WHO’s Evidence-Based Guidelines for Family Planning

POSTGRADUATE TRAINING IN REPRODUCTIVE HEALTH

Mary Lyn Gaffield, PhD
What option would you prefer?

Faith Versus Facts

WE HAVE TWO OPTIONS. EITHER AN EVIDENCE-BASED TREATMENT OR AN EXCITING, RISKY ALTERNATIVE.
The Four Cornerstones of evidence-based guidance

- Medical Eligibility Criteria for Contraceptive Use
- Selected Practice Recommendations for Contraceptive Use
- Guidelines for policy-makers and programme managers
- Tools for health-care providers
- Decision-Making Tool for Family Planning Clients and Providers
- Handbook for Family Planning Providers

World Health Organization, Geneva
Reproductive Health and Research
Information and Knowledge for Optimal Health for Family Planning Clients and Providers
Why are the Four Cornerstones needed?

- To base family planning practices on the best available evidence
- To set global standards of care
- To improve quality of care
The evidence-based guidelines

**Who** can use contraceptive methods

**How to use** contraceptive methods
Medical Eligibility Criteria for Contraceptive Use

- Addresses large gap in family planning guidance for women with medical problems or other special conditions
- Gives over 1700 recommendations on who can use contraceptive methods
Methods of contraception

- Combined oral contraceptives
- Combined hormonal contraceptives (1 month injectables, patch, vaginal ring)
- Progestogen-only contraceptives (pills, implants, 2-3 month injectables)
- Emergency contraceptive pills
- IUDs (copper bearing and levonorgestrel)
- Emergency IUD
- Barrier methods (condoms, spermicides & diaphragm)
- Fertility awareness-based methods
- Lactational amenorrhoea (LAM)
- Coitus Interruptus
- Sterilization (male and female)
Selected Practice Recommendations for Contraceptive Use

- Standardizes guidance for the delivery of contraceptive services
- 33 selected questions on how to use contraceptive methods
Medical Eligibility Criteria for Contraceptive Use

Third edition, 2004

A WHO FAMILY PLANNING CORNERSTONE
Identification of conditions

- Conditions represent either:
  - an individual’s characteristics (e.g., age, parity) or
  - a known pre-existing medical condition (e.g., hypertension)

- Identify based on national/local screening practice, according to public health importance

- Client history often most appropriate approach
Condition Classification Categories

1. No restriction for the use of the contraceptive method
2. The advantages of using the method generally outweigh the theoretical or proven risks
3. The theoretical or proven risks usually outweigh the advantages of using the method
4. An unacceptable health risk if the contraceptive method is used
# Simplified Classification of Conditions

<table>
<thead>
<tr>
<th>Classification</th>
<th>With Clinical Judgement</th>
<th>With Limited Clinical Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use method in any circumstance</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Generally use the method</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Use of the method not usually recommended unless other more appropriate methods are not available or not acceptable</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>Method not to be used</td>
<td>No</td>
</tr>
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</table>
### Medical Eligibility Criteria
#### Smoking and Contraceptive Use

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>COC</th>
<th>CIC</th>
<th>POP</th>
<th>NET-EN</th>
<th>DMPA</th>
<th>NOR</th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
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<tr>
<td><strong>SMOKING</strong></td>
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<tr>
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<td>(i) &lt;15 cigarettes/day</td>
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<td>1</td>
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<tr>
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</table>
Case scenario 1

An 36 year old woman with three children comes to the health centre requesting oral contraceptives. She tells you she smokes 10 cigarettes per day.

A) Are oral contraceptives medically appropriate for her?

B) Does she have any other highly effective temporary contraceptive options?
Case scenario 1: the answer

A) Oral contraceptives are usually not appropriate for women who smoke over 35 unless other methods are not available or acceptable.

Women over 35 who smoke more than 15 cigarettes per day or more should not use combined oral contraceptives.

