



The Continuing Quandary: What's new about hormonal contraception and HIV?

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Overview of Presentation

- Objectives
- What are we talking about?
- When did this happen?
- What is new?
- What does it mean?
- What do we do next?
- What is USAID doing?
- Resources
- Q&A and general discussion
- Case studies exercise

Objectives

- Understand the difference between HC- HIV acquisition and HC-ART interactions.
- Understand the change in the Medical Eligibility Criteria for progestogen-only injectables for women at high risk of HIV.
- Understand the potential implications of HC-HIV issues on FP/HIV programming.
- Understand the work that USAID is doing on HC-HIV acquisition
- Identify key points of contact and resources for HC-HIV issues.

What are we talking about?

HIV-positive (+)
women taking
ART and HC

Do certain ARVs
interact with hormonal
contraceptives?

HIV-negative (-) women
taking HC

Do certain hormonal
contraceptives increase the risk of
HIV acquisition?

What are we talking about?

Key Questions for Three Populations

HIV-negative women

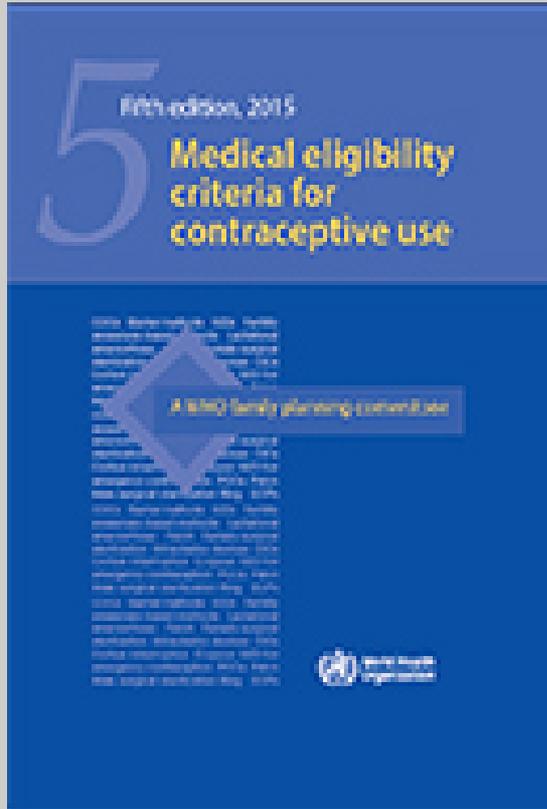
- **Whether HIV negative women who use specific methods of HC are at greater risk of acquiring HIV than HIV negative women who do not use specific methods of HC**

HIV-negative men

- Whether HIV-negative men are at higher risk of acquiring HIV from women living with HIV who are using HC compared to men whose partners are HIV positive and do not use HC

Women living with HIV

- Whether women living with HIV who use ART and HC will experience drug-drug interactions that diminish the effectiveness of their HC method (Jennifer Tang)
- Whether women living with HIV who use HC will experience faster disease progression than women who do not use HC

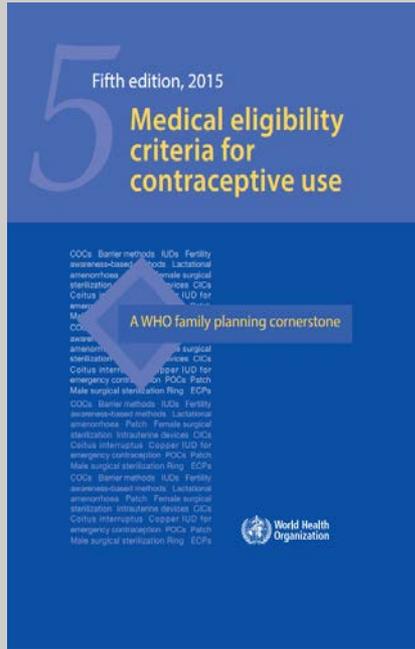


What are we talking about?

