What’s New in Contraception

Anne Burke, MD, MPH
Baltimore, MD
March 29, 2017
Types of Contraception

**Hormonal methods**
- Estrogen/progestin
  - OCP
  - Patch
  - Ring
  (Injectable – non-US)
- Progestin-only
  - Implant
  - Injectable Pill
  - Levonorgestrel IUD

**Non-hormonal methods**
- IUD
- Copper IUD

**Barrier Methods**
- Condoms
- Diaphragm/cap
- Spermicide

**Fertility Awareness**
- Calendar methods
- Cervical mucus
- Symptothermal

**Lactational Amenorrhea**
Objectives

• Update on long-acting reversible methods
• Counseling
• Adolescents
• Postpartum
• Vaginal rings
• WHO Injectable update
Comparing effectiveness of contraceptive methods

Average users
Includes users who sometimes forget or make mistakes and users who always use the method correctly and consistently. Most people can expect this level of effectiveness.

Correct & consistent users
Includes users who always use the method correctly and consistently. Only people who use the method in this way can expect this level of effectiveness.

- **Lead with the best!**

More effective
2 or fewer pregnancies per 100 women in one year

- **Sterilisation for women**
- **Implants**

Effective
3 to 9 pregnancies per 100 women in one year

- **Injectables**
- **LAM**
- **Pills**

Less Effective
10 to 30 pregnancies per 100 women in one year

- **Male condoms**
- **Female condoms**
- **Fertility Awareness-Based Methods (selected)**
- **Diaphragm**
- **Fertility Awareness-Based Methods (selected)**
- **Spermicides**
- **Injectables**
- **Sterilisation for women**
- **Vasectomy**
- **Male condoms**
- **Female condoms**
- **Fertility Awareness-Based Methods (selected)**
- **Diaphragm**
- **Spermicides**
<table>
<thead>
<tr>
<th></th>
<th>Can use the method</th>
<th>No restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Can use the method</td>
<td>Advantages generally outweigh theoretical or proven risks.</td>
</tr>
<tr>
<td>3</td>
<td>Should not use method unless no other method is appropriate</td>
<td>Theoretical or proven risks generally outweigh advantages</td>
</tr>
<tr>
<td>4</td>
<td>Should not use method</td>
<td>Unacceptable health risk</td>
</tr>
</tbody>
</table>

Can my client use this method?
Update on Long-Acting Methods
Long Acting Reversible Contraception (LARC)

Pregnancy rates in first year of use (per 1000 women)

6
1-2
~1

Trussell, Contraception, 2011
Contraceptive Failure: LARC vs. the rest

Cumulative % of women with contraceptive failure

Pregnancy prevention – highly effective

Winner, NEJM 2012
Continuation over 24 months

Twenty-Four-Month Continuation of Reversible Contraception. O’Neil-Callahan, Micaela; Peipert, Jeffrey; MD, PhD; Zhao, Qiuhong; Madden, Tessa; MD, MPH; Secura, Gina; PhD, MPH

Obstetrics & Gynecology. 122(5):1083-1091, November 2013. DOI: 10.1097/AOG.0b013e3182a91f45
Satisfaction with long-acting methods is high

![Pie chart for IUD (N=2,324) showing satisfaction levels: Very satisfied, satisfied, not so much.]

![Pie chart for Implant (N=522) showing satisfaction levels: Very satisfied, satisfied, not so much.]

Twenty-Four-Month Continuation of Reversible Contraception. O'Neil-Callahan, Micaela; Peipert, Jeffrey; MD, PhD; Zhao, Qiuohon; Madden, Tessa; MD, MPH; Secura, Gina; PhD, MPH Obstetrics & Gynecology. 122(5):1083-1091, November 2013. DOI: 10.1097/AOG.0b013e3182a914f5
Most women, most of the time, are candidates for LARC methods

- Almost all women can use implant
- Category 4:
  - Breast cancer
  - Allergy

<table>
<thead>
<tr>
<th>IUD Category 4 conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy</td>
</tr>
<tr>
<td>Cervix, breast, endometrial cancer</td>
</tr>
<tr>
<td>Distorted uterine cavity</td>
</tr>
<tr>
<td>Current PID</td>
</tr>
<tr>
<td>Current purulent CT/GC</td>
</tr>
</tbody>
</table>
Do not unnecessarily restrict insertion of LARC Methods

