

PrEP and women

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PrEP is an effective tool for HIV prevention, but it's underused by women in the UK. Even though cisgender women make up a quarter of new HIV diagnoses, only 2.8% of PrEP users in England are women.¹

In the UK, few women have been offered PrEP by a healthcare provider and there are very low rates of knowledge of PrEP among women. Even among women who are aware of PrEP, few have used it. A national study of women's experiences of HIV published in 2018 found that 74% of 151 women who had ever been 'concerned' about HIV were aware of PrEP, but none of them had used it.²

This briefing is about how well PrEP works for cisgender women. Cisgender women were assigned female at birth and still identify as female. It reviews relevant research about PrEP and women in the UK for sexual health and HIV services, and for advocacy.

What types of PrEP are available for women?

There are several different types of PrEP. However, not all of them can be used by women. And, of the PrEP options that women can use, not all of them are available in the UK.

Oral PrEP: Currently, in the UK, only one type of PrEP is approved for women. This is an oral tablet that contains both tenofovir disoproxil and emtricitabine (TDF/FTC); it is sometimes sold under the brand name **Truvada**.

A second type of oral PrEP is a tablet containing tenofovir alafenamide and emtricitabine (TAF/FTC), sold under the brand name **Descovy**. It is not yet licensed as PrEP for cisgender women at risk of acquiring HIV through vaginal sex because it has not been studied enough in this population. There is evidence to suggest it should work well for women,³ but the results of two ongoing African studies are needed to confirm this. The PURPOSE 1 study is investigating the efficacy of the injectable drug lenacapavir compared to both TDF/FTC and TAF/FTC. The first results are expected in 2024.⁴ The PrEPVacc study is comparing TDF/FTC to TAF/FTC over a short period of six months.⁵

It is rare for people to be unable to take emtricitabine, but if this is the case, women can take a tablet containing TDF alone as PrEP.⁶ In the Partners PrEP study, the effectiveness of both solo TDF and dual TDF/FTC was measured. The difference between the medications was not statistically significant.⁷

As well as oral PrEP, two other types of PrEP have also been shown to be effective for cisgender women: injectable

PrEP, and the vaginal ring. Neither are currently available in the UK.

Injectable PrEP: Injectable PrEP consists of antiretroviral medications which are given by injection. There is currently only one type of injectable PrEP, cabotegravir, which needs to be taken every two months.

Injectable PrEP has proved to be very effective for women. In 2020, the results of a study called HPTN 084 were released. The study compared cabotegravir injections with TDF/FTC in women aged 18–45 in seven African countries. Among 1586 women assigned to oral PrEP, 36 participants (2.3%) acquired HIV, whereas among 1592 women assigned to injectable PrEP, 4 participants (0.3%) acquired HIV.⁸ With nearly nine times fewer infections among women receiving the injections, this was the best effectiveness ever seen in a PrEP study. Nonetheless, oral PrEP tablets were still effective at stopping infections. The key difference in these results was probably due to adherence.

Injectable long-acting cabotegravir has been approved by the European Medicines Agency (EMA) but hasn't been approved in the UK yet. The World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC) both recommend long-acting injectable cabotegravir as prevention choice for people who are at substantial risk of HIV.^{9,10}

Lenacapavir is another HIV medication that's currently being studied to see if it can be used as PrEP, but clinical trials are still ongoing. A large study (PURPOSE 1) is looking at how well lenacapavir works as PrEP for 5000 women in Africa and is in the final stages. The results are expected in 2025.¹¹

Vaginal ring: A vaginal ring used for PrEP has also been developed. It's a ring made of silicone which contains the anti-HIV drug dapivirine. It's used by inserting it into the vagina where the drug is slowly released over the course of a month, after which it needs to be replaced.