The Medical Eligibility Criteria (MEC) for Contraceptive Use

- WHO's Evidence-based guidance to develop and implement family planning guidelines for national programmes.
- Provides information and guidance on the safety of various contraceptive methods for use in the context of specific health conditions and characteristics.

What are we talking about?



Category 1: No restriction on use

Category 2: Advantages generally outweigh theoretical or proven risks

Category 3: Theoretical or proven risks usually outweigh advantages

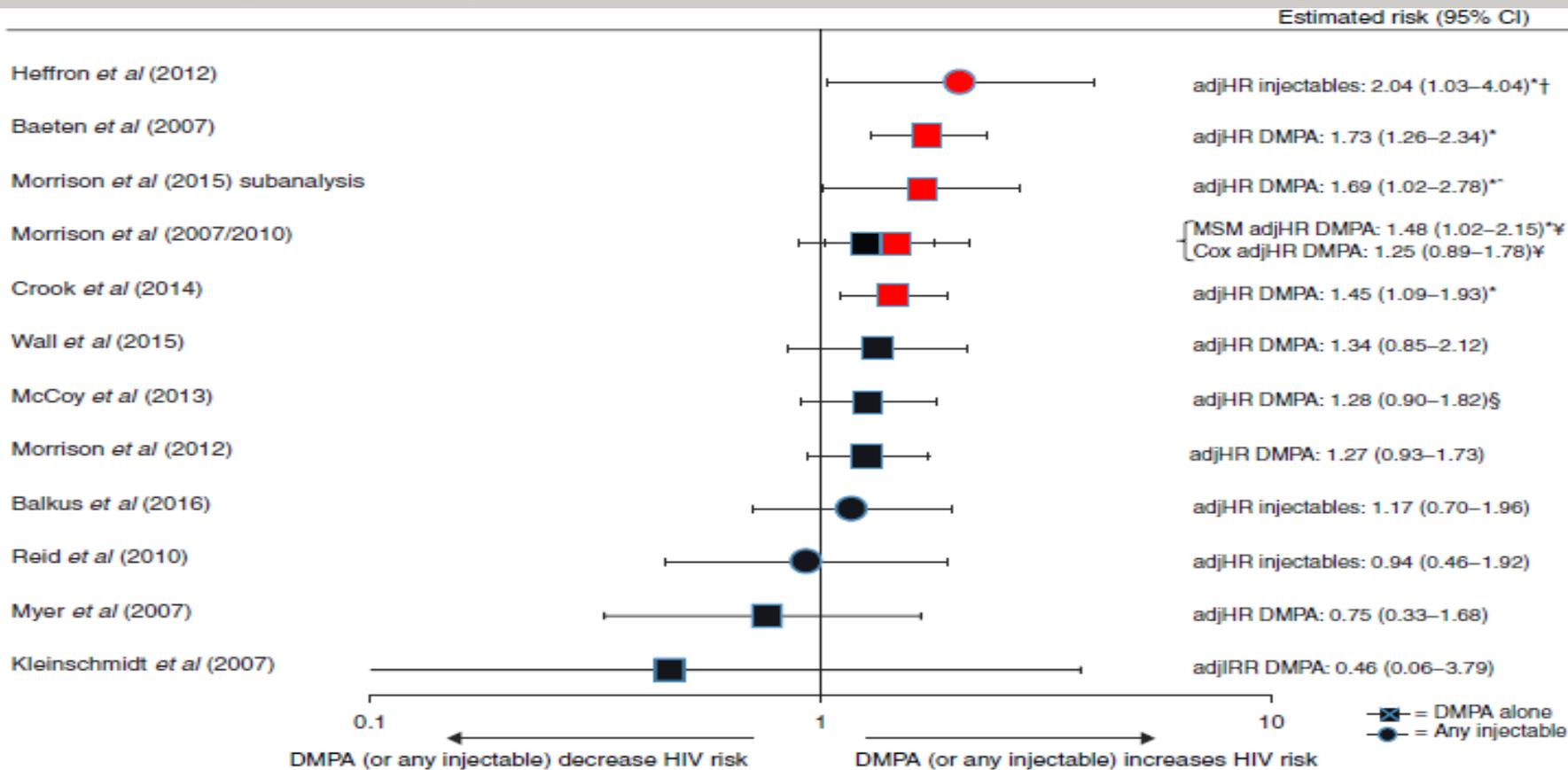
Category 4: Unacceptable health risk

When did this happen?

