WHO's evidence-based guidelines for family planning

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Training Course in Sexual and Reproductive Health Research
Geneva, February 2009
What option would you prefer?

WE HAVE TWO OPTIONS. EITHER AN EVIDENCE-BASED TREATMENT OR AN EXCITING, RISKY ALTERNATIVE.
The Four Cornerstones of Evidence-Based Guidance for Family Planning

1. Medical Eligibility Criteria for Contraceptive Use
2. Selected Practice Recommendations for Contraceptive Use
3. Decision-Making Tool for Family Planning Clients and Providers

Guidance for guides
Guidance for providers and clients
System for keeping the guidance up-to-date
Medical eligibility criteria for contraceptive use

Purpose:

Who can safely use contraceptive methods?

- Provides 1800+ recommendations
- 4th edition being finalized, will be published on WHO website and bound copies.
- Layout and design will address suggestions from the field.
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)
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
Classification of recommendations

- Divided into four categories:
  - 1 = a condition for which there is no restriction for the use of the contraceptive method,
  - 2 = a condition where the advantages of using the method generally outweigh the theoretical or proven risks,
  - 3 = a condition where the theoretical or proven risks usually outweigh the advantages of using the method,
  - 4 = a condition which represents an unacceptable health risk if the contraceptive method is used

- Four categories can be simplified where resources for clinical judgement are limited:
  - Woman *is* medically eligible to use the method (categories 1 & 2)
  - Woman *is not* medically eligible to use the method (categories 3 & 4)
Medical Eligibility Criteria
Smoking and Contraceptive Use

<table>
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<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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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 12 languages, six available on WHO website
- Impact on guidelines in over 50 countries
- Integrated into popular texts
- 40,000+ copies disseminated
4th edition of the *Medical eligibility criteria for contraceptive use*

- 86 new and 165 updated recommendations
- New medical condition – Systemic Lupus Erythematosus
- 12 new sub-conditions within currently existing medical conditions:
  - obesity and <18 years of age; deep venous thrombosis/pulmonary embolism (DVT/PE) and established on anticoagulant therapy; acute or flare for viral hepatitis; focal nodular hyperplasia of the liver; three classes of antiretroviral therapies; Lamotrigine (an anticonvulsant); and four classes of antimicrobials (broad-spectrum antibiotics, antifungals, antiparasitics, and rifabutin with rifampicin)
Briefly summarizes 86 new and 165 updated recommendations across 11 contraceptive methods.

Describes recommendation changes for female sterilization and barrier methods.

Highlights newly defined medical conditions.

Available on WHO website (http://www.who.int/reproductive-health/family_planning/updates.htm)

Changes will appear in revised, 4th edition of guidance; preparation underway.
New recommendations – Systemic Lupus Erythematosus (SLE)

- Divided into four sub-conditions
  - Positive (or unknown) antiphospholipid antibodies
  - Severe thrombocytopenia
  - Immunosuppressive treatment
  - None of the above

- When using these sub-conditions of SLE, it is assumed that no other risk factors for cardiovascular disease are present, otherwise categories must be modified in the presence of such risk factors.

- For severe thrombocytopenia, due to the increased risk of bleeding, assess the severity of the condition and its clinical manifestations. If thrombocytopenia is very severe, consultation with a specialist and pre-treatment may be warranted.
## Systemic Lupus Erythematosus (SLE) recommendations

<table>
<thead>
<tr>
<th></th>
<th>COC, Patch, Ring</th>
<th>CIC</th>
<th>POP</th>
<th>DMPA, NET-EN</th>
<th>LNG, ETG Implants</th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
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<td>3</td>
<td>I=1, C=1</td>
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<td>2</td>
<td>2</td>
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<tr>
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<td>I=2, C=2</td>
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<td>I=1, C=1</td>
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</table>

I = initiation of the method, C = continuation of the method
New recommendations - viral hepatitis

- Divided into three sub-conditions
  - Acute or flare
  - Carrier
  - Chronic

- Women who are carriers or have chronic disease are eligible to use any hormonal method or intrauterine device (category 1)

- Women with acute disease or a disease flare
  - Eligible to use any progestogen-only method or any intrauterine device (category 1)
  - For combined methods (COC, P, R, CIC)
    - Initiation – the theoretical or proven risks usually outweighs the advantages of using these methods (category 3)
      - If the condition is severe, use of COC, P, R, or CIC becomes a category 4
    - Continuation - the advantages of these methods generally outweighs the theoretical or proven risks (category 2)
New recommendations – liver tumours

- Divided into three sub-conditions
  - Benign
    - Focal nodular hyperplasia
    - Hepatocellular adenoma
  - Malignant (hepatoma)

- Women with focal nodular hyperplasia can use copper-bearing IUDs (category 1) and are generally eligible to use any hormonal method (category 2)

- For the hepatocellular adenoma or malignant tumour conditions,
  - Not eligible to use COCs, patch, or the ring (category 4)
  - CICs or progestogen-only methods (including LNG-IUD) are not recommended (category 3)
    - If malignant hepatoma is severe, use of CICs becomes a category 4
  - Can use copper-bearing IUDs (category 1)
Unchanged recommendations - age

- Expert Working Group (April 2008) re-evaluated the body of evidence
  - Recommendations should remain the same for progestogen-only and combined hormonal contraceptive methods.
  - There should be no restriction on the use of DMPA, including no restriction on duration of use, among women aged 18 to 45 who are otherwise eligible to use the method.
  - Among adolescents (menarche to <18) and women over 45, the advantages of using DMPA generally outweigh the theoretical safety concerns regarding fracture risk. Since data are insufficient to determine if this is the case with long-term use among these age groups, the overall risks and benefits for continuing use of the method should be reconsidered over time with the individual user.
Materials derived from the guidelines
The MEC wheel

• Published in 2007

• A job aid, developed in collaboration with John Hopkins University, Communication Partnership for Family Health (Jordan), and University of Ghana Medical School.

