

# IMAP Statement on Biomedical HIV Prevention

## Background

Recent advances in biomedical HIV prevention technologies mean more choices are available for people to protect themselves from HIV. Therefore, these technologies must be effectively made available and affordable to all populations who need them. All individuals have a right to sexual and reproductive health, and HIV prevention is a key component necessary to ensure health, well-being, positive sexual lives and the upholding of human rights. Access to these new technologies is a key to successfully meeting the Sustainable Development Goal 3.3: ending the AIDS epidemic by 2030. [\(1\)](#)

HIV impacts the health of millions of people globally, especially young women and marginalised groups. Without appropriate attention to HIV prevention, sexual and reproductive health, and rights, cannot be achieved. Every week, around 4,900 young women aged 15–24 become infected with HIV. In sub-Saharan Africa, six in seven new HIV infections among adolescents aged 15–19 years are among girls, and girls and young women

aged 15–24 years are twice as likely to be living with HIV than young men. Globally, women and girls accounted for 49% of the 1.5 million new HIV infections in 2021; in sub-Saharan Africa, for 63%. Key populations, including sex workers and their clients, gay men and other men who have sex with men, people who inject drugs, and transgender people and their sexual partners accounted for 70% of HIV infections globally in 2021; in sub-Saharan Africa, 51% and, outside of sub-Saharan Africa, 94%. [\(2\)](#) Given available methods of HIV prevention, these HIV incidence rates are unacceptably high.

The ECHO Trial (Evidence for Contraceptive Options and HIV Outcomes), which compared HIV infection rates among study participants using three different types of highly effective contraceptive methods in Eswatini, Kenya, South Africa, and Zambia, showed a rate of new HIV infections of 3.81% per year, even when study participants, at every visit, received a comprehensive package of HIV prevention services, including HIV risk reduction counselling,

participant and partner HIV and STI testing and management, condoms, and, as it became a part of national standard of prevention, pre-exposure prophylaxis (PrEP). The trial commenced before oral PrEP was available at the clinical trial locations, and so inclusion of oral PrEP in the comprehensive package of HIV prevention services occurred relatively late in the trial. The high rates of HIV incidence in the ECHO trial demonstrated the need for women to have access to a range of effective and acceptable prevention methods, such as PrEP, and the importance of integrating HIV prevention within contraceptive service delivery platforms. (3)

For decades, few choices were available to effectively prevent sexual transmission of HIV besides male and female condoms. Now there are additional effective methods of biomedical HIV prevention recommended by the World Health Organization (WHO), which with country-level regulatory approval, is the first step to increase the choices of HIV prevention methods available to people. Governments then need to include these technologies in their national level policies and procurement lists, ensure they are affordable, and ensure that systems are in place to train health care workers on the new methods. As more choices for HIV prevention become available, more people will find products acceptable to them and their current circumstances, translating into more opportunities for people to protect themselves from HIV.

### **Purpose and intended audience of this statement**

This statement is intended to update Member Associations across the Federation on biomedical HIV prevention technologies and support their integration of new biomedical HIV prevention services into comprehensive sexual and reproductive health service delivery.

### **What is combination prevention?**

WHO defines combination prevention programmes as “rights-based, evidence-informed, and community-owned programmes that use a mix of biomedical, behavioural, and structural interventions, prioritized to meet the HIV prevention needs of individuals and communities, to have the greatest sustained impact on reducing new infections.” (4)

This IMAP statement does not specifically cover behavioural and structural interventions.

### **What is Biomedical HIV Prevention?**

Biomedical HIV prevention refers to methods of preventing HIV transmission that include a technological component such as a barrier method, for example, internal and external condoms; use of drugs, such as antiretrovirals (ARVs), with different delivery routes (pill, vaginal ring, injection, etc.); procedures such as voluntary medical male circumcision; vaccines (which are still in development), and any combination of these methods. Biomedical HIV prevention technologies are tested in clinical trials for safety and effectiveness, and when found to be safe and effective, are recommended by WHO for specific populations and uses. These technologies are also recommended or approved by country-level public health and regulatory agencies. Effectiveness levels are initially demonstrated through clinical trials, with no method being 100% effective. Therefore, a combination of HIV prevention methods should be offered to individuals, including information on the different methods, their effectiveness levels, and how to use them to protect from HIV as well as whether they protect against other sexually transmitted infections (STIs) and pregnancy. Information should also be provided about effective methods to prevent STIs and pregnancy. Although the effectiveness and safety of these methods have been demonstrated in

clinical trials, effectiveness in real-life settings depends on people seeking HIV prevention information, accessing these methods, and successfully using them at or before the time of HIV exposure. This can be complex and challenging given the social, cultural, economic, and legal structures in which people live.