WHO Timeline

- 2014 WHO commissioned systematic review of HC-HIV acquisition studies and issued “Guidance Statement on hormonal contraceptive methods for women at high risk of HIV and living with HIV”.
- 2016 WHO convened a group to review new evidence on risk of HC-HIV acquisition.
- March 2017 WHO issued “Guidance Statement on Hormonal Contraceptive Eligibility for Women at High-Risk for HIV”.

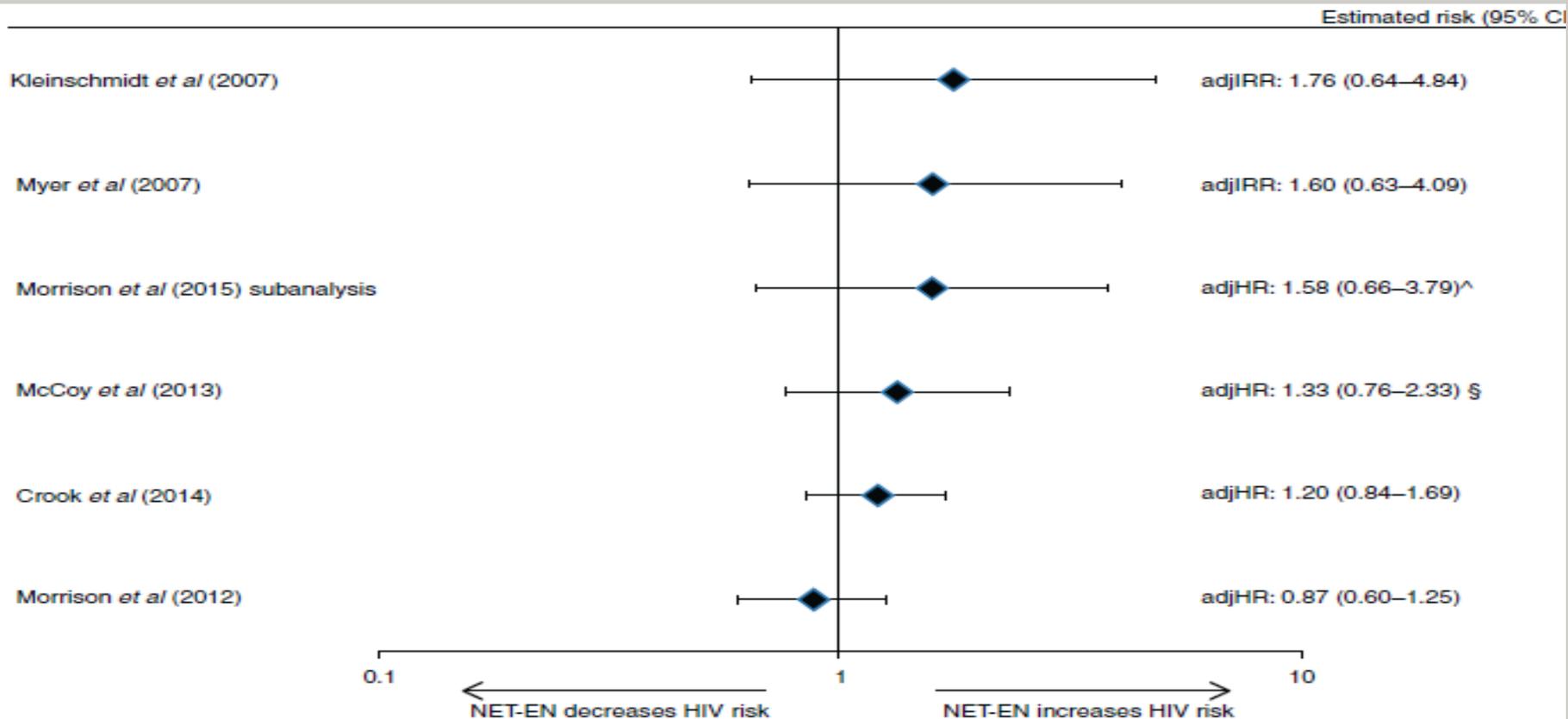
DMPA/Unspecified Injectables versus Non-HC and HIV Acquisition



