World Health Organization Updates Guidance on How To Use Contraceptives

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KEY POINTS

The World Health Organization (WHO) issued new guidance in 2004 on how to use certain contraceptives safely and effectively, including the following:

- **A woman who misses combined oral contraceptive pills should take a hormonal pill as soon as possible and then continue taking one pill each day.** This basic guidance applies no matter how many hormonal pills a woman misses. Only if a woman misses three or more hormonal pills in a row will she need to take additional steps (see p. 3). The new guidance simplifies the missed-pill rules issued by WHO in 2002.

- **Men should wait three months after a vasectomy procedure before relying on it.** Previous guidelines advised men to wait either three months after the procedure or until they had had at least 20 ejaculations, whichever occurred first. Recent studies have shown, however, that the 20-ejaculation criterion is not a reliable gauge of vasectomy effectiveness. A three-month waiting period is more reliable (see p. 4).

- ***Norplant*® implants can remain in place for up to seven years in women weighing less than 70 kg.** Regulatory agencies generally have approved *Norplant* implants for a maximum of five years of use. Recent evidence shows that the implants remain effective for seven years for most women. Heavier women may need to have them removed after four or five years (see p. 5).

- **Emergency contraceptive pills (ECPs) should be taken as soon as possible after unprotected sex but can be taken up to 120 hours later.** WHO recommends that a woman take ECPs as soon as possible after having unprotected sex—ideally within 72 hours. Taking them even as late as 120 hours after unprotected sex can help prevent pregnancy. The longer a woman waits to take ECPs, however, the less likely they are to be effective (see p. 5).

- **A single dose of levonorgestrel alone is the best regimen for emergency contraception.** WHO recommends three options for ECP regimens. The preferred regimen is 1.5 mg of levonorgestrel in a single dose. This regimen is best both because people tend to prefer and comply with single-dose regimens and because the levonorgestrel-only option has fewer side effects than the combined estrogen-levonorgestrel option. Two other regimens are acceptable alternatives if the single dose of levonorgestrel is not available (see p. 6).

The new WHO recommendations reflect consensus reached at a meeting of family planning experts in April 2004 at WHO headquarters in Geneva, Switzerland. The Expert Working Group of 29 international family planning specialists from 15 countries comprised clinicians, epidemiologists, policy makers, and program managers (see box below).

Source of Evidence Related to WHO Recommendations

In this issue of *INFO Reports*, the citations to research studies come from systematic reviews conducted on behalf of the WHO Secretariat for the April 2004 Expert Working Group Meeting. The Expert Working Group reviewed this evidence in considering and reaching its decisions about the Selected Practice Recommendations.

In general, these systematic reviews selected articles that were:
- Found through searches of MEDLINE, POPLINE, and similar bibliographic databases;
- Published in peer-reviewed journals through February 2004; and
- Reported studies, systematic reviews of studies, or meta-analyses that examined the biomedical and behavioral components of the questions posed to the Expert Working Group, from which the Selected Practice Recommendations stemmed.

These systematic reviews were conducted by: Kathryn Curtis and Anshu Mohllajee of the US Centers for Disease Control and Prevention; Mary Lyn E. Gaffield of WHO; and Kavita Nanda of Family Health International.

Participants in the 2004 WHO Expert Working Group include: Yasmin H. Ahmed, Halida Akhter, Marcos Arevalo, Tsungai Chipato, Maria del Carmen Cravioto, Soledad Diaz, John Guillebaud, Kerstin Hagenfeldt, Ezzeldin Othman Hassan, Robert Hatcher, Mihai Horga, Douglas Huber, Roy Jacobstein, Pisake Lumbiganon, Pamela Lynam, Trent MacKay, Polly Marchbanks, Olav Meirik, Noel McIntosh, Helen Rees, Roberto Rivera, Fred Sai, Pramilla Senanayake, James Shelton, Irving Sivin, Connie Smith, Fatiha Terki, Marcel Vekemans, and Edith Weisberg.

Updating the WHO recommendations. To ensure that WHO's guidance stays current, new research articles whose study objectives concern topics addressed by the Selected Practice Recommendations or Medical Eligibility Criteria are identified by the online system CIRE (Continuous Identification of Research Evidence). Any updates to current WHO guidance appear on WHO's Web site. Records of all articles that CIRE has identified can be found at http://www.infoforhealth.org/cire/cire_pub.pl. Visitors to this Web page can sign up for e-mail notification when CIRE posts new records. Also, *The Pop Reporter* e-zine, at http://www.infoforhealth.org/popreporter/current.shtml, notifies its readers of new postings. Free subscription is available at http://prds.infoforhealth.org/signup.php.

