW.

More information can be found at:

[The REACH Study \(MTN-034\) | Microbicide Trials Network](#)

The DELIVER (MTN-042) study was a Phase IIIb study designed to evaluate the safety and acceptability of the monthly DVR among pregnant women. DELIVER was conducted in Malawi, South Africa, Uganda and Zimbabwe. Results showed no safety concerns with use of the DVR beginning during the second trimester of

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pregnancy and up to the time of delivery. Researchers believe there is now sufficient evidence that the monthly DVR is safe throughout pregnancy. The Population Council plans to submit a request to the EMA in early 2025 to expand the label for the 1-month DVR to include pregnant women.

More information can be found at:

[MTN-042 - DELIVER | Microbicide Trials Network](#)

The B-PROTECTED (MTN-043) study was a Phase IIIb open-label study that evaluated the safety and acceptability of the monthly DVR in women who are breastfeeding. The study enrolled 200 breastfeeding mothers and their 6- to 12-week-old babies in Malawi, South Africa, Uganda and Zimbabwe. Researchers assessed how much drug passes into breastmilk and how much passes to the baby after breastfeeding, and measured the effects, if any, this may have had on their health. Thanks to B-PROTECTED, the Population Council has successfully expanded the EMA label for the 1-month DVR to include breastfeeding women. We are working to include this expansion to the label in the African countries in which the monthly DVR is already approved.

More information can be found at:

[MTN-043 - B-PROTECTED | Microbicide Trials Network](#)

Our assumption is that given the modest difference in drug levels achieved with the 3-month ring when compared to the 1-month ring, regulators will consider the data for the 1-month ring in these populations also relevant for the 3-month ring.