

CONTRACEPTION FOR WOMEN AT HIGH RISK OF HIV TECHNICAL UPDATE

This update replaces the PEPFAR and USAID brief from July 2017, "Hormonal Contraception and HIV Technical Update".

December 2020

Purpose of this technical update

To summarize current evidence and the WHO (World Health Organization) revised guidance regarding use of contraception by women at high risk of acquiring HIV. Programmatic implications and the USG response follow on page two.

Who are the audiences for this brief?

- U.S. Government family planning (FP) and HIV program managers and technical staff at global and country level
- Ministry of Health and national policy makers responsible for FP and HIV programming
- FP and HIV programs implementing organizations

Revised WHO guidance

On August 29, 2019 the World Health Organization (WHO) released its updated Guidance Statement on the contraceptive medical eligibility for women at high risk of acquiring HIV. The Medical Eligibility Criteria for Contraceptive Use (also known as MEC) offers a set of recommendations on the medical safety of contraceptive methods and many countries use the MEC to set country specific policy. Through consensus, the Guideline Development Group (GDG) determined that women at high risk of acquiring HIV can use **all** methods of contraception without restriction. **All contraceptive methods are now a MEC Category 1 for this population; there is no restriction for use.**

In the updated WHO 2019 guidance, progestogen-only injectables (intramuscular and subcutaneous depot medroxyprogesterone acetate [DMPA-IM and DMPA-SC] and norethisterone enanthate [NET-EN]) and intrauterine devices (copper-bearing [Cu-IUD] and levonorgestrel-releasing [LNG-IUD]) were changed from a MEC Category 2 (advantages of using the method generally outweigh the theoretical or proven risks) to MEC Category 1 (there is no restriction for the use of the contraceptive method). All other methods (combined hormonal contraceptives [CHCs], progestogen-only pills [POPs], and implants [levonorgestrel (LNG) and etonogestrel (ETG)]) remained unchanged at a MEC Category 1. These recommendations were formed based on the totality of the available evidence, including data from observational studies and the recently published Evidence for Contraceptive Options and HIV Outcomes Trial (ECHO) study.

Evidence update

The 2019 WHO revised recommendations were strongly informed by the new epidemiological evidence from the ECHO trial, a large, high-quality randomized clinical trial conducted in Eswatini, Kenya, South Africa, and Zambia. The ECHO trial was designed to compare HIV incidence among women using three contraceptive methods: DMPA-IM, LNG-implants, and Cu-IUDs. The trial included 7,829 sexually-active, HIV-negative women ages 16 to 35 years who were seeking contraception. Women who decided to enroll in the trial were randomly assigned to one of the three contraceptive methods. All participants received counseling on contraceptive methods and comprehensive HIV prevention services. The trial was coordinated by FHI360, University of Washington, Wits Reproductive Health and HIV Institute, and the WHO in partnership with research institutions in each participating country, with funding from various donors*.

The ECHO study results were announced on June 13, 2019. The study showed no substantial difference in HIV risk among women who were using any of the three contraceptive methods evaluated, and all methods were safe and highly effective. The hazard ratios for HIV acquisition were 1.04 (95% CI: 0.82–1.33, $p=0.72$) for DMPA-IM compared with Cu-IUD, 1.23 (0.95–1.59, $p=0.097$) for DMPA-IM compared with LNG-implant, and 1.18 (0.91–1.53, $p=0.19$) for Cu-IUD compared with LNG-implant from the intention-to-treat analysis. The results showed a high incidence of HIV and other sexually transmitted infections (STIs) irrespective of the method used with an overall HIV incidence of 3.81 per 100 woman-years: 4.19 per 100 woman-years [95% CI: 3.54–4.94] in the DMPA-IM group, 3.94 per 100 woman-years [95% CI: 3.31–4.66] in the Cu-IUD group, and 3.31 per 100 woman-years [95% CI: 2.74–3.98] in the LNG-implant group.

WHO also reviewed available evidence for combined oral contraceptives (COCs) and NET-EN injectables which showed no increased risk of HIV infection. Although there was no available direct evidence for DMPA-SC, LNG-IUDs, or ETG-implants, there was no biological or clinical reason to believe that a lower hormonal dose, different delivery mechanism, or different progestin would modify HIV risk. The WHO GDG also considered additional evidence including biological data and client values and preferences during their deliberations.

New guidance from the World Health Organization (WHO) emphasizes the following key points:

- A woman's risk of HIV should not restrict her contraceptive choice;
- Efforts to expand access to voluntary family planning and contraceptive options must continue;
- A renewed emphasis on HIV and STI prevention services is urgently needed in settings with high HIV prevalence; and
- HIV testing and prevention should be integrated into family planning services in settings with high HIV prevalence.