New Guidance Updates Previous Recommendations

The World Health Organization's 2004 Selected Practice Recommendations offer updated advice on how family planning clients can best use their contraceptive methods to protect against pregnancy, as well as on how to manage side effects or other problems during contraceptive use (66). This new guidance includes important departures from what has been commonly advised about certain contraceptive methods.

The 2004 WHO guidance updates the *Selected Practice Recommendations for Contraceptive Use* first issued in 2002 (64). The 2004 edition includes 10 new recommendations as well as revisions of 12 recommendations from the 2002 edition. (For information on obtaining the full 2004 WHO report, see box, below left.)

This issue of *INFO Reports* focuses on the new 2004 WHO guidance that is likely to have the greatest impact on service delivery. It also summarizes the other new recommendations, which pertain to the levonorgestrel-releasing IUD (LNG-IUD) (see p. 7). ❖

Evidence-Based Family Planning Guidance: What's New, What's Next?

The 2004 edition of the World Health Organization (WHO) publication *Selected Practice Recommendations for Contraceptive Use* is the second of four cornerstones of evidence-based family planning guidance from WHO. The first cornerstone is the 2004 publication, *Medical Eligibility Criteria for Contraceptive Use*. WHO is in the process of developing the third and fourth cornerstones of the evidence-based guidelines series (see below). The development of the series was led by Herbert Peterson, former coordinator for the Promoting Family Planning Team of the Department of Reproductive Health and Research at WHO.

The WHO Medical Eligibility Criteria provide guidance on who can use contraceptive methods safely in the presence of certain health conditions (65). (For a summary of recent additions and changes, see *INFO Reports*, "WHO Updates Medical Eligibility Criteria for Contraceptives," No. 1, August 2004, at http://www.infoforhealth.org/inforeports/mec/index.shtml.)

The full texts of both the *Selected Practice Recommendations for Contraceptive Use* and *Medical Eligibility Criteria for Contraceptive Use* are available on the WHO Web site at: http://www.who.int/reproductive-health/family_planning/evidence.html. Printed copies can be requested by postal mail, telephone, fax, or e-mail:
Postal mail: World Health Organization, Department of Reproductive Health and Research, Documentation Centre, 1211 Geneva 27, Switzerland
Telephone: 0041 22 791 4447/3346
Fax: 0041 22 791 4189
E-mail: reproductivehealth@who.int

New Evidence-Based Guidance Available in 2005

The third cornerstone in the WHO evidence-based series, the *Decision-Making Tool for Family Planning Clients and Providers,* is a flipchart for family planning clients and providers to use together to help clients choose and use a contraceptive method. It is being prepared in collaboration with The INFO Project.

The fourth cornerstone is a handbook intended as the successor to *The Essentials of Contraceptive Technology*. Written for family planning clinic staff, the handbook will provide up-to-date, evidence-based information on contraceptive methods. The new handbook is being prepared in collaboration with The INFO Project and more than 20 other reproductive health organizations.

The Decision-Making Tool and handbook are expected to be available in spring 2005 and winter 2006, respectively, through The INFO Project. Requests can be sent to:
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WHO Simplifies the Missed-Pill Recommendation

Research has found that the WHO missed-pill recommendation for combined oral contraceptives (OCs) published in 2002 is too complex for many OC users to understand (11). The recommendation included detailed and differing instructions depending on the number of pills missed and when they were missed. Similar instructions from the US Food and Drug Administration (US FDA) have proved difficult to understand, as well (47). The 2004 WHO Expert Working Group simplified the missed-pill recommendation by giving one overarching instruction to women who miss any number of combined pills[1] and one additional overarching instruction to women who miss three or more hormonal pills in a row:

- A woman who misses any number of hormonal pills should **take a hormonal pill as soon as possible and then continue taking one pill each day.**[2]
- A woman who misses three or more hormonal pills in a row needs to take an additional step. She should **use condoms or abstain from sex until she has taken hormonal pills for seven days in a row** (see Figure 1). A woman must take hormonal OCs for seven days continuously in order to prevent ovulation reliably (40).

[1] This guidance refers to combined OCs containing more than 20 µg of the estrogen ethinyl estradiol.

[2] If a woman follows a pill-taking schedule that involves starting on a certain day of the week, she must throw away the missed hormonal pills if she wants to maintain her schedule.

