Family Planning: A Global Handbook for Providers

Summary of Major Changes from 2008 and 2011 Updates

Since Family Planning: A Global Handbook for Providers was first published in 2007, the World Health Organization has issued new or revised guidance on specific aspects of contraceptive choice and use. There have been a number of other important developments, too, concerning family planning methods. Such changes have been incorporated into new printings of the Global Handbook in 2008 and 2011.

These are some important changes since 2007 that appear in the Global Handbook 2011 update:

- A woman may have a repeat injection of depot-medroxyprogesterone acetate (DMPA) up to 4 weeks late. There is no need to check whether she might be pregnant.
- Appropriately trained community health workers can provide injectable contraceptives safely, effectively, and acceptably. Such services should be part of a family planning program offering a range of contraceptive methods.
- During breastfeeding, antiretroviral (ARV) therapy for the mother, for the HIV-exposed infant, or for both significantly reduces the chances of HIV transmission through breast milk.
- Generally, women taking antiretroviral (ARV) drugs for HIV/AIDS can generally use any contraceptive method. There is one exception: Ritonavir or ritonavir-boosted ARVs may make combined hormonal methods and progestin-only pills less effective.

The table on the following pages summarizes substantive changes since the first printing in 2007. Please note:

- The column "Text Revisions" shows an example of handbook text that reflects the new or changed guidance. Other pages affected are noted in italics above this new text, but the new wording for those pages is not given. (On request, the Knowledge for Health Project can provide a complete list of text changes.)
- The date in the right-hand column, "Year Updated," indicates when the change was first made—in 2008 or 2011. Readers who have a 2008 handbook can look just at changes made in 2011.
- Changes to the table of WHO Medical Eligibility Criteria (which starts on page 325 in the handbook) are shown here in a table beginning on page 11.

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Text Revisions

viii-ix What's New in This Handbook? updated

2011

The first two paragraphs remain the same. The rest of the section is replaced with the following text, starting with new heading: "New WHO Guidance Since 2007" (replaces heading "Updates from 2008 WHO Working Group Meeting").

New WHO Guidance Since 2007

Since the handbook was first published in 2007, the Department of Reproductive Health and Research of WHO convened an expert Working Group in April 2008 and two technical consultations in October 2008 and January 2010 to address questions for the Medical Eligibility Criteria (MEC) and the Selected Practice Recommendations and a technical consultation in June 2009 on the provision of progestin-only injectables by community health workers. Also, the HIV Department of WHO convened an expert Working Group in October 2009 to update guidance on infant feeding and HIV. This 2011 printing of the Global Handbook reflects new guidance developed in these meetings. (See p. 354.) Updates include:

- A woman may have a repeat injection of depot-medroxyprogesterone acetate (DMPA) up to 4
 weeks late. (Previous guidance said that she could have her DMPA reinjection up to 2 weeks
 late.) The guidance for reinjection of norethisterone enanthate (NET-EN) remains at up to 2
 weeks late. (See p. 74.)
- During breastfeeding, antiretroviral (ARV) therapy for the mother, for the HIV-exposed infant, or for both can significantly reduce the chances of HIV transmission through breast milk. HIVinfected mothers should receive the appropriate ARV therapy and should exclusively breastfeed their infants for the first 6 months of life, then introduce appropriate complementary foods and continue breastfeeding for the first 12 months of life. (See p. 294.)
- Postpartum women who are not breastfeeding can generally start combined hormonal methods at 3 weeks (MEC category 2). However, some women who have additional risk factors for venous thromboembolism (VTE) generally should not start combined hormonal methods until 6 weeks after childbirth, depending on the number, severity, and combination of the risk factors (MEC category 2/3). These additional risk factors include previous VTE, thrombophilia, caesarean delivery, blood transfusion at delivery, postpartum hemorrhage, pre-eclampsia, obesity, smoking, and being bedridden. (See p. 325.)
- Women with deep vein thrombosis who are established on anticoagulant therapy generally can
 use progestin-only contraceptives (MEC category 2) but not combined hormonal methods (MEC
 category 4). (See p. 327.)
- Women with systemic lupus erythematosus generally can use any contraceptive except that: (a)
 A woman with positive (or unknown) antiphospholipid antibodies should not use combined
 hormonal methods (MEC category 4) and generally should not use progestin-only methods (MEC
 category 3). (b) A woman with severe thrombocytopenia generally should not start a progestin only injectable or have a copper-bearing IUD inserted (MEC category 3). (See p. 328.)
- Women with AIDS who are treated with ritonavir-boosted protease inhibitors, a class of ARV drugs, generally should not use combined hormonal methods or progestin-only pills (MEC category 3). These ARV drugs may make these contraceptive methods less effective. These women can use progestin-only injectables, implants, and other methods. Women taking only other classes of ARVs can use any hormonal method. (See p. 330.)
- Women with chronic hepatitis or mild cirrhosis of the liver can use any contraceptive method (MEC category 1). (See p. 331.)
- Women taking medicines for seizures or rifampicin or rifabutin for tuberculosis or other conditions generally can use implants. (See p. 332.)