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Timing of Initiation</th>
<th>Additional Contraception Needed as Back-up</th>
<th>Examinations or Tests Needed before Initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper-containing IUD</td>
<td>Any time</td>
<td>Not needed</td>
<td>Bimanual examination and cervical inspection§</td>
</tr>
<tr>
<td>Levonorgestrel-releasing IUD</td>
<td>Any time</td>
<td>If more than 7 days after menses started, use back-up method or abstain from sexual intercourse for 7 days.</td>
<td>Bimanual examination and cervical inspection§</td>
</tr>
<tr>
<td>Hormonal implant</td>
<td>Any time</td>
<td>If more than 5 days after menses started, use back-up method or abstain from sexual intercourse for 7 days.</td>
<td>None</td>
</tr>
</tbody>
</table>

*This table is adapted from Curtis et al.17
† LARC methods can be initiated if the provider is reasonably certain that the woman is not pregnant.
‡ The recommendations for the use and duration of a back-up method were determined on the basis of the mechanism of action of the contraceptive method and on the basis of data on the minimum duration of use necessary for contraceptive effectiveness.
§ Most women do not require additional screening for sexually transmitted diseases (STDs) at the time of insertion of an IUD. If a woman with risk factors for STDs has not been screened for gonococcal infection and chlamydial infection according to the STD Treatment Guidelines of the Centers for Disease Control and Prevention (CDC) (www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion.
# How to be reasonably sure a woman is not pregnant

<table>
<thead>
<tr>
<th>If all answers are</th>
<th>PREGNANCY CHECKLIST</th>
<th>If any answer is</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>...then cannot rule out pregnancy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then? | | ...
| Have you abstained from sexual intercourse since your last menstrual period or delivery? |
| Have you had a baby in the last 4 weeks? | | ...then can be reasonably sure she is not pregnant |
| Did your last menstrual period start within the past 7 days (or within the past 12 days if you are planning to use an IUD)? |
| Have you had a miscarriage or abortion in the past 7 days (or within the past 12 days if you are planning to use an IUD)? |
| Have you been using a reliable contraceptive method consistently and correctly? |

Source: USAID, FHI 2008
<table>
<thead>
<tr>
<th>(LNG-IUS)</th>
<th>(LNG-IUS)</th>
<th>(Copper T IUD)</th>
<th>(Copper T IUD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>28x30mm</td>
<td>32x32mm</td>
<td>32x36mm</td>
<td>24x30mm</td>
</tr>
<tr>
<td>3 years</td>
<td>5 years</td>
<td>12 years</td>
<td>5 years</td>
</tr>
<tr>
<td>0.4% failure</td>
<td>0.2% failure</td>
<td>0.6% failure</td>
<td>0.6% failure</td>
</tr>
<tr>
<td>Initially releases</td>
<td>Initially releases</td>
<td>No hormone</td>
<td>No hormone</td>
</tr>
<tr>
<td>14mcg/day</td>
<td>20mcg/day</td>
<td>Copper ions</td>
<td>Copper ions</td>
</tr>
<tr>
<td>levonorgestrel</td>
<td>levonorgestrel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>→ 5mcg/day (3 yrs)</td>
<td>→ 10mcg/day (5 yrs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spermicidal</td>
<td>Spermicidal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Change in ovum</td>
<td>- Change in ovum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>transport speed</td>
<td>transport speed</td>
</tr>
</tbody>
</table>

- Thickens cervical mucus
- Thins endometrial lining
- Spermicidal
- Incomplete ovulation suppression

- Spermicidal
- Change in ovum transport speed
IUDs: Mechanism

- Mechanism: primarily by preventing fertilization
  - Copper has direct effects on uterus, sperm and ova
  - Levonorgestrel:
    - THICKENS cervical mucus
    - THINS endometrial lining
IUDs and bleeding patterns

Luukkainen and Toivonen. 1992;90

Mean Bleeding Days

0
2
4
6

Copper IUD

LNG IUS

0  4  8  12  16  20  24

Months

IUDs and bleeding patterns

Luukkainen and Toivonen. 1992;90
LNG IUD: Treatment Heavy Bleeding

- Women with heavy menses
- Women with anemia
- Women with bleeding disorders
IUDs for nulliparous women?