Figure 1. What To Do If You Miss Hormonal Pills*

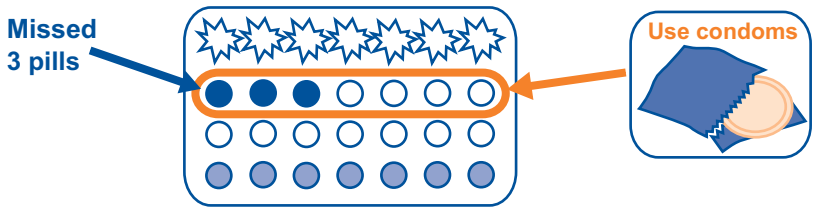
Always take a hormonal pill† as soon as you remember and continue to take one pill each day.

Missed 3 or more hormonal pills?

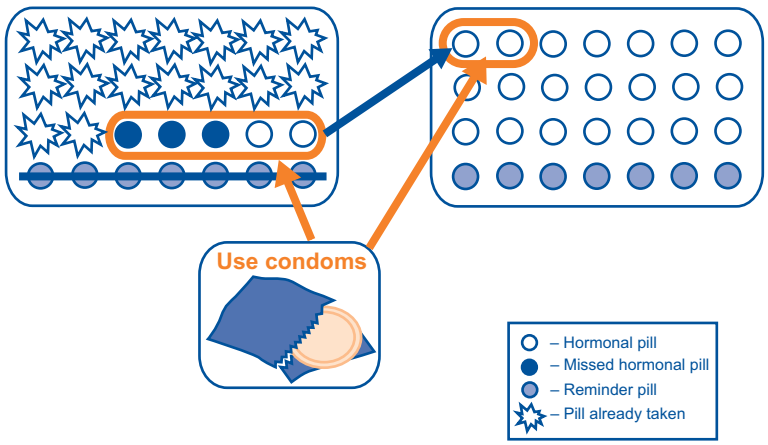
You must take hormonal pills for 7 days in a row to get back full protection.

SO —

Starting with the first pill you missed, keep taking one pill each day,† AND use condoms or avoid sex until you have taken hormonal pills for 7 days in a row.



ALSO, if you missed 3 or more hormonal pills in week 3:
Finish only the hormonal pills in that pack, throw away the reminder pills, and then start a new pack the next day.



*These instructions apply to combined oral contraceptive pills containing more than 20µg of the estrogen ethinyl estradiol.

†If you follow a pill-taking schedule that involves starting on a certain day of the week, you must throw away the missed hormonal pills if you want to maintain your schedule. Get back on your daily pill-taking schedule by starting with the current day's hormonal pill (not shown in the diagram).

It is particularly important to avoid extending the gap between taking hormonal pills. Therefore, if a woman misses three or more hormonal pills during the third week of the pill pack, she should finish only the hormonal pills in that pack and then start a new pack on the next day. She should throw away all the reminder pills (see Figure 1). Also, if a woman misses three or more hormonal pills in the first week of the pill pack and has had unprotected sex, the Expert Working Group advises that she may wish to consider using emergency contraception, because the risk of pregnancy in such a case could be substantial.

In addition, since the reminder pills do not contain hormones, a woman who misses any number of reminder pills simply should throw away the missed reminder pills and continue taking one pill each day.

The 2004 Expert Working Group considered three to be the critical number of missed pills that should prompt women to take extra precautions. They based their judgment on evidence that up to nine days without hormones is not likely to lead to ovulation (12, 16, 17, 24, 25, 28, 29, 33, 34, 36, 37, 55, 57). Therefore, if a woman misses hormonal pills immediately before or after the seven-day hormone-free interval (that is, in either the third or first week of the pill pack), she could miss up to two hormonal pills—but not three—without risking pregnancy (two missed hormonal pills plus seven nonhormonal reminder pills equals nine days without hormones).

The more complex 2002 missed-pill recommendation instructed women to take extra precautions after missing two hormonal pills in a row, not three. Also, the 2002 recommendation for when to take extra precautions depended on when she missed the pills. For example, women who miss pills in the second or third week of the pill pack would have been taking hormonal pills for at least seven days previously, so they actually do not need to use additional contraception.

The 2004 guidance does not make such a distinction, however. The 2004 Expert Working Group's advice to use condoms or abstain from sex applies to all weeks of the pill pack. The Expert Working Group decided to sacrifice some scientific precision in the interest of simpler, easier to follow guidelines.