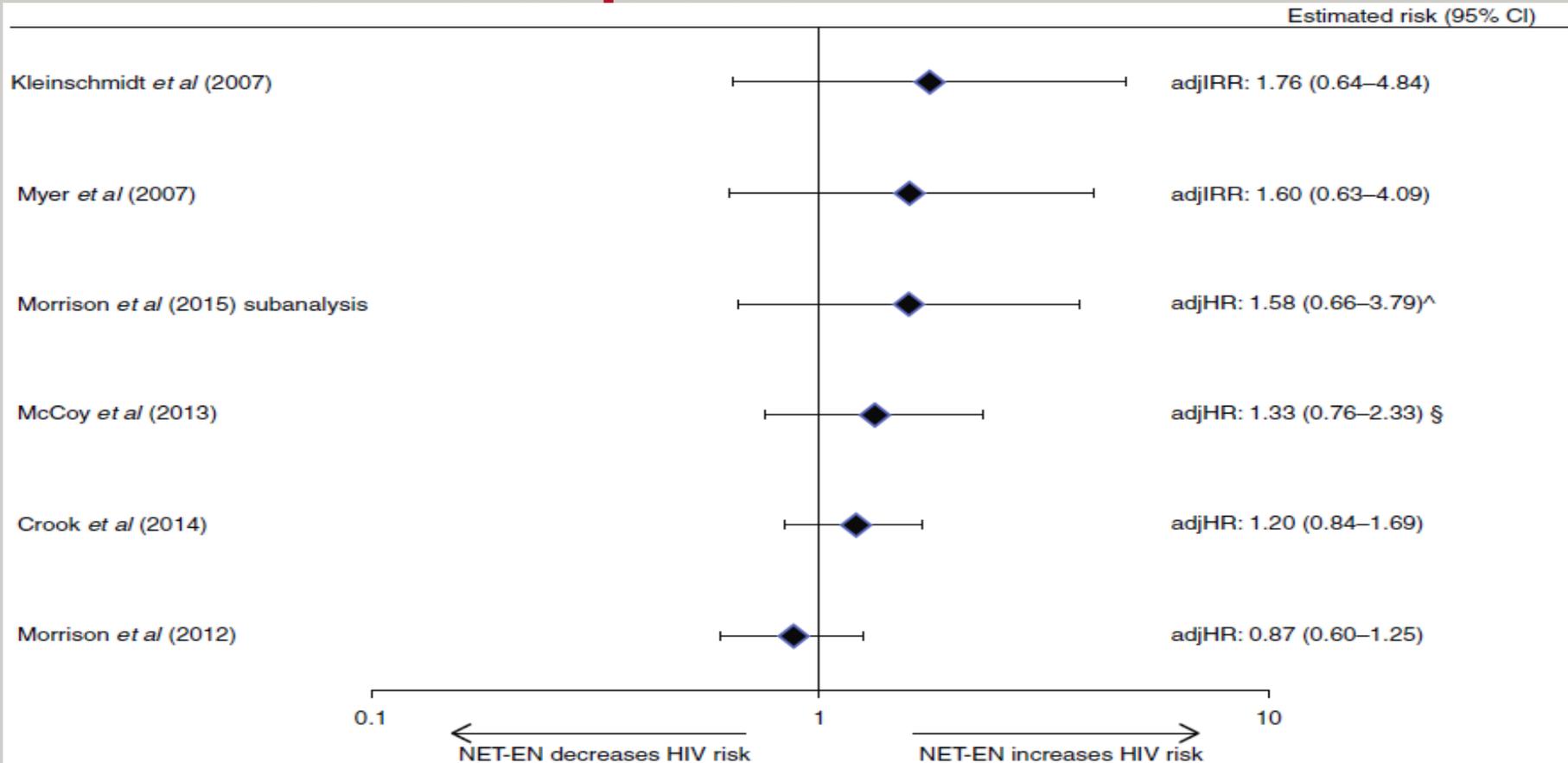
Source: Polis, et al. *AIDS* 2016;30(17):2665-2683.