• Yes!
  • Women who’ve not had children can still get IUD
  • Sometimes the uterus is smaller
  • Newer, smaller IUD may be recommended
  • Today’s IUDs do NOT cause infertility
  • Complication rates are LOW
Rate of PID by Duration of IUD Use

- <21 days of use: 9.25 per 1,000 woman years
- 21 days - 8 years of use: 1.6 per 1,000 woman years

n=~20,000 women

Provision of no-cost LNG IUS over 9 years in Brazil (N=15,000): Health effects of preventing unplanned pregnancy

Jessica M Ferreira et al. J Fam Plann Reprod Health Care
doi:10.1136/jfprhc-2016-101569
Continuation: Does IUD type make a difference?

# Comparison of Hormonal Implants

<table>
<thead>
<tr>
<th></th>
<th>Jadelle</th>
<th>ImplanonNXT</th>
<th>Sino-implant (II)/Zarin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Bayer Healthcare</td>
<td>Merck/MSD</td>
<td>Shanghai Dahua Pharmaceutical Ltd.</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>150 mg levonorgestrel in 2 rods</td>
<td>68 mg etonogestrel in 1 rod</td>
<td>150 mg levonorgestrel in 2 rods</td>
</tr>
<tr>
<td><strong>Mean Insertion &amp; Removal time</strong></td>
<td>Insertion: 2 min Removal: 5 min</td>
<td>Insertion: 1 min Removal: 2-3 min</td>
<td>Insertion: 2 min Removal: 5 min</td>
</tr>
<tr>
<td><strong>Labeled duration</strong></td>
<td>5 years</td>
<td>3 years</td>
<td>4 years</td>
</tr>
<tr>
<td><strong>Trocars</strong></td>
<td>Autoclavable and Disposable</td>
<td>Pre-loaded disposable</td>
<td>Disposable</td>
</tr>
</tbody>
</table>
Implanon/Nexplanon™
Etonogestrel Implants

- Progestin-only method
- Prevents ovulation
- Long-acting (3 years)

- Main side-effect is unpredictable menstrual cycles
- Fertility returns within a few days of removal
Median number of bleeding/spotting days

Single-rod IMPLANT: bleeding

Zheng 1999 Contraception
Levonorgestrel implant: Bleeding patterns

Roke et al, Journal of Primary Health Care 8(1) 13-19
http://dx.doi.org/10.1071/HC15040; 2016
Implant satisfaction

• Most women (70-80%) satisfied
• “Fit and forget”
• Reasons for removal:

Roke et al, Journal of Primary Health Care 8(1) 13-19
http://dx.doi.org/10.1071/HC15040
Longer than 3 years?

- Study comparing ENG and LNG implants showed continued efficacy up to 5 years of use

Reproductive Justice Considerations

• Is Efficacy everything?

• Not magic solution to unintended pregnancy (UIP)
  • Access is important but...
  • Research indicates this is not always the reason for UIP
  • UIP as a cause or consequence of social inequality?

• What WE want or what Clients want?
Factors influencing contraceptive choice

**Mechanistic:**
- Ease of use
- Frequency of Use
- Hormones?
- Mistake proof?

**Method effect:**
- Efficacy
- Side effects
- Benefits

**Social/normative**
- Personal experience
- Partner support
- “vicarious” experience
- Consent needed?

**Practical!**
- Cost
- Availability

## Importance of Counseling

### Percentage of Women Who Reported Being Counseled to Expect Commonly Occurring Side Effects by Method Adopted

<table>
<thead>
<tr>
<th>Method and Side Effect Counseled to Expect</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implant (N=135)</strong></td>
<td></td>
</tr>
<tr>
<td>Irregular bleeding</td>
<td>28 (20.7)</td>
</tr>
<tr>
<td>Decreased bleeding</td>
<td>14 (10.4)</td>
</tr>
<tr>
<td>No menses</td>
<td>37 (27.4)</td>
</tr>
<tr>
<td>Not counseled on any of these side effects</td>
<td>39 (28.9)</td>
</tr>
<tr>
<td><strong>Injectables (N=109)</strong></td>
<td></td>
</tr>
<tr>
<td>Decreased bleeding</td>
<td>12 (11.0)</td>
</tr>
<tr>
<td>No menses</td>
<td>46 (42.2)</td>
</tr>
<tr>
<td>Weight gain</td>
<td>13 (11.9)</td>
</tr>
<tr>
<td>Not counseled on any of these side effects</td>
<td>34 (31.2)</td>
</tr>
<tr>
<td><strong>IUD (N=52)</strong></td>
<td></td>
</tr>
<tr>
<td>Irregular bleeding</td>
<td>6 (11.5)</td>
</tr>
<tr>
<td>Increased bleeding</td>
<td>16 (30.8)</td>
</tr>
<tr>
<td>Not counseled on any of these side effects</td>
<td>26 (50.0)</td>
</tr>
</tbody>
</table>
Diversity and Disparities