B) This client is medically eligible to use combined injectables, progestogen-only contraceptives, and IUDs.
Case Scenario 2

A 25 year old woman has just given birth and plans to breastfeed. She would like an injection for contraception prior to returning home. Which of the following options is medically appropriate?

A) A combined injectable contraceptive provided immediately

B) A combined injectable contraceptive provided at six weeks postpartum

C) A progestogen-only injectable contraceptive provided immediately

D) A progestogen-only injectable contraceptive provided at 6 weeks postpartum
Case scenario 2: the answer

D) A progestogen-only injectable contraceptive provided at 6 weeks postpartum.

Comment

• Combined injectables are not medically appropriate in breastfeeding women prior to 6 weeks postpartum, and generally should not be used until after 6 months postpartum.

• Progestogen-only injectables are medically appropriate in breastfeeding women at 6 weeks postpartum.

• Neonate may be at risk of exposure to steroid hormones during the first six weeks postpartum.
Global impact of the Medical Eligibility Criteria

- Translated into 11 languages
- Impact on guidelines in over 50 countries
- Integrated into popular texts
Selected Practice Recommendations for Contraceptive Use
33 questions on contraceptive use

- When to start
- When to re-administer
- How to manage problems
  - Missed pills
  - Bleeding (progestogen-only methods and IUDs)
  - Prophylactic antibiotics and IUD insertion
- What exams or tests should be done routinely
- Follow-up
- How to be reasonably sure a woman is not pregnant
Selected Practice Recommendations

For each question:

• **Working Group’s recommendations for key situations**
• **Comments by the Working Group**
• **Key unresolved issues**
• **Information about the evidence**
  – Literature search question
  – Level of evidence
  – References identified by systematic review
When can a woman start COCs?

**Having menstrual cycles**

- She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She can also start COCs at any other time, if it is reasonably certain that she is not pregnant. If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.
When can a woman start COCs?

Working Group comments:

• Risk of ovulation within the first 5 days of the cycle is low.

• Suppression of ovulation was less reliable when starting COCs after day 5.

• 7 days of continuous COC use was necessary to reliably prevent ovulation.
When can a woman start COCs?

Key unresolved issues
• Does starting each pill pack on a specific day of the week increase correct COC use?

Evidence
• Level II-1, fair
• Indirect
Routine exams or tests

**Class A** = essential and mandatory in all circumstances for safe and effective use of the method

**Class B** = contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context.

**Class C** = does not contribute substantially to safe and effective use of the method
## Routine exams or tests

<table>
<thead>
<tr>
<th>Exam or screening</th>
<th>Hormonal methods</th>
<th>IUD</th>
<th>Condoms / Spermicide</th>
<th>Female sterilization</th>
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<tr>
<td>Breast exam</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Pelvic exam</td>
<td>C</td>
<td>A</td>
<td>C</td>
<td>A</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>Routine lab tests</td>
<td>C</td>
<td>C</td>
<td>C</td>
<td>C</td>
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<tr>
<td>Haemoglobin</td>
<td>C</td>
<td>B</td>
<td>C</td>
<td>B</td>
</tr>
<tr>
<td>STI risk assessment</td>
<td>C</td>
<td>A</td>
<td>C*</td>
<td>C</td>
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<tr>
<td>STI screening</td>
<td>C</td>
<td>B</td>
<td>C*</td>
<td>C</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>**</td>
<td>C</td>
<td>C</td>
<td>A</td>
</tr>
</tbody>
</table>

**Class A:** essential and mandatory in all circumstances

**Class B:** contributes substantially to safe and effective use

**Class C:** does not contribute substantially to safe and effective use
How to be reasonably sure a woman is not pregnant

No signs and symptoms of pregnancy AND Meets any of the following criteria:

- No intercourse since last normal menses
- Correctly and consistently using reliable method of contraception
- Within the first 7 days after normal menses
- Within 4 weeks postpartum for non-lactating women
- Within 7 days post-abortion or post-miscarriage
- Fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum
Case Scenario 1

A woman comes to the clinic requesting combined oral contraceptives on day 7 of her menstrual cycle. She has not had sexual intercourse since the first day of her menstrual period.