New Guidance for Community-Based Provision of Injectables

• Community-based provision of progestin-only injectable contraceptives by appropriately trained community health workers is safe, effective, and acceptable. Such services should be part of a family planning program offering a range of contraceptive methods. (See p. 63.)

1 6 Changes in Medical Eligibility Criteria for VTE postpartum

2011

See table of changes for the Medical Eligibility Criteria (page 11), row for page 325, for the complete classifications. In the handbook the changes are also reflected in combined oral contraceptives (page 11) and monthly injectables (pages 85, 88, 90).

Examples of changes:

Page 6: Medical Eligibility Criteria for Combined Oral Contraceptives

New wording for question and answer to Question 2:

Have you had a baby in the last 3 weeks and you are not breastfeeding?

□NO □YES Give her COCs now and tell her to start taking them 3 weeks after childbirth. (If there is an additional risk that she might develop a blood clot in a deep vein (deep vein thrombosis, or VTE), then she should not start COCs at 3 weeks after childbirth, but start at 6 weeks instead. These additional risk factors include previous VTE, thrombophilia, caesarean delivery, blood transfusion at delivery, postpartum hemorrhage, pre-eclampsia, obesity (≥30 kg/m²), smoking, and being bedridden for a prolonged time.)

Page 9: Using Clinical Judgment in Special Cases

New bullet added.

 Not breastfeeding and between 3 and 6 weeks postpartum with additional risk that she might develop a blood clot in a deep vein (VTE)

1 9 Revised Medical Eligibility Criteria for drug interactions

2008

Interaction of rifabutin, ritonavir and lamotrigine with certain hormonal methods added.

See table of changes for the Medical Eligibility Criteria (page 11), row for page 330 for drug interactions with antiretroviral therapy, and page 332 for rifabutin and lamotrigine. In the handbook the changes are also reflected in the following chapters: combined oral contraceptives (pages 5, 8, 20), progestin-only pills (pages 28, 29, 30, 41), monthly injectables (pages 84, 87, 88, 97), implants (pages 114, 115, 127), and STI/HIV/AIDs (pages 282-283).

Examples of changes:

Page 9: Using Clinical Judgment in Special Cases

Underlined text added:

- Taking barbiturates, carbamazepine, oxcarbazepine, phenytoin, primidone, topiramate, rifampicin, <u>rifabutin</u>, or <u>ritonavir or ritonavir-boosted protease inhibitors</u>. A backup contraceptive method should also be used because these medications reduce the effectiveness of COCs.
- Taking lamotrigine. Combined hormonal methods may make lamotrigine less effective.

Page 9: Combined Oral Contraceptives for Women With HIV

1st bullet, new underlined text:

 Women can safely use COCs even if they are infected with HIV, have AIDS, or are on antiretroviral (ARV) therapy <u>unless their therapy includes ritonavir</u>. Ritonavir may reduce the effectiveness of COCs. (See Medical Eligibility Criteria, p. 330.)

Last sentence of 2nd bullet deleted.