### Biomedical HIV prevention methods

- External and internal (male and female) condoms act as a barrier and are highly versatile because they protect against HIV, STIs, and pregnancy, and can be used on demand. When used consistently and correctly, condoms are estimated to be 70-99.5% effective in preventing HIV transmission. [\(5,6\)](#)
- Voluntary medical male circumcision (VMMC) is used to reduce heterosexual transmission in men who do not have HIV and has been recommended by the WHO since 2007. Three randomized controlled trials showed that VMMC reduced men's risk of heterosexually acquired HIV by 59%. [\(7-9\)](#)
- Prevention of vertical transmission of HIV uses antiretroviral drugs (ARVs) to reduce transmission from a woman with HIV to her foetus during pregnancy and childbirth and from a woman to her infant during childbirth and breastfeeding. It is estimated that prevention of vertical transmission using ARVs reduces the risk of HIV transmission to less than 5% in breastfeeding populations from a background risk of 35% and to less than 2% in non-breastfeeding populations from a background risk of 25%. [\(10-12\)](#)
- Post-exposure prophylaxis (PEP) uses oral ARVs to reduce transmission when someone without HIV has had possible exposure to HIV. PEP should be used within 72 hours after a possible exposure to HIV (such as following rape or needle stick in a health care setting). [\(13-16\)](#)
- Pre-exposure prophylaxis (PrEP) PrEP refers to using an antiretroviral medication by people not infected with HIV to reduce the risk of HIV acquisition. PrEP is used when individuals believe they are vulnerable to HIV infection. There are different delivery methods for PrEP medications, which are outlined below. New methods are currently being researched; therefore, more methods are expected to be available in the future.
  - Oral PrEP: using a daily pill was first recommended by WHO in 2012. Oral PrEP with tenofovir/emtricitabine (TDF/FTC) reduces the risk of HIV from sex by an estimated 88-99%. Oral PrEP reduces the risk of HIV from injection drug use by at least 74%. [\(17\)](#) Over 3 million people have initiated oral PrEP globally [\(18\)](#) since then; however, many more people would benefit from having access to this highly effective method of HIV prevention. As of 2015, WHO recommends that people at substantial risk of HIV infection should be offered tenofovir disoproxil fumarate (TDF)-based oral PrEP as a comprehensive prevention package. [\(19\)](#)
    - Oral "Daily use" PrEP refers to using a daily pill and is recommended for any person uninfected with HIV to reduce their risk of HIV. Individuals should start oral PrEP by taking one pill per day for seven days before potential exposure to HIV and can stop taking daily PrEP seven days after the last possible exposure. [\(17,20,21\)](#)
    - Oral "Event-driven" pill use (ED-PrEP), also known as "on-demand PrEP" or "intermittent PrEP," is only recommended for gay, bisexual, and other men who have sex with men. The current guidance on event-driven PrEP is to take two pills 2-24 hours before sex, one pill 24 hours after the first dose, and one pill 24 hours after the second dose. The "2-1-1" schedule effectively protects gay and bisexual men and other men who have sex with men when having anal sex without a condom [\(22\)](#) The potential effectiveness of "On-demand" PrEP has

not been validated among heterosexual men and women, people who inject drugs, and transgender persons. (23,24)

- Vaginal ring – A vaginal ring is a device a woman places in her vagina that slowly releases ARVs to reduce the sexual acquisition of HIV. Currently, the vaginal ring shown to be safe and effective is the dapivirine Ring (DPV-VR), which the WHO recommended in January 2021. (25) The dapivirine ring lasts 30 days and is inserted monthly when a woman wants to reduce her risk of acquiring HIV. The dapivirine ring was shown to reduce HIV infection by 35% in The Ring Study (26,27) and 27% in the ASPIRE Study. (28,29) Recent open-label studies show greater adherence to the ring, and modelling data suggest that HIV risk could be reduced by about 50%. (30) The dapivirine ring has received regulatory approval in a number of countries and is currently being reviewed by several more.
- Long-acting injectable PrEP is a new form of PrEP that does not require daily dosing. Currently, the long-acting injectable drug that was demonstrated to be safe and effective is Cabotegravir-Long Acting (LA) which is injected intramuscularly every two months to prevent HIV. The WHO recommended it in 2022. (31) The HIV Prevention Trials Network (HPTN) 083 study, conducted in gay, bisexual, and other men who have sex with men, showed a 69% reduction of HIV (32,33) and the HPTN 084 study, conducted in heterosexual women, showed a 92% risk reduction of HIV. (34,35) It has received regulatory approval in a number of countries and is currently being reviewed in several more.
- Treatment as prevention (TasP) or U=U “undetectable = untransmittable.” This biomedical HIV prevention method refers to how the successful use of antiretroviral therapy (ART) in persons living with HIV can reduce the risk of onward transmission to an