Which of the following is medically appropriate?

A) advise her to return to clinic on the first day of her next menstrual period.

B) provide her with pills and tell her that she can start now without any further precautions.

C) provide her with pills and tell her that she can start now, but should abstain from sex or use additional contraceptive protection for the next 7 days.
Case Scenario 1: the answer

C) provide her with pills and tell her that she can start now, but should abstain from sex or use additional contraceptive protection for the next 7 days.

Suppression of ovulation was considered to be less reliable when starting after day 5 or during amenorrhoea, seven days of continuous COC use was deemed necessary to reliably prevent ovulation.
Keeping the guidance up-to-date

Guidelines for policy-makers and programme managers

System for keeping the guidance up-to-date

Tools for healthcare providers
Keeping up with the evidence...
Guidance based on evidence

- Adherence to WHO ‘Guidelines for Guidelines’

- Systematic reviews of evidence

- Continuous monitoring of new evidence through the Continuous Identification of Research Evidence (CIRE System)

- Citations of evidence used for decision-making
Step 1: Identify new evidence pertaining to contraceptive safety and efficacy

Step 2: Post records on CIRE database

Step 3: Screen for relevance to MEC and SPR
Step 4: Update existing or conduct new systematic review

Step 5: Send for peer review

Step 6: Evaluate the need to update guidance in MEC/SPR
SYSTEMATIC REVIEW

SR Number: 11
SR Status: Complete
SR Document: SPR 1 Start COCs.pdf
SR Actions: Retrieve/Update

Article Information

**Article Question:** 1. When can a woman start combined oral contraceptives (COCs)?

**Bleeding patterns after immediate vs. conventional oral contraceptive initiation: a randomized, controlled trial.**
*Fertility and Sterility, 2003 Feb;79(2):322-329*

- **Authors:** Westhoff C, Morroni C, Kerns J, and Murphy PA
- **Doc Number:** M175100
- **Article Number:** 1038
- **Language:** English
- **Status:** Complete

**Does anovulation induced by oral contraceptives favor pregnancy during the following two menstrual cycles?**
*Fertility and Sterility, 2000 Apr;73(4):742-7*

- **Authors:** Fukuda M, Fukuda K, Andersen CY, and Syskow AG
- **Doc Number:** M142062
- **Article Number:** 1617
- **Language:** English
- **Status:** Complete

**Quick Start: a novel oral contraceptive initiation method.**
*Contraception, 2002 Sep;66(3):141-145*

- **Authors:** Westhoff C, Kerns J, Morroni C, Cushman LF, and Nezzi L
- **Doc Number:** M172177
- **Article Number:** 431
- **Language:** English
- **Status:** Complete

**Predicting risk of ovulation in new start oral contraceptive users.**
*Obstetrics and Gynecology, 2002 Feb;99(2):177-82*

- **Authors:** Schwartz JL, Greinich MD, Pymar HC, and Reid L
- **Doc Number:** M164610
- **Article Number:** 45
- **Language:** English
- **Status:** Complete
Evaluating the need to update the guidance

If consistent with current guidance or not urgent:

Review at next Expert Working Group Meeting

If inconsistent and urgent:

Consult Guideline Steering Group and post guidance updates on web
Reviewer Information

Consensus Information

Update Status:
- In Progress
- Sent
- Responses Received
- Complete

Disposition:
- Current recommendation consistent with evidence.