Implications of the ECHO Trial findings on reproductive health programming

What do the results of the ECHO Trial mean for women, healthcare providers, and policymakers?

- **Women at high risk of HIV should not be restricted from using any contraceptive method.** All women who are medically eligible to use contraceptives, including progestogen-only injectables (DMPA-IM, DMPA-SC, and NET-EN), should have the option to do so. Women at high risk of HIV should not be denied access to contraceptives, if they choose to use them.
- **Women who seek voluntary FP counseling and services should receive HIV prevention information and be advised that dual method use (condoms plus an effective contraceptive method) can reduce risk of STIs/HIV acquisition and unintended pregnancy.** All women who receive contraceptive counseling and who choose to use contraceptive methods should be advised that male and female condoms are the only contraceptive methods that can reduce the risk of STI and HIV transmission. In addition, women at high risk for HIV infection should be given access to pre-exposure prophylaxis (PrEP).
- **Every effort should be made to ensure that women and couples have access to a wide range of contraceptive methods through voluntary FP services and are able to make a free and informed choice about the method that best fits their individual and life situation.** Expanding contraceptive availability so that women have a broad range of contraceptive options (long-acting reversible contraceptives such as IUDs and implants; short-acting hormonal contraceptives such as injectables, pills, patches, and rings; barrier methods; fertility-awareness based methods; permanent sterilization; and emergency contraception) from which to choose should be a priority.
- **Expanding access to HIV testing services and prevention should be prioritized and integrated into voluntary FP services in settings with HIV prevalence.** Antiretroviral therapy (ART) initiation followed by linkage to ongoing HIV treatment services for HIV-positive partners; PrEP; and HIV self-test kits for at-home and couples testing, should be made available as appropriate and in accordance with national guidelines. Providing more comprehensive services may increase uptake and improve adherence and continuation, as providers are able to tailor contraceptive counseling based on the client's HIV status and fertility intentions
- **Testing for HIV and STIs should be part of high-quality, voluntary FP services for women at risk, particularly for those living in areas of high HIV and STI incidence.** Syndromic management of STIs is not highly effective and STI/HIV programs should move towards diagnostic management.

United States Government (USG) Response

- **Disseminate revised guidelines:** The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), its implementing agencies [the U.S. Centers for Disease Control and Prevention, the U.S. Agency for International Development (USAID), and the Department of Defense], and USAID's family planning program will continue to work with WHO, Ministries of Health, U.N. agencies, U.S. Government agencies, and non-governmental organization partners to disseminate current guidelines and programmatic resources on contraceptive use for women at high risk of HIV acquisition. PEPFAR and the USAID FP program will collaborate with field missions and host country partners to ensure that essential information on this topic is widely disseminated and integrated into FP and HIV service delivery programs.
- **Improve contraceptive method choice:** Improving method choice is a key priority for PEPFAR and the USAID FP program. PEPFAR and the USAID FP program will continue to collaborate to support technical assistance on method choice for all PEPFAR-supported countries. Contraceptive method choice includes a coordinated approach to FP programming that addresses client values and preferences; the enabling environment for FP; a broad contraceptive method mix; and FP service readiness. To improve FP/HIV outcomes, USG agencies need to continue and strengthen coordination with country governments and FP technical organizations to identify activities and interventions that support both key PEPFAR outcomes and critical gaps in the national FP program, including policy and service delivery guideline updates. All FP activities and interventions must be based on and support long-standing principles of quality of care, such as voluntarism and informed choice.
- **Strengthen HIV prevention, including FP/HIV integration in settings with high HIV prevalence:** PEPFAR and the USAID FP program should continue to work closely with Ministries of Health, U.N. agencies, U.S. government agencies, and non-government organization partners to ensure access to integrated FP/HIV services, with differentiated service models to meet country context needs. PEPFAR and the USAID FP program should continue and deepen their collaboration to support FP/HIV integration initiatives in appropriate contexts, collating best practices that address commodity management, joint forecasting, work-flow analysis, ongoing supervision, referrals, adherence and retention monitoring, and PEPFAR reporting requirements. Both HIV and FP programs should continue to investigate innovative ways to improve the provision of integrated FP/HIV information and services that maximize access to both contraceptive choice and HIV prevention interventions, utilizing patient-centered approaches free of stigma and discrimination.

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Resources

- WHO updates recommendations for contraceptive eligibility for women at high risk of HIV, August 29, 2019 (www.who.int/reproductivehealth/contraceptive-eligibility-women-at-high-risk-of-HIV/en/)
- Webinar: WHO recommendations for use of contraceptive methods for women at high risk of HIV, August 29, 2019 (<https://www.youtube.com/watch?v=70t75qXGm-0>)
- New app for WHO's Medical eligibility criteria for contraceptive use, August, 29, 2019 (www.who.int/reproductivehealth/mec-app/en/)

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