Hormonal Contraception and HIV: What is going on?

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Two Different Questions and Two Different Populations

**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?
HIV-negative (-) women taking HC

Do certain hormonal contraceptives increase the risk of HIV acquisition?
WHO, Medical Eligibility Criteria (MEC)

- Provides evidence based guidance on who can safely use contraceptive methods
- 2014 MEC expert group reviewed evidence on hormonal contraception and HIV acquisition
  - Commissioned systematic review of relevant studies
## Summary of Evidence, Acquisition
*(C.Polis, 2014)*

<table>
<thead>
<tr>
<th>Method</th>
<th>Acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patches, Rings, EC</td>
<td>No Data</td>
</tr>
<tr>
<td>LNG-IUD</td>
<td>No Data</td>
</tr>
<tr>
<td>OCPs</td>
<td>No Current Concern</td>
</tr>
<tr>
<td>Implants</td>
<td>No Current Concern</td>
</tr>
<tr>
<td>NET-EN</td>
<td>Some Concern (limited data)</td>
</tr>
<tr>
<td>DMPA</td>
<td>Concern</td>
</tr>
</tbody>
</table>

Systematic review concluded that the relationship between injectable HC and HIV risk is **inconclusive** *(22 studies)*.
• 2014 MEC expert panel reviewed evidence, recommended 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.
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
Programmatic Implications

• No clear answers about hormonal contraception and HIV acquisition
• 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
• 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
What is USAID doing?

- PRH/OHA 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 Malawi
  - Method mix analysis (Net-En)
  - 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
HIV-positive (+) women taking ART and HC

Do certain ARVs interact with hormonal contraceptives?
What is a drug to drug interaction (DDI) ?

- A pharmacokinetic drug interaction occurs when a drug interferes (in a positive or negative way) with another drug, resulting in higher or lower levels of either drug in the body.

- Certain hormonal contraceptive methods and certain ARVs have the potential to interact with each other and, in theory, to lead to decreases in efficacy of either medication or to increased side effects or toxicity.
Do hormonal contraceptive methods reduce the efficacy of ART?

- While data are limited, ART efficacy does not appear to be impacted by use of hormonal contraceptive methods.
Do specific ARVs reduce the efficacy of hormonal contraceptive methods?

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined oral contraceptives</td>
<td>Efavirenz and boosted PIs see reduced blood progestin levels of COCs. No efficacy data are available, however, reduced progestin could lead to unintended pregnancies.</td>
</tr>
<tr>
<td>Progestin only pills</td>
<td>No efficacy data are available; and data on POP levels when used with efavirenz or nevirapine are not available</td>
</tr>
<tr>
<td>Progestin-only injectables</td>
<td>Levels of DMPA do not appear to be reduced by ARVs. Studies on Net-En when used with ART are not available.</td>
</tr>
<tr>
<td>Emergency contraception</td>
<td>Limited evidence suggests that levonorgestrel levels are significantly reduced among women using LNG ECPs and efavirenz, but no efficacy data are available.</td>
</tr>
<tr>
<td>Levonorgestrel-releasing IUD</td>
<td>Limited evidence suggests that efficacy of the levonorgestrel-releasing IUD is unlikely to be affected by ART.</td>
</tr>
<tr>
<td>Implants</td>
<td>Data review on next slides</td>
</tr>
</tbody>
</table>
There are two distinctly different types of progestin based hormonal contraceptive subdermal implants available:

- Implanon (etonogestrel) 1 rod
- Jadelle (levonorgestrel) 2 rods

These implants differ in their hormonal formulations, mechanisms of action to prevent pregnancy, and duration of effectiveness (three versus five years, respectively)

Expected failure rate is less than 1%
How much is out there?

- Implants are the fastest growing method of contraception in Sub-Saharan Africa
- In 2014, USAID’s Deliver Project shipped 1.9 million implants to 10 countries
- Efavirenz are WHO first line therapy
- 13 million women in Sub-Saharan Africa living with HIV are candidates for efavirenz use
- USAID shipped over 10 million units of efavirenz containing medication in 2014
What is the MEC Guidance?

- Use of implants by HIV-positive women who use certain ART regimens are classified by the WHO via their medical eligibility criteria guidance as category 2:

  - The advantage of using the method generally outweigh the theoretical or proven risks
• Reported increase in contraceptive failures with concomitant Jadelle and efavirenz use

• Despite an apparent decrease in contraceptive efficacy for women using implants and an EFV-based ART regimen, *the data from the Kenya study suggest that implants are still more effective in preventing unintended pregnancy than shorter-acting contraceptive methods*, such as the DMPA injection, pills or condoms

• Data needed to support alternative strategies for optimizing the effectiveness of contraceptive implants in combination with efavirenz
Take Home Messages

- Implants still appear to be more effective in preventing unintended pregnancy than many other contraceptive methods used.

- HIV programs and providers need to actively engage women in conversations about the potential risks and benefits of each contraceptive method.
What is USAID doing?

- PRH/OHA activities to provide guidance to USAID missions, partners and MOH counterparts.
  - USG/USAID Briefs
  - Research (MCSP and Envision)
    - Prospective PK/PD study – ETG (is ETG better than LNG – for how long?)
    - Retrospective chart review
      - Method Choice support
What is USAID doing?

– APC/Envision work on updating HC DDI chart and provider information
– 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
Key Considerations for HC-HIV: Rights Based Approach

Women and couples should retain the right to make an informed decision about their contraceptive and reproductive health options.
Key Considerations for HC-HIV: Counseling & Access

- 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.
- 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.
Integrating FP services into HIV platforms provides important opportunities for providers to reach women and their partners with information about how their medications may interact.


Thank you!