Selected Peer Reviewer Information:

<table>
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<tr>
<th>Reviewer Info</th>
<th>Date Sent</th>
<th>Status</th>
<th>See Review</th>
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<td>CDC Appendix Box</td>
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<tr>
<td>Dr. Polly Marchbanks, PhD</td>
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<tr>
<td>Dr. Bart Peterson (SSR), M.D.</td>
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<td>Dr. Kate Curtis</td>
<td>Oct 08, 2004</td>
<td>Sent</td>
<td>View / Modify</td>
<td>Oct 06, 2004</td>
<td>Oct 27, 2004</td>
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</table>

Article Notes:

Peer Reviewers Summary:

- CDC: No, Poor
- Reviewer 1: Yes. No statistical difference between the Sunday Start and Quick Start groups for side effects; suggestion of better compliance / continuation amongst QS group (especially since there was a selection bias against compliance in the QS group.)

[Buttons: Update Info, Print Consensus]
Welcome to CIRE - the Continuous Identification of Research Evidence - a collaborative effort of the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs (CCP).

To ensure that its evidence-based family planning guidance remains current, the WHO collaborates on the CIRE system with the WHO Collaborating Centre in Reproductive Health at the CDC and the INFO Project at CCP. The system is supported by the United States Agency for International Development (USAID) and the National Institute of Child Health & Human Development (NICHD).

The CIRE system facilitates the updating of WHO's evidence-based family planning guidance. The system identifies articles whose study objectives concern a topic addressed by WHO's Medical Eligibility Criteria for Contraceptive Use (MEC) or the Selected Practice Recommendations for Contraceptive Use (SPR). Identification begins with screening of new articles entered into the PPOLINE database since January 2002. These articles are then reviewed to determine whether the evidence they provide is relevant to WHO guidance. Any updates to current guidance based on evidence from the CIRE system will be noted on the electronic versions of the MEC or SPR. Changes to classifications of the MEC or recommendations in the SPR will ordinarily be made only following expert working group meetings.

The new articles that have been identified to date are accessible by searching the CIRE system and are also available through a regular email bulletin.

- Send this email to receive regular CIRE system postings from the email bulletin.

WHO's online versions of the MEC and the SPR also feature the availability of new articles identified by the CIRE system. In addition, new postings to the CIRE system will be featured in CCP's weekly e-zine, The Pop Reporter. You may visit PPOLINE for more information on obtaining full-text articles from CCP or view the WHO Family Planning Page for more information about family planning guidance.
Family Planning

Guidance updates

To ensure that its evidence-based family planning guidance remains current, the WHO collaborates on the CIRE system (Continuous Identification of Relevant Evidence) with the WHO Collaborating Centre in Reproductive Health at the CDC and the INFO Project at CCP. In this way, WHO monitors the publication of new research evidence that may affect the recommendations contained in the Medical Eligibility Criteria for Contraceptive Use.

Since the latest publications of the Medical Eligibility Criteria in 2004, and the Selected Practice Recommendations in 2005, new evidence or new recommendations by other WHO bodies have been identified to warrant comments on or changes to the original guidelines. The new updates are shown below.

New information is available on the following:

- WHO Statement on hormonal contraception and risk of STI acquisition (July 2005)
- WHO Statement on hormonal contraception and bone health (July 2005)

The CIRE system identifies articles whose study objectives concern a topic addressed by WHO’s Medical Eligibility Criteria for Contraceptive Use (MEC) or the Selected Practice Recommendations for Contraceptive Use (SPR). Identification begins with screening of new articles entered into the POPLINE database since January 2002. These articles are then reviewed to determine whether the evidence they provide is relevant to WHO guidance. Any updates to current guidance based on evidence from the CIRE system will be noted on the electronic versions of the MEC or SPR. Changes to classifications of the MEC or recommendations in the SPR will ordinarily be made only following expert working group meetings.

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Family Planning

Unmet needs
There are still some 123 million women around the world, mostly in developing countries, who are not using contraception in spite of an expressed desire to space or limit the numbers of their births.

An estimated 30% of all pregnancies occurring around the world every year are unintended, and around 6 out of 10 such unplanned pregnancies result in an induced abortion.