Pooled adjusted HR 1.40 (1.23-1.59)

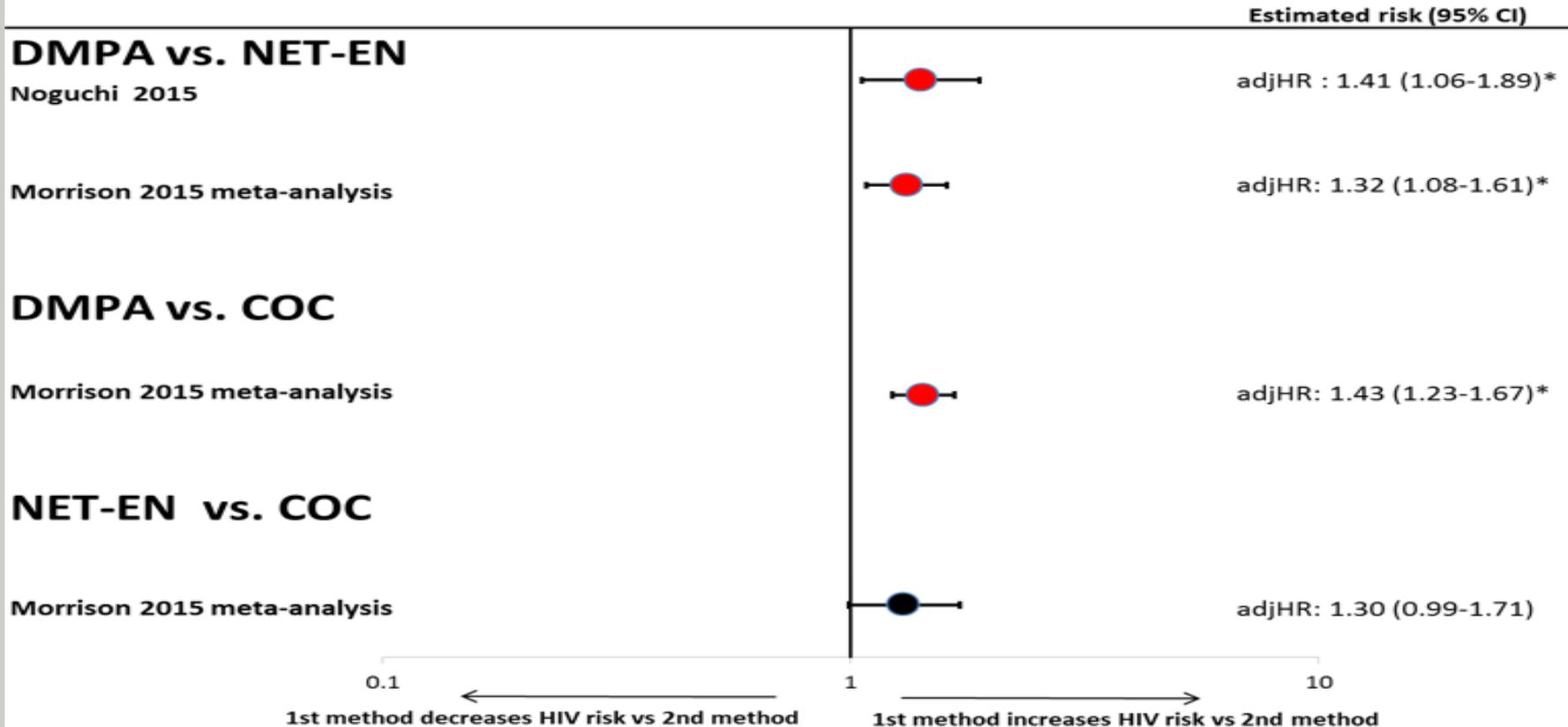
NET-EN & HIV acquisition



NET-EN & HIV acquisition



Head-to-head comparisons



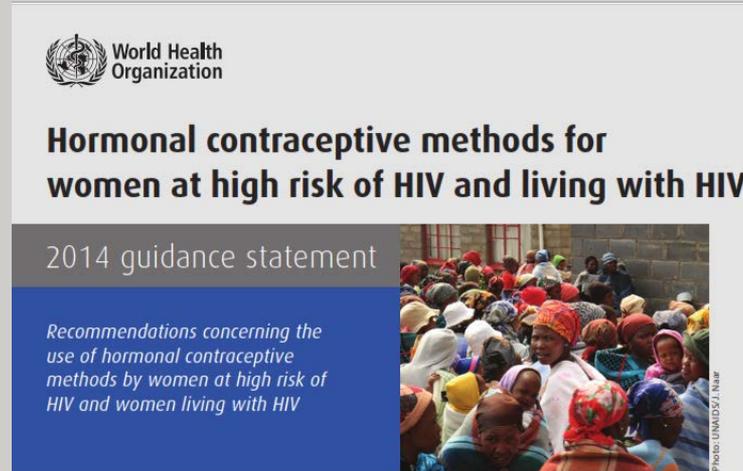
Meta-analyses for DMPA & NET-EN (summary)

Meta-analysis	DMPA estimate (95% CI)
Polis et al 2016	1.40 (1.23-1.59)
Morrison et al 2015	1.50 (1.24-1.83)
Ralph et al 2015	1.40 (1.16-1.69)
Brind et al 2015	1.49 (1.28-1.73)

Meta-analysis	NET-EN estimate (95% CI)
Polis et al 2016	1.15 (0.93-1.42)
Morrison et al 2015	1.24 (0.84-1.82)
Ralph et al 2015	1.10 (0.88-1.37)
Brind et al 2015	N/A

Previous WHO MEC Recommendation

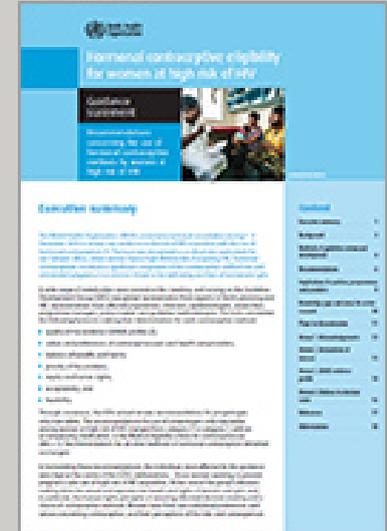
- **2014 MEC Recommendation-** no restriction on any HC method for women at high risk of HIV, but with a clarification



Women at high risk of HIV infection should be informed that progestogen-only injectables may or may not increase their risk of HIV acquisition. Women and couples at high risk of HIV acquisition considering progestogen-only injectables should also be informed about and have access to HIV preventive measures, including male and female condoms.

What is the new MEC Guidance?

- 2017 MEC Guidance applies to progestogen-only injectables (*norethisterone enanthate [NET-EN] and depot medroxyprogesterone acetate [DMPA, in both intramuscular or subcutaneous forms, including Sayana Press]*) for women at high risk of HIV acquisition.
- The recommendation has changed to a category 2, meaning women can use progestogen-only injectables but should be advised about concerns that these methods may increase risk of HIV acquisition, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV.
- “Progestogen-only injectables can be used by women at high risk of HIV, because the advantages of these methods generally outweigh the possible, but unproven, increased risk of HIV acquisition”.