• Clinician counseling can be biased
  • Often unconscious, but it’s there

• Providers may communicate differently depending on patient’s race/ethnicity

• Providers may treat patients differently based on socio-economic status (SES), race/ethnicity, age

Dehlendorf, 2014; Dehlendorf, 2010; Burgess, 2007
Diversity and Disparities

- Recognition of differences and biases can help to improve quality, equity
Adolescents and contraception

• A 16-year-old student who has never been pregnant presents to the clinic requesting birth control.
• She is healthy.
• She plans to become sexually active with her boyfriend in the near future.
• She is worried about getting pregnant.
• How would you counsel her?
WHO Guidance

• In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices.

• Age alone does not constitute a medical reason for denying any method to adolescents.

• While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents these concerns must be balanced against the advantages of avoiding pregnancy.
WHO Guidance

• Consider:
  • Social and behavioral context (example: STI risk)
  • Daily regimens more challenging than for adults
  • Sporadic patterns of sexual intercourse
  • Need to conceal (married vs. unmarried)

• Counseling is very important
## WHO MEC Recommendations

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>MEC Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined hormonal methods</td>
<td>1</td>
</tr>
<tr>
<td>Injectable</td>
<td>2</td>
</tr>
<tr>
<td>Progestin-only pill</td>
<td>1</td>
</tr>
<tr>
<td>Implant</td>
<td>1</td>
</tr>
<tr>
<td>IUD</td>
<td>2</td>
</tr>
<tr>
<td>Barrier</td>
<td>2</td>
</tr>
<tr>
<td>Emergency Contraceptive Pills</td>
<td>OK</td>
</tr>
</tbody>
</table>
LARC Continuation among adolescents

Adolescents, side effects, and the implant: “Wear dark underpants, mainly”

• In a study of adolescents discontinuing by 6 months, most experienced **significant and prolonged negative side effects**, which they were often unprepared for.

• Reported knowing side effects were possible, but they hoped they would not be affected.

• Wanted more specific examples of side effects rather than general descriptions

• Offered examples of how to counsel for irregular bleeding:

• “wear dark underwear, buy pads, think about how irregular bleeding will affect your relationship with your parents or others.”

Lunde, et al, 2017
Postpartum contraception
35% of women do not return for follow-up visit.

Ogburn et al. Contraception 2005
Importance of Birth Spacing

• Developing countries:
  • 40% do not obtain contraception within 1 yr.

• United States:
  • 12% are using no method and 7% low-efficacy method in 9 mos.

Ross & Winfrey 2001 IFPP
Conde-Agudelo et al 2000 BMJ
http://www.cdc.gov
MMWR Morb Mortal Wkly Rep, 2009
Fanello et al 2007 J Gynecol Ostet
Effect of Short Inter-pregnancy Intervals
Neonatal Outcomes

Odds Ratio at pregnancy intervals of <6 months vs. 18-23 months
N=1.2 million

Conde-Agudelo et al. Ob/Gyn 2005
Postpartum contraception: WHO MEC

Breastfeeding

**Combined methods**

- **Progestin only pills**
- **DMPA/NET-EN Implants**

• **<6 weeks**: 4
  - (or 2?)
  - 2
  - 1
  - 1
• **6 weeks to 6 months**: 3 (or 2?)
  - 1
  - 1
• **>6 months**: 2 (or 1)
  - 1
  - 1

Source: WHO MEC2015, CDC MEC 2016

**Same evidence, different conclusions? (example: injectables)**

**WHO MEC: Clarification:** There is theoretical concern about the potential exposure of the neonate to DMPA/NET-EN during the first 6 weeks postpartum. In many settings, however, pregnancy-related morbidity and mortality risks are high, and access to services is limited. In such settings, DMPA/NET-EN may be among the few methods widely available and accessible to breastfeeding women immediately postpartum.