A woman’s ability to space or limit the number of her pregnancies has a direct impact on her health and well-being as well as the outcome of her pregnancy. In enabling women to exercise their reproductive rights, family planning programmes can also improve the social and economic circumstances of women and their families.

WHO’s role in promoting FP
The reasons why family planning needs are often not met are varied, but include: poor access to quality services, a limited choice of methods, lack of information, concerns about safety or side-effects and partner disapproval.

WHO is currently addressing some of these needs in working to help
- improve the safety and effectiveness of contraceptives methods;
- widen the range of family planning methods available to women and men.

Progress newsletter
Issue 68 (June 2003)
Contraceptive methods—better information for a wider choice
Who is eligible to use the different types of contraceptives?
Safe and effective use of contraceptives
Some recommendations for the use of oral contraceptives
Some recommendations for the use of emergency contraception
Some recommendations for the use of levonorgestrel releasing intrauterine devices (LNG IUDs)

How to be reasonably certain a woman is not pregnant
6 pages (PDF 205 KB)
Family Planning

Unmet needs

There are still some 123 million women around the world, mostly in developing countries, who are not using contraception in spite of an expressed desire to space or limit the numbers of their births. ¹

An estimated 36% of all pregnancies occurring around the world every year are unintended, and around 6 out of 10 such unplanned pregnancies result in an induced abortion. ²

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WHO is currently addressing some of these needs in working to help

- improve the safety and effectiveness of contraceptives methods;
- widen the range of family planning methods available to women and men;
- improve the quality of family planning service delivery.
Tools for health care providers

Decision-Making Tool for Family Planning Clients and Providers

Handbook for Family Planning Providers
Decision-making Tool for Family Planning Clients and Providers

- A tool for primary and secondary level FP providers and their clients
- Facilitates the interaction between the client and the provider
- Promotes informed choice of a contraceptive method
- Adaptable to local contexts
You can find a method right for you

We can discuss:
- Your needs & concerns
- Your partner’s or family’s attitudes
- HIV / AIDS, other sexually transmitted infections (STIs)
- How methods are used
- Want more children?
- Experiences with family planning

Let’s talk about your situation.

Decision-Making Tool for Clients...

...and Providers

1. Encourage client to tell own story. You can ask, “What leads you to seek family planning?”
- Note other health and social needs for help or referral.

2. Raise issues at left if client does not discuss them.
- If client is unsure of HIV/AIDS/STI risk or story suggests STI risk, go to dual protection tab now.

3. Ask questions to see if method suits client’s personal circumstances. For example: “Are you the kind of person who can remember to take a pill each day?” (Asking questions enables client to agree or explain.)
- Continue discussing until method needs are clear to both you and the client.

Next Move:
1. Once client expresses needs, summarize (for example, “long-acting, very effective, reversible”).
2. “Now let’s talk about which methods offer this.” Go to next page.

You can find a method right for you

We can discuss:
- Your needs & concerns
- Your partner’s or family’s attitudes
- HIV / AIDS, other sexually transmitted infections (STIs)
- How methods are used
- Want more children?
- Experiences with family planning

No method in mind

Go to next page.
Best Practices in Client-Provider Interaction

Do you have a method in mind?

If you do, let’s talk about how well it suits your needs
- What have you heard about it?
- What do you like about it?

If not, we can find a method right for you

Important for choosing a method:
Do you need protection from pregnancy AND sexually transmitted infections?
Evidence-Based Technical Information

If you miss pills:

ALWAYS:

1. Take a pill as soon as you remember
2. Take the next pill at the usual time
3. Continue to take your pill as usual, one each day

4. If you miss 2 or more pills, or start pack 2 or more days late, you ALSO need to:
   - USE BACK-UP: Avoid sex or use condoms for 7 days
   - SKIP WEEK 4: (inactive pills or pill-free week) and go straight to next pack
   - AND

Special rule for Inactive Pills
(28 day packs only!)