Guidance more cautious for very low dose hormonal pills. Some combined OCs contain 20 µg or less of the estrogen ethinyl estradiol—a very low dose. If a woman misses any of these pills, WHO advises following the same rules as for other combined OCs—but with one key difference: A woman should take extra precautions after missing two hormonal pills, instead of after missing three.❖

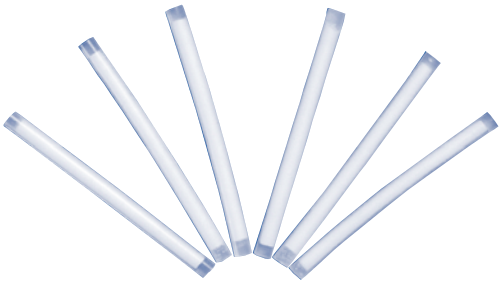
Vasectomy Procedure Effective after Three Months

The new WHO recommendations advise that a man should wait three months after vasectomy before relying on it for contraception. During this period he should resume sexual activity in order to clear any remaining sperm from the semen, while he or his partner use additional contraceptive protection to avoid pregnancy.

Previous service delivery guidelines advised a man undergoing vasectomy that he could rely on the vasectomy either after three months or once he had had at least 20 ejaculations, whichever occurred first. Recent studies have shown, however, that the

20-ejaculation criterion is not a reliable gauge of vasectomy effectiveness (6, 54).

Substantial evidence shows that a three-month waiting period is long enough for vasectomy to become effective in most men (5, 6, 8, 9, 20, 32, 41, 54). While the most reliable way to determine whether vasectomy has become effective is through semen analysis, this procedure requires a microscope, slide, and dropper—equipment that is not readily available in many places.❖



Duration of *Norplant* Implants Extended to Seven Years for Most Women

Regulatory agencies generally recommend a five-year limit on use of *Norplant* implants applicable to all women. Studies of *Norplant* implants have found, however, that a woman's weight and age affects the duration of contraceptive effectiveness (23, 50). Based on this evidence WHO now recommends that the time between insertion and removal of the implants can depend upon the user's weight. The Expert Working Group did not make any references to a woman's age in the recommendation because younger women tend to have higher pregnancy rates than older women regardless of the contraceptive method used, due to their higher fecundity.

The Expert Working Group advises that:

- Women who weigh **less than 70 kg (154 pounds)** at insertion of their *Norplant* implants and who continue to weigh less than 70 kg can leave the implants in place for up to seven years.

- Women who weigh **between 70 and 79 kg (154 and 174 pounds)** at insertion should be advised that their *Norplant* implants will be less effective after five years of use if they still weigh between 70 and 79 kg at that time (23, 50). The effectiveness of *Norplant* implants in women in this weight range in years six and seven of use is reduced but still greater than that of most other contraceptive methods, including injectables, OCs, and condoms (all as typically used) (61). After five years the woman, with counseling from her health care provider, can decide whether to leave the implants in place for the additional two years, to replace them with a new set of implants, or to switch to a different contraceptive method.

- All women should be counseled that, if they weigh **80 kg (176 pounds) or more** at the end of four years of *Norplant* use, they should seriously consider having their implants replaced because of their reduced contraceptive effectiveness. The Expert Working Group reviewed evidence that women weighing 80 kg or more have an approximately 6% chance of getting pregnant in the fifth year of *Norplant* implant use (50). While this pregnancy rate is comparable to that of combined oral contraceptive pills as typically used, it is much higher than in earlier years of *Norplant* implant use.❖

Emergency Contraception Advice Expanded

Emergency contraceptive pills (ECPs) should be taken as soon as possible after unprotected sex for maximum effectiveness. WHO now advises that they can be taken up to a maximum of 120 hours after unprotected sex, however, rather than the previously recommended maximum of 72 hours. The Expert Working Group also recommends a new regimen for ECPs—a single dose of 1.5 mg of levonorgestrel.

In addition, the expert group reiterates earlier advice that a woman can have an advance supply of ECPs.

Take ECPs as soon as possible. The new WHO guidance supports previous advice to take ECPs as soon as possible after having unprotected sex—ideally within 72 hours. Recent research shows ECPs also can be effective if taken up to 120 hours after unprotected sex (15, 42, 46, 63). Still, the longer a woman waits to take them, the less likely they are to prevent pregnancy (15, 42, 46, 63).