HIV-negative partner. When a person living with HIV correctly and consistently takes ART and achieves viral suppression, defined as 200 copies of HIV per millilitre of blood or less, they are unable to transmit HIV to a partner through sexual intercourse. (36–40)

- There are many products in the biomedical HIV prevention pipeline, such as the dual prevention pill—a daily pill that prevents both pregnancy and HIV. <https://www.prepwatch.org/research-pipeline/>

### Recommendations for IPPF Member Associations

#### Supporting quality comprehensive service delivery design and integration of biomedical HIV prevention methods in sexual and reproductive health services

#### Member Associations are encouraged to:

- Ensure greater involvement of people living with HIV in decision making processes as per the principle of Greater Involvement of Affected Populations (GIPA) (41)
- Rapidly introduce and integrate available biomedical HIV prevention methods into comprehensive sexual and reproductive health services. When specific methods cannot be offered, effective referrals should be made where these services can be accessed.
- Develop systems to ensure the integration of all services for clients, so that clients are informed of all services available, no matter their initial reason for their visit.
- Deepen and expand collaborative partnerships with community-based organisations representing key, priority, marginalised and other populations who would benefit from biomedical HIV prevention to generate demand for these products in the country, support efforts to get regulatory approval, and support the design and roll-out of inclusive and rights-based services.
- Design differentiated and de-medicalized

services, offering services using a range of avenues that are acceptable to different stakeholder groups (e.g. youth friendly spaces, mobile clinics, tele-health), enabling peer-provided services when possible.

- Ensure that clinic and service delivery environments are welcoming and accessible to all people and that services are offered in an inclusive, non-discriminatory, and confidential manner that values autonomy, choice, and a sex and pleasure-positive orientation of sex. This may require conducting training and experiential exercises with staff members on issues related to human and sexual rights, anti-discrimination, unconscious bias, diversity, and inclusion.
- Develop culturally and locally sensitive ways to present comprehensive information to clients, understanding that in each setting there is diversity among clients, and that providing clients with information is key to upholding their sexual and reproductive health rights.
- Develop robust systems for data collection to monitor and evaluate programs effectively, that address community needs, for example:
  - Accurately track specific forms of biomedical HIV prevention services offered, provided, referred, and adopted (e.g., oral PrEP, PEP, injectable PrEP, vaginal ring, voluntary medical male circumcision, prevention of vertical transmission).
  - Accurately track the integration of services, which requires individual level data with respect to different services offered, received, referred to, and adopted, during each visit.
  - Accurately track important demographic information to know that Member Associations are serving stakeholders in need, such as age and other characteristics.
- Develop, implement, and share innovative implementation science research to determine best practices for rolling out and integrating new biomedical HIV prevention methods into comprehensive sexual and reproductive health services.

- Stay updated on the latest developments and biomedical pipeline via AVAC and PrEPWatch: <https://www.prepwatch.org/research-pipeline/>

### Advocacy

#### Member Associations are encouraged to:

- Advocate for regulatory bodies to review new biomedical HIV prevention products and for product manufacturers to submit applications to regulatory bodies in countries where these products are needed.
- Advocate for national policies to be updated to reflect the most recent WHO recommendations on biomedical prevention of HIV and to facilitate rollout of these products.
- Advocate for fair pricing of new biomedical HIV prevention methods.
- Advocate for national legislative bodies to remove legal barriers to accessing and optimally using HIV prevention services and products for youth, key, priority, marginalised, and other populations.
- Advocate at all levels for social and structural barriers, including social norms, to be addressed, in support of societies that are inclusive, equal and just, thereby facilitating all people to access HIV prevention services and successfully use products.
- Advocate for comprehensive sexuality education to be included in schools and out of school programming.
- Advocate for data on use, access and availability of biomedical methods of HIV prevention to be included in the national health information systems (HIS).

### Resources & Guidance

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## Who we are

The International Planned Parenthood Federation (IPPF) is a global service provider and a leading advocate of sexual and reproductive health and rights for all. We are a worldwide movement of national organizations working with and for communities and individuals

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UK Registered Charity No. 229476

Published March 2023