THROW AWAY pills that were missed, and keep taking pills as usual

Inactive Pills

Inactive Pills
The Handbook for Family Planning Providers
The Handbook for Family Planning Providers

- A reference guide/tool for providers
- To contain all WHO FP guidance
- Publication expected in 2007
- Being produced in partnership with the creators of ‘The Essentials of Contraceptive Technology’ (JHU/CCP)
### FHI's Quick Reference Chart

**for the Medical Eligibility Criteria of the WHO**

**to initiate the use of**
- Combined Oral Contraceptives (COC), Noristerat (NET-EN), Depo-Provera (DMPA), Copper Intrauterine Devices (Cu-IUD)

<table>
<thead>
<tr>
<th>Age</th>
<th>COC</th>
<th>NET-EN/DMPA</th>
<th>Cu-IUD</th>
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<tbody>
<tr>
<td>Menarche to 20 years</td>
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<td>40 years or more</td>
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<td>Menarche to 17 years</td>
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<td>Less than 20 years</td>
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<tr>
<td>20 years or more</td>
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<tr>
<td>Nulliparous</td>
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<tr>
<td>Breastfeeding</td>
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<tr>
<td>Less than 6 weeks postpartum</td>
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<tr>
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<tr>
<td>Age ≥ 35 years, &lt; 15 cigarettes/day</td>
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<tr>
<td>Age ≥ 35 years, ≥ 15 cigarettes/day</td>
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<td>Hypertension</td>
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<tr>
<td>History of hypertension where blood pressure CANNOT be evaluated</td>
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<tr>
<td>Systolic 140 - 159 or Diastolic 90 - 99</td>
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<td>Systolic ≥ 160 or Diastolic ≥ 100</td>
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<tr>
<td>Headaches</td>
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<tr>
<td>Non-migrainous, Mild or severe</td>
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<td></td>
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<tr>
<td>Migraine without focal neurologic symptoms</td>
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<tr>
<td>Age &lt; 35 years</td>
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<td></td>
<td></td>
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<tr>
<td>Age ≥ 35 years</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Migraine with focal neurologic symptoms</td>
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<tr>
<td>History of deep venous thrombosis</td>
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<tr>
<td>Superficial thrombophlebitis</td>
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<tr>
<td>Complicated vascular heart disease</td>
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<tr>
<td>Ischemic heart disease / stroke</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Non-vascular disease</td>
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<td>Vascular disease or diabetes of &gt; 20 years</td>
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**Known hyperlipidemias**
- Cancers: Cervical, Endometrial, Ovarian
- Breast disease: Undiagnosed mass, Family history of cancer, Current cancer
- Cirrhosis: Mild, Severe
- Endometriosis
- Trophoblastic disease
- Vaginal bleeding patterns: Irregular without heavy bleeding, Heavy or prolonged, regular and irregular, Unexplained bleeding
- Hepatitis: Active, Related to the pregnancy, Related to oral contraceptives

**Category 1**: There are no restrictions for use.
**Category 2**: Generally use.
**Category 3**: Usually not recommended; clinical judgment and access to clinical services are required for use.
**Category 4**: The method should not be used.

*Postpartum IUD use by breastfeeding and non-breastfeeding women is Category 2 up to 48 hours postpartum, Category 3 from 48 hours to four weeks, and Category 1 four weeks and after.

The Medical Eligibility Criteria Wheel

- A new tool for providers
- An easy to use job aid
- Helps providers quickly identify Medical Eligibility Criteria relevant to their clients
- IN PRESS
Reproductive Choices and Family Planning For People with HIV

- Two-day training and job aid – an adaptation of the Decision-Making Tool for Family Planning Clients and Providers
- Developed as part of Integrated Management of Adolescent and Adult Illness (IMAI) series
- Field tested in Uganda and Lesotho
- Completed and printed in late 2006
- Developed in collaboration with the INFO Project at Johns Hopkins Bloomberg School of Public Health