WHO MEC guidance on use of hormonal contraception for women at high risk of HIV

- 2017 guidance: MEC 2 for progestogen-only injectables:
“progestogen-only injectables (norethisterone enanthate [NET-EN] and depot medroxyprogesterone acetate [DMPA, intramuscular or subcutaneous]) can be used by women at high risk of HIV, because the advantages of these methods generally outweigh the possible, but unproven, increased risk of HIV acquisition”.
- Quality of evidence: **Low to low-moderate**

What we don't know...

Why hasn't the research determined if the association between DMPA and HIV is causal?

- All observational data
 - Varying quality of the research
 - Secondary analysis: HIV acquisition was not the primary question driving study design
 - Problem of confounding factors
 - Condom use
 - Other unknown factors



What does it mean?

- The global health community must do the best to assist women and couples who wish to prevent pregnancy
 - Make an informed decision about the contraceptive method that best fits their needs
 - People have a right to receive information about the risks and benefits of all contraceptive methods
 - Importance of dual protection and dual method use (including use of PrEP)
- The potential risk with DMPA must be balanced against risks of unintended pregnancy, including:
 - Maternal morbidity and mortality
 - Unsafe abortion
 - Infant mortality
 - Increase in risk of HIV acquisition which may possibly be associated with pregnancy itself

Key Considerations for HC-HIV: Counseling & Access

For HIV-negative women

- FP and HIV Providers must be trained on potential HC-HIV acquisition and interactions issues and on counseling approaches
- Women at risk for HIV/STIs should be counseled on dual method use in FP, HIV and MNCH settings.
- Women at risk for HIV should be counseled that there is a potential increased risk for HIV acquisition when using DMPA.

For HIV-positive women

- Implant users (Jadelle or Implanon) who are living with HIV and using ART should be informed about the possibility of decreased contraceptive effectiveness
- FP/MNCH services should be strengthened to better serve the needs of PLHIV; including counseling on HC-ART interactions

Key Considerations for HC-HIV: Expanding Method Choice

- Every effort should be made to ensure that women and couples have access to a wide variety of contraceptive methods
- There are real/significant reasons for current method mix that are not easily shifted
- Reliance on DMPA/injectables and lack of access to LARC in Southern Africa is limiting women's ability to make choices regarding FP use.
- Alternative FP methods should be available for women who choose not to use DMPA or implants.



What is USAID doing?

- USAID's Office of Population and Reproductive Health and Office of HIV/AIDS is carrying out activities to provide guidance to USAID missions, partners and MOH counterparts.
 - USG and USAID Briefs on Hormonal Contraception and HIV
 - Strategic Communication Framework for Hormonal Contraception Methods and HIV Related Risks
 - Plan to evaluate roll out of HC-HIV messages in Tanzania
 - Method mix analysis
 - Support to USG partners, USAID missions and implementing partners in integrating HC-HIV messages into HIV and FP programming
 - Collaboration with WHO and UNFPA to disseminate information to MOH and UN offices



ECHO Trial



- Evidence from observational studies suggest that use of progestogen-only injectables, specifically DMPA, is associated with an increased risk of acquiring HIV
 - Uncertainty remains about whether DMPA use actually increases risk
 - WHO has determined that women at high risk of HIV infection may use DMPA, the benefits outweigh the risks
 - However, higher quality research is needed
- ECHO - Evidence for Contraceptive Options and HIV Outcomes Trial
 - Randomized clinical trial running in Kenya, South Africa, Swaziland and Zambia
 - Comparing HIV acquisition risks between women using DMPA, Cu-IUD and Jadelle
 - Results anticipated in early 2019

The trial strives to:

- ❑ Answer the public health question of the relative risks (HIV acquisition) and benefits (pregnancy prevention) of three commonly-used, effective contraceptive methods; and
- ❑ Provide clear guidance for policymakers and programs on contraception and and risk of HIV acquisition

Take Home Messages



- For women at high risk of HIV, no restrictions for: Combined hormonal contraceptives, progestogen-only pills or progestogen-only implants.
- Women at high risk of HIV infection can use DMPA (IM or SC) and NET-EN
- **Women should not be denied the use of progestogen-only injectables – irrespective of their risk for HIV acquisition.**
- Women who choose to use progestogen-only injectables (NET-EN, DMPA) should be counseled to also use condoms (male or female) and/or to access PrEP.
- Women should be advised about the possible increased risk of HIV infection and about the uncertainty of whether there is a causal association

Resources

- USAID HC-HIV Inquiries HCHIVmailist@usaid.gov
- USAID/Washington Points of Contact
 - Jen Mason (jmason@usaid.gov)
 - Dr. Abdulmumin Saad (asaad@usaid.gov)
 - Tabitha Sripipatana (tsripipatana@usaid.gov)
 - Nithya Mani (nmani@usaid.gov)
 - Sarah Yeiser (syeiser@usaid.gov)
- WHO Guidance Statement and FAQs <http://www.who.int/reproductivehealth/faqs-hormonal-contraceptive-hiv/en/>
- Counseling Framework : <http://healthcommcapacity.org/hc3resources/strategic-communication-framework-for-hormonal-contraceptive-methods-and-potential-hiv-related-risks/>
- Hormonal contraceptive methods for women at high risk of HIV and living with HIV 2014 Guidance statement, WHO:http://www.who.int/reproductivehealth/publications/family_planning/HC_and_HIV_2014/en/
- USG HC-HIV Technical Brief: <http://www.usaid.gov/sites/default/files/documents/1864/hormonal-contraception-and-HIV.pdf>
- USG HC-ART Drug Interactions Brief: http://www.usaid.gov/sites/default/files/documents/1864/HC_ART-brief.pdf

- **Cases studies exercise:** Participants will be grouped into 3-4 groups depending on the number of participants. Each group will discuss in 8 minutes a case provided to the group and present their responses in the plenary in 7 minutes.

HC-HIV Case Studies: HIV Acquisition

Case I

Country A has very high incidence and prevalence of HIV. There is limited access to LARC in the public and private sector due to supply chain and provider capacity issues. The most commonly used FP method is DMPA-IM, followed by Net-En. Condoms are not widely used by women between the ages of 24-45.

MOH officials from that country recently attended a USAID sponsored workshop on HC-HIV acquisition. While they strongly support informed choice for all women they are not sure if they should include HC-HIV information in their FP counseling. They are very concerned that providers and women will not understand the messages and that public opinion will turn against the use of DMPA-IM or all injectables.

Discuss in your group and develop several suggestions for how Country A should approach the problem and what their next steps could be.

HC-HIV Case Studies: HIV Acquisition

Case 2

Country B has very high incidence and prevalence of HIV, with highest rates of acquisition among adolescent girls and young women (AGYW). Although there is wide availability of implants in the public and private sectors, and limited availability of IUD in the private sector, AGYW have very limited access to LARC due to legal restrictions and provider bias. The most commonly used FP method among AGYW is DMPA-IM, followed by OCs. Condom use among AGYW is sporadic and inconsistent.

Country B's National AIDS program has begun to lobby the MOH to restrict DMPA-IM access to AGYW due to concerns about HIV acquisition. They have suggested that FP service providers should stop offering DMPA to AGYW at public and private health facilities, school health centers and community outreach activities. They suggest that AGYW be counseled to use dual methods such as condoms + OCs or condoms + LARC. Although the MOH is concerned about voluntarism and informed choice, they are committed to major reductions in HIV incidence, especially among AGYW.

Discuss in your group and develop several suggestions for how Country A should approach the problem and what their next steps could be.

Thank you!