The vaginal ring might not be as effective as oral PrEP. Two early studies found that the ring only prevented a quarter to a third of HIV infections.^{12,13} However, this is partly due to the fact that the rings weren't being used as prescribed. In more recent studies where the ring has been used more consistently, it has proved to be more effective.¹⁴

Vaginal rings for HIV prevention are not currently available in the UK. They have been approved by the WHO and EMA for use in low- and middle-income countries.^{15,16}

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Cost is likely to be a barrier to the widespread use of new forms of PrEP, including injections. Decision makers in the NHS need to compare the cost and effectiveness of new types of PrEP against the cost and effectiveness of oral TDF/FTC. As the latter is now available as a low-cost generic medicine, any alternative must demonstrate substantial advantages over TDF/FTC. A new type of PrEP is unlikely to become a first-line option, but may be recommended for specific groups of PrEP users. For example, TAF/FTC is currently only recommended for individuals for whom TDF/FTC is not suitable, such as adolescents and those with kidney problems.¹⁷ As mentioned above, it is not yet available to women.

Is oral PrEP as effective for women as for men?

When taken consistently, as prescribed, PrEP can be highly effective at preventing HIV transmission for cisgender women.^{18,19} Studies showing this were conducted in sub-Saharan Africa.

Nonetheless, a number of PrEP studies and PrEP programmes with women have had less encouraging results than has been seen elsewhere with gay and bisexual men. Major reasons for this are lower levels of adherence and social barriers to consistent use of PrEP.

There may also be some biological differences. Different concentrations of the two main PrEP drugs (TDF and FTC) are achieved in rectal and vaginal tissues.²⁰ After stopping PrEP (or missing a few days of doses), drug levels decline more quickly in vaginal tissue.²¹

Different groups of experts have re-analysed data from research studies to estimate required levels of adherence. As they have used different methods and assumptions, they have sometimes come to different conclusions. One analysis found that for cisgender women who managed daily dosing, PrEP had an average likely efficacy of 99%. But if they took 4–6 doses a week it was 88% and 2–4 doses, 80%.²² Similarly, another analysis found that women who took seven, four and two pills a week PrEP had an efficacy of 96%, 84% and 59%.²³

A third analysis found that with three doses per week, efficacy was 95% (confidence interval: 90–98%), but efficacy dropped substantially at one dose per week.²⁴ Importantly, this group of researchers found that differences in drug levels between vaginal and rectal tissue did not help explain the results – drug levels in blood cells were much more relevant. As these are the same in men and women, biological differences may be less relevant to PrEP effectiveness than sometimes thought.

How soon after starting PrEP will it provide protection?

Women taking oral PrEP are recommended to have a lead-in period of taking PrEP before a possible HIV exposure. This should allow an effective level of PrEP to build up in the body. Guidelines often recommend a longer lead-in period for women than men, because of the time it takes for tenofovir (one of the drugs in PrEP) to build up in the vagina. For example, the World Health Organization (WHO) recommends a lead-in period of seven days.²⁵

However, some experts point to data which suggests that taking one pill a day for three days before sex should be long enough to protect women from acquiring HIV from vaginal sex.²⁶ If this isn't possible, starting with a double dose of PrEP between 2 and 24 hours before potential exposure to HIV (such as condomless sex) is expected to provide some protection.

Women should continue to take PrEP daily for at least seven days after their last sex.

Event-based PrEP has not been tested in women and guidelines do not recommend it for women at risk of acquiring HIV from vaginal sex – but it should be effective for women who need to protect themselves during anal sex. (Event-based PrEP is sometimes called on-demand PrEP or 2-1-1 PrEP. It involves taking two pills of TDF/FTC between 2 and 24 hours before condomless sex, one pill 24 hours later, and one pill 24 hours after that.)

Does taking PrEP affect your contraception options?

Taking TDF/FTC PrEP does not affect how well any contraceptive works.^{27,28} These drugs have been widely used by women living with HIV for many years, including by women using contraceptives.

However, studies have suggested that bone mineral density loss can be worsened by using intramuscular DMPA contraceptive injectable and TDF at the same time.²⁹ Experts recommend that women using DMPA should consider an alternative contraceptive method, particularly if they are already at a higher risk of bone problems.³⁰

There are no known drug interactions between contraceptives and injectable cabotegravir or the dapivirine vaginal ring. However, the dapivirine vaginal

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ring (PrEP) shouldn't be used at the same time as a contraceptive vaginal ring. Vaginal rings containing both dapivirine and a contraceptive are being developed.

Does PrEP affect the menstrual cycle?

There's no evidence that PrEP will affect the menstrual cycle or fertility.