**US CDC MEC: Evidence:** Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum.

Similar (or maybe lower quality) of evidence for combined methods and breastfeeding
Contraception and Breastfeeding: Implants

• Observational studies mostly found no difference in outcomes in the first 6 weeks postpartum.
• Two studies found no difference in supplementation comparing LNG implant with IUD users; one of these also found no difference in breastfeeding duration.
• Breastfeeding duration similar between users of an etonogestrel (ETG) implant compared with Cu-IUD.

Contraception and Breastfeeding: Injectables

- No effect or improved outcomes
- DMPA vs. nonhormonal method postpartum: no difference in breastfeeding frequency or continuation up to 6 months.
- One study found no differences in exclusive breastfeeding up to 6 months for those who did not initiate DMPA compared with those who initiated by 3 or 6 months.
- DMPA vs. other contraceptive methods
  - DMPA: more likely to be fully breastfeeding at 3 and 6 months postpartum
  - more likely to continue breastfeeding through 12 and 18 months. (67% vs 35%)

Postpartum IUD: Definitions

• Immediate post-placental/postpartum (IPP) IUD insertion: IUD insertion within 10 minutes of delivery of the placenta

• Early postpartum (EP) period: 10 minutes to 48 hours after delivery

• Interval (INT) IUD insertion: 4-8 weeks postpartum
Uterus, Immediately Postpartum
PP IUC: Techniques

Two techniques of postplacental IUD insertion and proper location of IUD after insertion

1. A) IUD strings placed in palm of hand
2. B) Manual insertion at top of fundus

Ring only with copper IUC - for LNG use inserter
## WHO Medical Eligibility for Contraceptive Use

<table>
<thead>
<tr>
<th>Postpartum*</th>
<th>LNG IUS</th>
<th>Copper IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 minutes after delivery of the placenta</td>
<td>1/2</td>
<td>1</td>
</tr>
<tr>
<td>10 minutes after delivery of the placenta to &lt;4 weeks</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>≥4 weeks</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Puerperal sepsis</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

*including post-Cesarean section

Why 10 minutes? Does timing matter?

Postpartum IUD Insertion

Adjusted Cumulative Expulsion Rates

- ≤10 mins: 9.5%
- 2–23 hrs: 31.5%
- 24–47 hrs: 37.3%
- 48–72 hrs: 28.8%

p<0.001 (≤10 minutes compared to all other groups)

## CDC Medical Eligibility for Contraceptive Use

<table>
<thead>
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<th>LNG IUS</th>
<th>Copper IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10 minutes after delivery of the placenta</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>10 minutes after delivery of the placenta to &lt;4 weeks</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>≥4 weeks</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Puerperal sepsis</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

*Breastfeeding or non-breastfeeding women, including post-Cesarean section

Cochrane Review 2010

- Nine trials
- No increase in infection, bleeding, or perforation
- Expulsion rates are higher for immediate versus delayed insertion
Immediate postpartum IUD and implant program outcomes: hot off the press

• Prospective study, 2013-16
• Copper IUD, LNG-IUS, Single-rod implant
• 6-month continuation rate >80% for all methods

• Of 211 IUD -→ 21 expelled
  • LNG-IUS: 17% expulsion
  • Copper IUD: 4% expulsion
  • Why the difference?
  • Does it matter?

Eggebroten, et al, AJOG, 2017
Vaginal rings: a longer-acting, short-acting method?

• Can be left in place for 3 weeks (or longer)
• Recent analysis suggests well tolerated, possibly with better bleeding profile than oral contraceptive pills
• Opportunities for better compliance →
  • Potential to be more effective in preventing pregnancy
  • In recent study, ring users about half as likely as pill users to have unintended pregnancy
  • 20% more likely to use consistently/correctly

Lopez-Picado, Eur J Contra Health Care, 2017
Bleeding/Spotting on Ring

Nestorone® / Ethinyl Estradiol CVR

NES Core

*Delivers NES, 13 cycles 3 weeks on followed by 1 week off

Developed by the Population Council
Sponsored by USAID, NICHD, WHO

NES / EE Core

8.4 mm (3/8”) in cross section
58 mm (2 1/4”) in diameter
Nestorone/Ethinyl Estradiol CVR (Contraceptive Vaginal Ring)

• Use for 1 year
  • In for 21 days, remove for 7
  • 13 Cycles of use
• Effective, safe
• 2 ¼ inches (~6cm) in diameter
• No refrigeration
• Woman-controlled
• 3-month ring under study
CVR: What did you like the most?