Chapter	Page	Text Revisions	Year Updated
1	15	Missed pills instructions for combined oral contraceptives revised	2008
		Also affects tool on missed pills, inside back cover.	
		Example of changes:	
		Page 15: Making Up Missed Pills With 30–35 μg Estrogen	
		Under 3 rd heading, first sentence, underlined text revised:	
		Missed pills 3 or more days in a row in the first or second week?	
		Under "Severe vomiting or diarrhea", second bullet, "1 or 2" changed to "3 or more", to read:	
		If she has vomiting or diarrhea for more than 2 days, follow instructions for $\underline{3}$ or more missed pills, above.	
2	29	Revised Medical Eligibility Criteria for women with blood clots (DVT/PE)	2008
		See table of changes for the Medical Eligibility Criteria (page 11), row for page 327, for the complete classifications. In the handbook the changes are also reflected in the following chapters progestin-only injectables (page 66), implants (page 114), and levonorgestrel IUD (page 160).	
		Example of changes:	
		Page 29: Medical Eligibility Criteria for Progestin-Only Pills	
		Question 3 answer, underlined text added:	
		□NO □YES If she reports a current blood clot (not superficial clots), <u>and she is not on anticoagulant therapy</u> , do not provide POPs. Help her choose a method without hormones.	
2	30	New Medical Eligibility Criteria classifications for lupus	2008
		See table of changes for the Medical Eligibility Criteria (page 11), rows for page 328 and 333, for the complete classifications. In the handbook the changes are also reflected in the following chapters: combined oral contraceptives (page 8), progestin-only injectables (page 67), monthly injectables (page 87), implants (page 115), copper-bearing IUD (page 136), levonorgestrel IUD (page 161), female sterilization (page 171), and vasectomy (page 188).	
		Example of changes:	
		Page 30: Using Clinical Judgment in Special Cases	
		New bullet:	
		Systemic lupus erythematosus with positive (or unknown) antiphospholipid antibodies	
2	36	Missed pill instructions for progestin-only pills containing desogestrel added	2008
		Also affects progestin-only pills chapter, page 43.	
		Example of changes:	
		Page 36: Managing Missed Pills	
		First paragraph, 3rd sentence, underlined text added:	
		If a woman is 3 or more hours late taking a pill (12 or more hours late taking a POPs containing desogestrel 75 mg) or she misses a pill completely, she	

Chapter	Page	Text Revisions	Year Updated
3	50	New emergency contraceptive pill formulation, ulipristal acetate, added	2011
		Also affects page 46, "What Pills Can Be Used as Emergency Contraceptive Pills?"	
		Example of changes:	
		Page 50: Dosing Information	
		New row added to end of table:	
		Ulipristal acetate dedicated product	
		30 mg of ulipristal acetate in a single dose.	

4 63 New Guidance for Community-Based Provision of Injectables

2011

Also affects table, page 311, "Who Provides Family Planning?"

New box replaces "New Formulation of DMPA."

Delivering injectable contraception in the community

More and more women are asking for injectable contraceptives. This method can be more widely available when it is offered in the community as well as in clinics.

A WHO technical consultation in 2009 reviewed evidence and program experience and concluded that "community-based provision of progestin-only injectable contraceptives by appropriately trained community health workers is safe, effective, and acceptable" to clients.

Community-based providers of injectables should be able to screen clients for pregnancy and for medical eligibility. Also, they should be able to give injections safely and to inform women about delayed return of fertility and common side effects, including irregular bleeding, no monthly bleeding, and weight gain. They also should be able to counsel women about their choice of methods, including methods available at the clinic. All providers of injectables need specific performance-based training and supportive supervision to carry out these tasks.

It is desirable, if possible, to check blood pressure before a woman starts an injectable (see p. 65, question 3). However, in areas where the risks of pregnancy are high and few other methods are available, blood pressure measurement is not required.

For success, clinic-based providers and community-based providers must work closely together. Programs vary, but these are some ways that clinic-based providers can support community-based providers: treating side effects (see pp. 75–77), using clinical judgment concerning medical eligibility in special cases (see p. 67), ruling out pregnancy in women who were more than 4 weeks late for an injection of DMPA or 2 weeks late for NET-EN, and responding to any concerns of clients referred by the community-based providers.

The clinic also can serve as "home" for the community-based providers, where they go for resupply, for supervision, training, and advice, and to turn in their records.

New formulation of DMPA

A new type of prefilled, single-use syringe could be particularly useful to provide DMPA in the community. These syringes have a short needle meant for subcutaneous injection (that is, injection just below the skin). They contain a special formulation of DMPA, called DMPA-SC. It is meant only for subcutaneous injection and not for injection into muscle. This formulation of DMPA is available in conventional prefilled auto-disable syringes and in the Uniject system, in which squeezing a bulb pushes the fluid through the needle (see photo below). Like all single-use syringes, these syringes should be placed in a sharps box after use, and then the sharps box should be disposed of properly (see Infection Prevention in the Clinic, p. 312).