Does PrEP affect pregnancy and breastfeeding?

The World Health Organization (WHO) recommends that pregnant and breastfeeding women who are at risk of acquiring HIV should be offered daily oral PrEP containing TDF/FTC.³¹

Safety

All the evidence suggests that PrEP is safe for women to take when they are trying to get pregnant and throughout their pregnancy.^{32,33,34} These drugs have been widely used by women living with HIV for many years, including during pregnancy.

Studies have found minimal differences in the weight, growth, bone health or neurological development of babies born to mothers taking PrEP, or in the rate of adverse pregnancy outcomes such as stillbirth, premature birth or neonatal death.^{35,36}

It is worth noting that many studies of PrEP have excluded pregnant and breastfeeding women. Most of the guidelines that advise on PrEP use for pregnant and breastfeeding women are relatively new. There are some ongoing studies and planned studies which will provide further data about safety.^{37,38}

Currently, there isn't enough data to recommend cabotegravir during pregnancy or breastfeeding.³⁹ The first studies following women using the vaginal ring for PrEP raised no safety concerns when used in the third trimester of pregnancy and while breastfeeding.^{40,41}

Efficacy

PrEP should still work well during pregnancy, which is a time of increased risk of HIV acquisition. There is some evidence to suggest that levels of PrEP in the body might be reduced during pregnancy.⁴² Until we have more research data, we can't know for sure if this affects how well it works. What we do know is that women who are at risk of acquiring HIV greatly reduce their risk when they use PrEP, regardless of whether they are pregnant.

Does PrEP affect menopause?

In general, there is very limited data about how well PrEP works for older women compared to younger women.⁴³ However, women living with HIV have been taking the same medications used in PrEP for decades, and this means we have lots of information about potential side effects and drug interactions.

Taking PrEP shouldn't make symptoms of menopause, such as hot flushes, worse. There don't seem to be any drug interactions with PrEP and hormone therapies.⁴⁴ This means it should be safe to take when using HRT to treat menopausal symptoms.

However, taking TDF can affect bone mineral density. This is important to know because post-menopausal women are already at higher risk of bone loss and osteoporosis. Women going through menopause, or who are post-menopausal, can have their bone health monitored more closely when taking TDF/FTC.

How can women access PrEP?

In the UK, PrEP can be accessed through NHS sexual health clinics, free of charge. It's also possible to pay for PrEP through a UK-based online pharmacy or private clinic, or a private online pharmacy in another country.

Women should be able to get PrEP for free through sexual health clinics simply by asking for it. Women who feel that they need PrEP will probably benefit from it. This may be, for example, if their sexual partner(s) is living with HIV and has a detectable viral load or if they sell sex. However, PrEP might not be prescribed if a doctor or nurse thinks the risk of taking PrEP outweighs the benefit, or if a woman is not at high risk of acquiring HIV.

Guidelines that advise healthcare providers about who needs PrEP⁴⁵ have been criticised as too restrictive by the community organisations.⁴⁶ When thinking about whether PrEP is right for someone, wider risk factors should also be considered, such as intimate partner violence, a history of child sexual abuse, socioeconomic stress, insecure housing, and undocumented migrant status. Current intimate partner violence is particularly strongly associated with HIV diagnosis.⁴⁷

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What are the barriers to PrEP use among women?

In England in 2022, just 2467 of 86,324 PrEP users (2.8%) were women.⁴⁸ However, very little research has investigated barriers to PrEP use among women in the UK or elsewhere in Europe. The studies that are available often have small sample sizes or are qualitative. More research has been conducted in sub-Saharan Africa or the United States, where many of the contextual factors are different. Nonetheless, in 2023 researchers synthesised the available evidence from the UK to identify individual, interpersonal and structural barriers to PrEP use among women.⁴⁹

Individual

- Low awareness and knowledge of PrEP: in several studies, more than 80% of women had not heard of it. This sometimes reflects a more general lack of knowledge about HIV. Women who have heard of PrEP may perceive that it is only intended for gay and bisexual men.
- Concerns about the effectiveness of PrEP, side-effects and pregnancy. These concerns are sometimes linked with gaps in knowledge.
- Low self-perceived risk of HIV acquisition. For example, in one study, women struggled to judge their individual vulnerability to HIV; providing information about PrEP wasn't enough to overcome this.⁵⁰