Three dosage options. WHO recommends three options for ECP dosage:

1. 1.5 mg of levonorgestrel in a single dose;

2. Two doses of levonorgestrel (one dose of 0.75 mg of levonorgestrel, followed by a second dose of 0.75 mg of levonorgestrel 12 hours later); or

3. Two doses of combined estrogen-levonorgestrel ECPs—the "Yuzpe regimen"[3] of one dose of 100 µg of ethinyl estradiol plus 0.5 mg of levonorgestrel, followed by the same dose 12 hours later.

The first regimen is the best choice, the Expert Working Group advises. A single dose is the best option because people generally are more likely to take a single dose than multiple doses. In addition, the levonorgestrel-only regimen causes less nausea and vomiting than the combined formulation (see below).

Brochures about ECPs in many languages are available at www.path.org/resources/ec_client-mtrls.htm.

The preferred regimen might not be available everywhere, however. The other two regimens are acceptable alternatives, the Expert Working Group concluded. In some places the regimens are prepared and labeled specifically for use as ECPs. They also can be prepared from a variety of OCs that contain levonorgestrel.

Levonorgestrel-only ECPs cause less nausea and vomiting. WHO recommends that women use levonorgestrel-only ECPs because they cause less nausea and vomiting than combined estrogen-levonorgestrel ECPs (26, 58). Nausea and vomiting are common side effects associated with ECP use (45, 58).

WHO does not recommend routine use of antiemetics (medication that helps prevent nausea and vomiting) before taking ECPs. Predicting which women will experience side effects usually is difficult, and many women taking ECPs do not experience nausea and vomiting. Antiemetics are effective for some women, however (43, 45). Thus the Expert Working Group advises that clinicians offer antiemetics on a case-by-case basis according to their medical judgment. Clinicians should take into account that antiemetics themselves may cause other side effects, such as drowsiness and dizziness.

Advance supply encouraged. The 2004 Expert Working Group supported previous recommendations that allow a woman to receive an advance supply of ECPs. The group based its recommendation on recent evidence that:

- A woman is more likely to take ECPs after unprotected sex if she has a supply on hand (7, 14, 21, 27, 38, 44, 48); and

- Having ECPs on hand does not affect a woman's contraceptive use, does not increase her frequency of unprotected sex, and does not increase her frequency of ECP use (7, 14, 21, 27, 44, 48).❖

[3] The Yuzpe regimen is named after Canadian professor A. Albert Yuzpe, who published the first studies demonstrating the safety and effectivenss of using combined OCs as ECPs (67, 68).

Guidance for Cu-IUDs Extended To the LNG-IUD

The 2004 WHO recommendations now extend to the LNG-IUD some of the 2002 recommendations for copper-bearing IUDs (Cu-IUDs), including:

- Prophylactic antibiotics generally are not recommended for Cu-IUD or LNG-IUD insertion (22). Use of prophylactic antibiotics can be considered, however, where cervical gonococcal and chlamydial infections are common and STI screening is limited.

- Neither a Cu-IUD nor an LNG-IUD needs to be removed if a woman is diagnosed with pelvic inflammatory disease (PID) during its use. Removal does not improve the woman's condition once the PID is being treated with appropriate antibiotics (1, 35, 53, 60).

- If a woman becomes pregnant while using a Cu-IUD or LNG-IUD, the IUD should be removed if the strings are visible or if they can be retrieved safely from the cervical canal. If the IUD is left in place, the woman is at increased risk of first- or second-trimester miscarriage and of preterm delivery (2, 4, 13, 19, 30, 31, 39, 49, 52, 56, 59, 62).

In addition, the 2004 Expert Working Group modified the earlier Cu-IUD recommendations on insertion and on menstrual abnormalities to apply them to the LNG-IUD:

- The LNG-IUD generally should be inserted only within the first seven days of a woman's menstrual cycle. In contrast, Cu-IUDs can be inserted within the first 12 days of the menstrual cycle, because of its 5-day emergency contraceptive effect. Both types of IUDs, however, can be inserted at any other time during a woman's menstrual cycle if it is reasonably certain she is not pregnant.

- The LNG-IUD should not be inserted immediately postpartum, as Cu-IUDs can be, because the hormonal effects from the LNG-IUD on uterine involution (return of the uterus to its size before pregnancy) are unknown (65).

- Amenorrhea (the absence of menstrual periods) is a common side effect with the LNG-IUD but not with Cu-IUDs (3, 10, 18, 51). A woman who experiences amenorrhea while using an LNG-IUD does not require medical treatment, according to the 2004 WHO guidance. Reassuring counseling and explanation should be sufficient response to such amenorrhea.❖

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