CVR: What did you dislike the most?

- Nothing
- Having to Remove
- Inserting
- Side effects
- Feeling it
- Partner complains

TFV/Levonorgestrel (LNG) IVR: Segmented Reservoir Design

- Builds on the TFV-only reservoir IVR design
- Segmented approach allows for independent optimization of each drug’s delivery needs
- LNG release rate is controlled by:
  - Rate-controlling membrane (thickness and diffusivity)
  - Length of the LNG segment
Most Contraceptives Not Linked to HIV Infection, but Depo-Provera May Raise Risk

Details  Category: HIV Prevention  Published on Wednesday, 10 August 2016 00:00  Written by Liz Highleyman

Birth control pills and some types of injectable and implanted contraceptives were not associated with an increased risk of HIV acquisition in an updated meta-analysis that included several recent studies, researchers reported in the August 5 online edition of AIDS. However, evidence continues to suggest that use of depot medroxyprogesterone acetate (DMPA or Depo-Provera) raises the likelihood of HIV infection. The World Health Organization (WHO) plans to meet soon to assess whether guidance needs to change in the light of the new findings.
Hormonal contraceptive eligibility for women at high risk of HIV

Guidance statement

Recommendations concerning the use of hormonal contraceptive methods by women at high risk of HIV
Background: rights-based approach

• Informed and free decision making
• Importance of contraceptive choice
• Risks of unintended pregnancy and HIV infection may be weighed differently by individual women
  • The woman should have a significant voice in the conversation

• “Based on current evidence, FP Programmes delivering services to women at high risk of HIV infection can continue to offer all methods of contraception.”
Hormonal contraception and HIV acquisition: WHO Guidance statement

• “The preponderance of data for oral contraceptive pills, injectable NET-EN, and levonorgestrel implants do not suggest an association with HIV acquisition, though data for implants are limited.

• “The new, higher quality studies on DMPA (or mixed injectables) had hazard ratios between 1.2 and 1.7,

• Although confounding cannot be excluded, new information increases concerns about DMPA and HIV acquisition risk in women.
  • But - If the association is causal, the magnitude of effect is likely hazard ratio 1.5 or less.

• Data for other hormonal contraceptive methods, including NET-EN, are largely reassuring.
  • Why DMPA?
The bottom line: women at high risk of HIV acquisition

<table>
<thead>
<tr>
<th>Condition</th>
<th>CATEGORY</th>
<th>Clarifications/evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I = initiation, C = continuation</td>
<td></td>
</tr>
<tr>
<td>POP</td>
<td>DMPA/NET-EN</td>
<td>LNG/ETG</td>
</tr>
<tr>
<td>High risk of HIV</td>
<td>1</td>
<td>2</td>
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<tr>
<td>POP</td>
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<td>1</td>
</tr>
</tbody>
</table>

**CLARIFICATION:** There continues to be evidence of a possible increased risk of acquiring HIV among progestogen-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestogen-only injectables are among the few types of methods widely available. Women should not be denied the use of progestogen-only injectables because of concerns about the possible increased risk. Women considering progestogen-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV.

**EVIDENCE:** Evidence from 13 observational studies of DMPA, NET-EN or non-specified progestogen-only injectables, which were considered to be "informative but with important limitations" (4), continues to show some association between use of progestogen-only injectables and risk of HIV acquisition, but it remains unclear whether this results from a causal relationship or methodological limitations. Two small studies assessing levonorgestrel implants, which were considered to be "informative but with important limitations" (4), did not suggest an elevated risk, although the risk estimates were imprecise. One study reported no association between use of progestogen-only pills and HIV acquisition (4).

POP = progestogen-only pill; DMPA = depot medroxyprogesterone acetate (injectable); NET-EN = norethisterone enanthate (injectable); LNG/ETG = levonorgestrel and etonogestrel (implants).
Why Category 2?

• “Advantages generally outweigh theoretical or proven risks.”
• 13 observational studies are “informative but with important limitations”:
  • Low-to-moderate quality
• Incorporate women’s preferences and values
• Support informed consent and a wide range of available options
Thank you!.... & discussion