Interpersonal

- HIV stigma: in several studies, women were concerned that even discussing PrEP would lead others to assume they were living with HIV or were promiscuous.
- Race and ethnicity: the intersections of race, ethnicity and gender compound inequities in HIV prevention. Black women report distrust of the establishment and experiences of racism in the NHS, which reduces engagement with healthcare. Black Africans are often conceived of as a homogenous group, but outreach workers are likely to be more successful if they understand the cultural norms in specific communities.

Structural

- PrEP is only available at sexual health clinics. However, these services are not used by everyone who is vulnerable to HIV (for example, most heterosexual people newly diagnosed with HIV have never previously attended a sexual health clinic^{51,52}). HIV stigma discourages some women from being seen at sexual health clinics.
- Eligibility criteria in clinical guidelines may miss women who could benefit from PrEP. Compared with gay and bisexual men, fewer heterosexual women whose behaviour and clinical characteristics align with a need for PrEP have that need recognised by sexual health

clinicians and even fewer start using PrEP.⁵³

- Access to the NHS for migrants: although sexual health and HIV services are exempt from NHS charging regulations, the complexity of the rules and data sharing with the Home Office discourages access.
- Women were under-represented or excluded from several PrEP clinical trials, leading to a lack of data to support women's use of PrEP.

However, the review did identify some facilitators.⁵⁴ When women are aware of PrEP, many are interested in using it. Targeted, community-specific outreach can be effective at raising awareness. Focused efforts to identify individual women at risk of HIV and to offer PrEP have shown promise⁵⁵ and HIV testing provides an opportunity to discuss prevention, including PrEP.

Can your male partner use PrEP?

Male partners of cisgender women are able to use PrEP to prevent HIV transmission during vaginal sex. They can use daily PrEP in the same way as women, or they can use event-based PrEP.⁵⁶ Event-based PrEP is sometimes called on-demand PrEP or 2-1-1 PrEP. It involves taking two pills 24 hours before condomless sex, one pill 24 hours later, and one pill 24 hours after that.

There haven't been any studies on event-based PrEP done in heterosexual people but scientists have used the data we have from gay and bisexual men to inform their advice. If men do take event-based PrEP to protect themselves from HIV transmission from vaginal sex they shouldn't take TDF alone as only TDF/FTC has been tested for event-based PrEP.