• Available in English, French. Arabic translation underway.

• Available in Chinese, Mongolian, Myanmar, Pacific Island Countries.
Other materials derived from the guidelines

Developed by Johns Hopkins University
WHO statement and provider briefs
Selected practice recommendations for contraceptive use

Purpose:

How to use contraceptive methods

33 selected practice questions


Updated recommendations published on the web
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.
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>
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<th>Exam or screening</th>
<th>Hormonal methods</th>
<th>IUD</th>
<th>Condoms / Spermicide</th>
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<td>C</td>
<td>C</td>
<td>A</td>
</tr>
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</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, amenorrhoetic, 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.
Selected practice recommendations for contraceptive use – 2008 update

- Briefly summarizes changes for five recommendations (questions 6, 9, 11, 18, 22) and clarifies wording for question 17.

- Can be inserted into current 2nd edition.

- 2nd edition should be consulted for complete wording of each recommendation.

- Available on WHO website (http://www.who.int/reproductive-health/family_planning/updates.htm)

- Changes will appear in revised, 3rd edition of guidance; preparation underway.
2008 update – recommendation changes

- Grace period for repeat injection of DMPA extended to 4 weeks (question #6)
  - Repeat DMPA injections can be given up to 4 weeks late for women who are late for their repeat injection
  - Repeat NET-EN injections can be given up to 2 weeks late for women who are late for their repeat injection.

- Postpartum IUD insertion timing clarified (questions #9 and #11)
  - No restrictions on copper-bearing or levonorgestrel-releasing IUD insertion up to 48 hours after delivery
  - Applies to vaginal and caesarean delivery, and for breastfeeding and non-breastfeeding women

- 75 µg desogestrel-containing pills added to comments for missed progestogen-only pills (question #18)
  - The existing guidance applies when one or more pills have been missed by more than 12 hours for women taking 75 µg desogestrel-containing pills.
2008 update – recommendation changes

- Expanded treatment options for women with bleeding or spotting while using progestogen-only injectables (question #22)
  - Two nonsteroidal anti-inflammatory drugs, mefenamic acid and valdecoxib, were added to the currently available recommendation for women experiencing either spotting or light bleeding, or heavy and prolonged bleeding

- Clarification of recommendation related to missed combined oral contraceptive pills (question #17)
  - The wording of the recommendation was changed to state that where recommendation text refers to 'missed active pills', it is meant that these pills are missed on *consecutive* days, i.e., 1 or 2 days *in a row*, or 3 or more days *in a row*. 
Guidance based on evidence and kept up-to-date

- Monitoring all new evidence
- Systematic review on selected issues
- Expert Working Groups
- Electronic Updates
  - www.who.int/reproductive-health/family_planning
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
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 PPOPLINE 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 on-line 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 PPOPLINE for more information on obtaining full-text articles from CCP or view the WHO Family Planning Page for more information about family planning guidance.

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**Search Evidence**

**Medical Eligibility Criteria (MEC):**

Choose a Method: [ ] AND/OR [ ] Choose a Condition [ ] Search
Consensus Information

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

Disposition:
Current recommendation consistent with evidence.

Selected Peer Reviewer Information:

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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.)

Update Info  Print Consensus
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
Family Planning

Guidance updates

To ensure that its evidence-based family planning guidance remains current, the WHO collaborates on the CIRE system (Continuous Identification and Recognition of 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)

Statement (PDF - 31 KB)

This statement does not affect current guidance.

WHO Statement on hormonal contraception and bone health  
(July 2005)

Statement (PDF - 2 pages - 103 KB)

This statement does not affect current guidance.

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 PLOLINE 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. The system is supported by the United States Agency for International Development (USAID) and the National Institute of Child Health & Human Development (NICHD).
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 38% 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
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 2005)
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
8 pages (PDF 285 KB)
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

World Health Organization

RHR Department of Reproductive Health and Research
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.

...and Providers

1. Encourage client to tell own story. You can ask, “What needs you to see family planning?”
2. Ask follow-up questions.
3. Note other health and social needs for help or referral.
4. HIV / AIDS, other sexually transmitted infections (STIs)
5. How methods are used
6. Want more children?
7. Experiences with family planning

No method in mind

You can find a method right for you

1. Raise issues at let if client does not discuss them.
2. 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?”
4. 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.
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?
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

**If you miss 2 or more pills, or start pack 2 or more days late, you ALSO need to:**

4. USE BACK-UP: Avoid sex or use condoms for 7 days
   AND
   - SKIP WEEK 4: (inactive pills or pill-free week) and go straight to next pack
   - **Special rule for Inactive Pills (28 day packs only!):**
     - THROW AWAY pills that were missed, and keep taking pills as usual

**Inactive Pills**

THROW AWAY pills that were missed, and keep taking pills as usual
Family Planning: A Global Handbook for Providers

- Launched in October 2007
- Over 100,000 copies distributed
- Printed in English, French, and Spanish
- Translations underway in Arabic, Chinese, Farsi, Hindi, Lithuanian, Portuguese, Romanian, Russian, Swahili, Urdu
- Accompanying curriculum under development
- Endorsed by close to 50 organizations
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

- Developed in collaboration with the INFO Project at Johns Hopkins Bloomberg School of Public Health

- First edition published in 2006 and available on WHO website
Adaptation of Reproductive Health (RH) guidelines

- Generic adaptation guideline for all RH Guidelines and Tools
- Published in 2007
- Available from WHO website or publication centre
For more information

- Contact: reproductivehealth@who.int