Hormonal Contraceptive and HIV risk

By

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Session Goal

- To acquire, update and refresh knowledge – this is a learning space -- what does the current research say about hormonal contraception and HIV and what might we learn—and how?

What Is Hormonal Contraception

- Hormones are substances in our body that regulate and affect many different processes: growth, fertility, hunger, emotions – and much more.
- Hormonal contraceptives use synthetic forms of our bodies' hormones to prevent us from falling pregnant
- There are many different kinds of synthetic hormones used in contraception these include: progestins, estrogins and others

What do we know about Hormonal Contraception & HIV Risk

- For many years, there has been a question about whether some hormonal contraceptives affect women's' risk of getting HIV
- The greatest concern has been about contraceptives that contain a specific progestin (a synthetic form of progesterone). This progestin is found in the injectable known as DMPA or “Depo” or sometimes just “the shot”

Mixed data about HC and HIV risk

- Some studies (observational) suggest that use of certain hormonal contraceptives--particularly injectable progestogen-only methods like **Depo Provera (DMPA)** increase women's risk of HIV infection
  - Depo Provera is a discrete long-acting injectable good for women living with HIV because ART may reduce efficacy of contraceptive implants
- Other studies do not suggest an increased risk
- WHO's latest systematic review (July 2016) did indeed find **increased concern around DMPA** and HIV acquisition

Why is the evidence mixed? In part because of where it comes from

Observational Studies

An ***observational study*** takes place when researchers don't assign choices they simply observe them:

For instance, a study trying to find a connection between students who play an instrument and academic performance. Instead of assigning some students to learn an instrument the researchers simply *observed* student who did and did not play an instrument and recorded their grades.

- This is also an example of a ***retrospective study*** because researchers first identified subjects who studied music and then collected data on their past grades.

WHO's latest systematic review

- 2014 women at risk of HIV must be informed of mixed data re impact of DMPA on HIV risk
- 2016 data strengthens concerns about DMPA but still not definite
- Oral contraceptive pills, injectable NET-EN and implants do not suggest an association with HIV
- WHO convened a working group to assess whether guidance needs to change
  - New guidance in 2017

Updated WHO Guidance, March 2017

WHO states “there continues to be evidence of a possible increased risk of HIV among progestogen-only injectable users.”

WHO changed the safety grade assigned to Depo and NET-EN from:

- “This method can be used safely by anyone.” MEC 1

to

- “This method can be used safely by anyone. But there are key things for women and health care workers to think about.”MEC 2

The message given to women needs to change

Who is most impacted by DMPA & HIV risk?

- If women stopped using DMPA and did not switch to another method, they would be at greater risk of unplanned pregnancy, maternal morbidity and mortality
- Of greatest relevance in East and Southern African countries where rates of HIV are high and where injectable hormonal contraceptives like DMPA are widely used

Will DMPA concerns be resolved?

- ECHO Trial launched in Q4 2015 (The Evidence for Contraceptive Options and HIV Outcomes Study)
  - Open-label RCT
  - Comparing three methods: DMPA, the Jadelle implant, the copper IUD
  - 7,800 women
  - Kenya, SA, Swaziland, Zambia
  - Results 2019

What is the ECHO Study?

- The **E**vidence for **C**ontraceptive options and **H**IV **O**utcomes is an open-label randomised clinical trial that will compare three highly effective, reversible methods of contraception to evaluate whether there is a link between use of any of these methods and increased risk of acquiring HIV infection.

Study approvals

- The study has been reviewed and approved by the ethics review boards of FHI 360 and KEMRI Ethics Review committee

- In addition, national regulatory authorities, including the Kenya's Pharmacy and Poison Board, have been notified and have approved the study.

Background

- **Women worldwide need family planning, and in Africa, the use of hormonal contraception, and especially Depo, provide women with a long-acting, reversible and safe option for birth control.**
  - More than 150 million women around the world use hormonal contraceptives.
- **African women are at high risk of HIV.**
  - 16 million women aged 15 years and older are living with HIV; 80% live in sub-Saharan Africa
  - Young women 15–24 years old in sub-Saharan Africa are twice as likely as young men to be living with HIV.

Objectives

Primary objective

- To compare the risks of HIV acquisition between women randomised to DMPA, levonorgestrel (LNG) implants, and copper IUDs

Secondary and tertiary objectives

- Pregnancy, safety, contraceptive continuation

Why do we need the ECHO Study?

- For over 25 years, the world has lived with the uncertainty about whether or not use of hormonal contraceptives increases HIV risk.

- ECHO aims to answer this critical public health question of the possible risks (HIV acquisition) and benefits (pregnancy prevention) of the three commonly-used, effective contraceptive methods among women who desire contraception

Purpose of the ECHO Study

When comparing women's use of the contraceptives— Depo, Jadelle and IUD:

–Is there an increased risk of acquiring HIV when they use one method over the others?

–Are there more or less side effects of each method?

–Are the pregnancy rates the same?

–How well do women stay on each of the three contraceptive methods?

Study groups

- When a woman enrols in ECHO, she will be randomly placed in 1 of 3 groups:
- **DMPA) Depo Provera** **Jadelle Implant** **Copper IUD (Cu-IUD)**

OR

OR

(condoms, HCT, STI treatment)

KEMRI-RCTP ECHO Current Status

- Completed Recruitment phase -Met target

- Participant follow up phase: Completed
- Data cleaning Ongoing
- Stakeholder engagement for trial results

What If No Trial

- The observational evidence base is unlikely to improve

- Without a trial, messaging will continue to be challenging for providers, policymakers, and patients. Essentially:
  - If HIV risk exists *in truth*, unnecessary infections will continue to occur.
  - If HIV risk does not exist *in truth*, policies and/or individual women's choices may alter, with potentially serious negative consequences for maternal morbidity/mortality
- ***Women need accurate information to exercise informed contraceptive choices***

HC/HIV: Key advocate considerations

- Track progress of WHO DMPA guidelines
- Push for women's *right to know* all available information regarding contraceptive methods
- Investment in method mix—expansion of contraceptive methods women can choose from
- Ongoing engagement with women to ensure their perspectives and experiences guide policy, programs and messaging (TWGs