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- 1 HIV pre-exposure prophylaxis (PrEP) need and use in England data tables. Published 3 October 2023. <https://assets.publishing.service.gov.uk/media/6512df31f6746b0012a4ba5d/2022-PrEP-need-and-use-by-demographic-group.ods>
- 2 Women and HIV: Invisible No Longer. Sophia Forum and Terrence Higgins Trust. Published April 2018. www.tht.org.uk/sites/default/files/2018-08/women-and-HIV_report_final_amended.pdf
- 3 Thurman, Andrea R., et al. "Safety and pharmacokinetics of a tenofovir alafenamide fumarate-emtricitabine based oral antiretroviral regimen for prevention of HIV acquisition in women: a randomized controlled trial." *EClinicalMedicine* 36 (2021). doi.org/10.1016/j.eclinm.2021.100893
- 4 Pre-Exposure Prophylaxis Study of Lenacapavir and Emtricitabine/Tenofovir Alafenamide in Adolescent Girls and Young Women at Risk of HIV Infection (PURPOSE 1). National Library of Medicine. Last updated 10 October 2023. clinicaltrials.gov/study/NCT04994509
- 5 PrEPVacc website. <https://www.prepvacc.org/>
- 6 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). British HIV Association. Published 2018. www.bhiva.org/PrEP-guidelines
- 7 Baeten, Jared M., et al. "Antiretroviral prophylaxis for HIV prevention in heterosexual men and women." *New England Journal of Medicine* 367.5 (2012): 399-410. doi: 10.1056/NEJMoa1108524
- 8 Delany-Moretlwe, Sinead, et al. "Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial." *The Lancet* 399.10337 (2022): 1779-1789. doi.org/10.1016/S0140-6736(22)00538-4
- 9 Guidelines on long-acting injectable cabotegravir for HIV prevention. World Health Organization. Published 28 July 2022. <https://www.who.int/publications/i/item/9789240054097>
- 10 Pre-exposure prophylaxis for the prevention of HIV infection in the United States – 2021 update. US Public Health Service. Published 2021. www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- 11 Pre-Exposure Prophylaxis Study of Lenacapavir and Emtricitabine/Tenofovir Alafenamide in Adolescent Girls and Young Women at Risk of HIV Infection (PURPOSE 1). National Library of Medicine. Last updated 10 October 2023. clinicaltrials.gov/study/NCT04994509
- 12 Baeten, Jared M., et al. "Use of a vaginal ring containing dapivirine for HIV-1 prevention in women." *New England Journal of Medicine* 375.22 (2016): 2121-2132. Doi:10.1056/NEJMoa1506110
- 13 Nel, Annalene, et al. "Safety and efficacy of a dapivirine vaginal ring for HIV prevention in women." *New England Journal of Medicine* 375.22 (2016): 2133-2143. Doi: 10.1056/NEJMoa1602046
- 14 Nel, Annalene, et al. "Safety, adherence, and HIV-1 seroconversion among women using the dapivirine vaginal ring (DREAM): an open-label, extension study." *The Lancet HIV* 8 (2021): e77-e86. DOI: [https://doi.org/10.1016/S2352-3018\(20\)30300-3](https://doi.org/10.1016/S2352-3018(20)30300-3)
- 15 WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection. World Health Organization. Published January 26, 2021. <https://www.who.int/news/item/26-01-2021-who-recommends-the-dapivirine-vaginal-ring-as-a-new-choice-for-hiv-prevention-for-women-at-substantial-risk-of-hiv-infection>
- 16 Vaginal Ring for HIV Prevention Receives Positive Opinion from European Regulator. National Institute of Allergy and Infectious Diseases. Published July 24, 2020. www.niaid.nih.gov/news-events/vaginal-ring-hiv-prevention-receives-positive-opinion-european-regulator
- 17 NHS England. Clinical Commissioning Policy Reimbursement for the use of generic and second line drugs for Pre Exposure Prophylaxis (PrEP) for the prevention of HIV [2112] [230402P]. Published April 2023. <https://www.england.nhs.uk/publication/reimbursement-for-the-use-of-generic-drugs-for-pre-exposure-prophylaxis-prep-for-the-prevention-of-hiv/>
- 18 Baeten, Jared M., et al. "Antiretroviral prophylaxis for HIV prevention in heterosexual men and women." *New England Journal of Medicine* 367.5 (2012): 399-410. doi: 10.1056/NEJMoa1108524
- 19 Delany-Moretlwe, Sinead, et al. "Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial." *The Lancet* 399.10337 (2022): 1779-1789. doi.org/10.1016/S0140-6736(22)00538-4
- 20 Seifert, Sharon M., et al. "Intracellular tenofovir and emtricitabine anabolites in genital, rectal, and blood compartments from first dose to steady state." *AIDS research and human retroviruses* 32.10-11 (2016): 981-991.
- 21 Cottrell ML et al. A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. *The Journal of Infectious Diseases*, Volume 214, Issue 1, 1 July 2016.
- 22 Anderson PL, Marzinke MA, Glidden DV. Updating the Adherence-Response for Oral Emtricitabine/Tenofovir Disoproxil Fumarate for Human Immunodeficiency Virus Pre-Exposure Prophylaxis Among Cisgender Women. *Clin Infect Dis*. 2023 May 24;76(10):1850-1853. doi: 10.1093/cid/ciad021. PMID: 36645796; PMCID: PMC10209433.
- 23 Moore M et al. Efficacy estimates of oral pre-exposure prophylaxis for HIV prevention in cisgender women with partial adherence. *Nature Medicine* 29: 2748–2752 (2023). <https://doi.org/10.1038/s41591-023-02564-5>
- 24 Zhang L et al. Model-based predictions of protective HIV pre-exposure prophylaxis adherence levels in cisgender women. *Nature Medicine* 29: 2753–2762 (2023). <https://doi.org/10.1038/s41591-023-02615-x>
- 25 Differentiated and simplified pre-exposure prophylaxis for HIV prevention: Update to WHO implementation guidance. World Health Organization. Published 27 Jul 2022. www.who.int/publications/i/item/9789240053694
- 26 Cottrell ML et al. A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. *The Journal of Infectious Diseases*, Volume 214, Issue 1, 1 July 2016.
- 27 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). British HIV Association. Published 2018. www.bhiva.org/PrEP-guidelines
- 28 FSRH CEU Guidance: Drug Interactions Between HIV Antiretroviral Therapy (ART) and Contraception. Faculty of Sexual and Reproductive Healthcare. Published 7 February 2023. www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-guidance-drug-interactions/hiv-drug-interactions-with-contraception-07feb2023.pdf
- 29 Kiweewa Matovu F, Kiwanuka N, Nabwana M, Scholes D, Musoke P, Glenn Fowler M, et al. Intramuscular depot medroxyprogesterone acetate accentuates

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bone loss associated with tenofovir disoproxil fumarate-containing antiretroviral therapy initiation in young women living with HIV (the BONE: CARE study): a prospective cohort study in Uganda. *Lancet Glob Heal* 2022;10:e694–704.

30 FSRH CEU Guidance: Drug Interactions Between HIV Antiretroviral Therapy (ART) and Contraception. Faculty of Sexual and Reproductive Healthcare. Published 7 February 2023. www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-guidance-drug-interactions/hiv-drug-interactions-with-contraception-07feb2023.pdf

31 Preventing HIV during pregnancy and breastfeeding in the context of PrEP. World Health Organization. Published 1 July 2017. www.who.int/publications/i/item/WHO-HIV-2017.09

32 Joseph Davey, Dvora L., et al. "Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading?" *Journal of the International AIDS Society* 23.1 (2020): e25426.

33 Stalter, Randy M., Jillian Pintye, and Kenneth K. Mugwanya. "Safety review of tenofovir disoproxil fumarate/emtricitabine pre-exposure prophylaxis for pregnant women at risk of HIV infection." Expert opinion on drug safety 20.11 (2021): 1367–1373.

34 Gómez L et al. Association of prenatal PrEP exposure with growth and neurodevelopmental outcomes beyond 24 months among Kenyan children. 24th International AIDS Conference, Montreal, Abstract OAC0502, 2022.

35 Wu L et al. No association between in-utero PrEP exposure and bone mineral density at 36 months of age among mother-infant pairs in Kenya. 12th IAS Conference on HIV Science, Brisbane, abstract OAC0402, 2023.

36 Joseph Davey DL et al. Emerging evidence from a systematic review of safety of pre-exposure prophylaxis for pregnant and postpartum women: where are we now and where are we heading? *Journal of the International AIDS Society*, 23: e25426, 2020.

37 Joseph Davey DL, Bekker LG, Bukusi EA, Chi BH, Delany-Moretlwe S, Goga A, Lierly AD, Mgodini NM, Mugo N, Myer L, Noguchi LM, Stranix-Chibanda L, Slack C, Pintye J. Where are the pregnant and breastfeeding women in new pre-exposure prophylaxis trials? The imperative to overcome the evidence gap. *Lancet HIV*. 2022 Mar;9(3):e214–e222. doi: 10.1016/S2352-3018(21)00280-0. Epub 2022 Jan 25. PMID: 35090604; PMCID: PMC9178651.

38 Donnell, Deborah. "Addressing the evidence gap for HIV prevention in pregnancy." *The Lancet HIV* 10.3 (2023): e144–e145.

39 Guidelines On Long-Acting Injectable Cabotegravir For HIV Prevention. World Health Organization. Published 28 July 2022. www.who.int/publications/i/item/9789240054097

40 Bunge K, Balkus JE, Fairlie L, Mayo AJ, Nakabiito C, Mgodini N, Gadama L, Matrimbira M, Chappell CA, Piper J, Chakhtoura N, Szyldo DW, Richardson B, Hillier SL. DELIVER: A Safety Study of a Dapivirine Vaginal Ring and Oral PrEP for the Prevention of HIV During Pregnancy. *J Acquir Immune Defic Syndr*. 2023 Sep 27. doi: 10.1097/QAI.0000000000003312. Epub ahead of print. PMID: 37757834.

41 Owor, M et al. Dapivirine ring safety and drug detection in breastfeeding mother-infant pairs. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 785, 2023. www.croiconference.org/wp-content/uploads/sites/2/posters/2023/CROI_2023_MTN043_poster_2023-02-10-133209613532694120.pdf

42 Pyra, Maria, et al. "Tenofovir and tenofovir-diphosphate concentrations during pregnancy among HIV-uninfected women using oral preexposure prophylaxis." *AIDS* 32.13 (2018): 1891–1898.

43 Karim QA et al. Women for science and science for women: Gaps, challenges and opportunities towards optimizing pre-exposure prophylaxis for HIV-1 prevention. *Front Immunol*. 2022 Dec 6;13:1055042. doi: 10.3389/fimmu.2022.1055042. PMID: 36561760; PMCID: PMC9763292.

44 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). British HIV Association. Published 2018. www.bhiva.org/PrEP-guidelines

45 BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP). British HIV Association. Published 2018. www.bhiva.org/PrEP-guidelines

46 Not PrEPared: Barriers to accessing HIV prevention drugs in England. Terrence Higgins Trust, National AIDS Trust, PrEPster, Sophia Forum, and One Voice Network. Published 03 November 2022. www.nat.org.uk/sites/default/files/publications/Not%20PrEPared.pdf

47 Kuchukhidze S et al. The effects of intimate partner violence on women's risk of HIV acquisition and engagement in the HIV treatment and care cascade: a pooled analysis of nationally representative surveys in sub-Saharan Africa. *Lancet HIV*. 2023 Feb;10(2):e107–e117. doi: 10.1016/S2352-3018(22)00305-8. Epub 2022 Dec 1. PMID: 36463914.

48 HIV pre-exposure prophylaxis (PrEP) need and use in England data tables. Published 3 October 2023. <https://assets.publishing.service.gov.uk/media/6512df31f6746b0012a4ba5d/2022-PrEP-need-and-use-by-demographic-group.ods>

49 Whelan I et al. "Barriers and facilitators to HIV pre-exposure prophylaxis for cisgender and transgender women in the UK." *The Lancet HIV* 10: e472–e481 (2023). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(23\)00080-2/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(23)00080-2/fulltext)

50 Nakasone S et al. "Risk perception, safer sex practices and PrEP enthusiasm: barriers and facilitators to oral HIV pre-exposure prophylaxis in Black African and Black Caribbean women in the UK". *Sexually Transmitted Infections* 96: 349–354 (2020).

51 Budu-Larbi W et al. Identifying HIV risk in heterosexuals in the era of PrEP. 4th Joint Conference of the British HIV Association (BHIVA) with the British Association for Sexual Health and HIV (BASHH); April 17–20, 2018 (abstract P96).

52 Grimshaw C et al. "Implementation of a national HIV pre-exposure prophylaxis service is associated with changes in characteristics of people with newly diagnosed HIV: a retrospective cohort study." *Sexually Transmitted Infections* 98: 53–57 (2022).

53 HIV pre-exposure prophylaxis (PrEP) need and use in England data tables. Published 3 October 2023. <https://assets.publishing.service.gov.uk/media/6512df31f6746b0012a4ba5d/2022-PrEP-need-and-use-by-demographic-group.ods>

54 Whelan I et al. "Barriers and facilitators to HIV pre-exposure prophylaxis for cisgender and transgender women in the UK." *The Lancet HIV* 10: e472–e481 (2023). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(23\)00080-2/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(23)00080-2/fulltext)

55 Strachan S et al. Distributing a questionnaire for women attending a sexual health clinic increases PrEP uptake. 5th Joint Conference of the British HIV Association (BHIVA) with the British Association for Sexual Health and HIV (BASHH); April 19–21, 2021 (abstract P074).

56 Differentiated and simplified pre-exposure prophylaxis for HIV prevention: Update to WHO implementation guidance. World Health Organization. Published 27 Jul 2022. www.who.int/publications/i/item/9789240053694