4 76 Progestin-only injectables: Side effects treatment

2008

Also affects page 75, "Irregular bleeding."

Example of changes:

Page 76: Heavy or prolonged bleeding...

2nd bullet revised as follows:

For modest short-term relief she can try (one at a time), beginning when heavy bleeding starts:

- 500 mg of mefenamic acid twice daily after meals for 5 days.
- 40 mg of valdecoxib daily for 5 days.
- 50 μg of ethinyl estradiol daily for 21 days.

4 80 New guidance on late injections

2008

Also affects pages 59, 73, and 74 in the chapter on progestin-only injectables and the job aid on comparing injectable, page 359.

Questions and Answers About Progestin-Only Injections

Revised text for Question 13:

What if a woman returns for her next injection late?

In 2008 WHO revised its guidance based on new research findings. The new guidance recommends giving a woman her next DMPA injection if she is up to 4 weeks late, without the need for further evidence that she is not pregnant. A woman can receive her next NET-EN injection if she is up to 2 weeks late. Some women return even later for their repeat injection, however. In such cases providers can use Further Options to Assess for Pregnancy, p. 370. Whether a woman is late for reinjection or not, her next injection of DMPA should be planned for 3 months later, or her next injection of NET-EN should be planned for 2 months later, as usual.

8 109 New type of implant

2011

New bullet added:

Many types of implants

Sino-Implant (II), also known as Femplant, Trust Implant, and Zarin: 2 rods, effective for 4 years (may be extended to 5 years)

8 129 Clarification on progestin-only methods for breastfeeding women in first 6 weeks postpartum

2011

Reference to the new Question and Answer 8, page 129, appear in the chapters on progestin-only injectables (pages 64, 67, 69), implants (pages 113, 115, 117), and levonorgestrel IUD (pages 161, 162).

Questions & Answers About Implants

New Question & Answer replacing Q&A 8 ("Do implants change women's mood or sex drive?")

8. How soon can a breastfeeding woman start a progestin-only method—implants, progestin-only pills or injectables, or LNG-IUD?

WHO guidance calls for waiting until at least 6 weeks after childbirth to start a progestin-only contraceptive (4 weeks for the LNG-IUD). In special cases a provider could make the clinical judgment that a woman can start a progestin-only method sooner (see p. 115).

A WHO expert consultation in 2008 endorsed WHO's current guidance, based on theoretical concerns about the effect on infant development of hormones in breast milk. These experts noted,

however, that, where pregnancy risks are high and access to services is limited, progestin-only methods may be among the few available. Also, starting implants and IUDs requires providers with special training. These providers may be available only when a woman gives birth. The experts concluded, "Any decisions regarding choice of a contraceptive method should also consider these facts."

Also note: Guidance in some countries, based on their own expert panel reviews, allows breastfeeding women to start progestin-only methods at any time. [‡] This includes starting immediately postpartum, a long-standing practice in these countries.

At bottom of page add footnote as follows:

[‡] See, for example, Faculty of Sexual and Reproductive Healthcare (FRSH). UK Medical Eligibility Criteria. London, FSRH, 2006. and Centers for Disease Control. U.S. Medical Eligibility Criteria for contraceptive use, 2010. Morbidity and Mortality Weekly Report 59. May 28, 2010.

9 140 Guidance revised on postpartum IUD insertion

2008

When to Start

First bullet under "Soon after childbirth," underlined text added:

Any time within 48 hours after giving birth, <u>including by caesarean delivery</u>. (Provider needs specific training in postpartum insertion.) <u>Fewest expulsions when done just after delivery of placenta (if possible).</u>

14 220 Revised guidance on reuse of female condom

2011

Questions and Answers About Female Condoms

Question 5 revised to read:

Can the female condom be used more than once?

Reuse of the female condom is not recommended. Reuse of currently available female condoms has not been tested.

Question 10 deleted.

22 294 New guidance on breastfeeding for women with HIV

2011

Also affects LAM chapter, pages 260 and 265.

Preventing Mother-to-Child Transmission of HIV

New text as follows:

A woman infected with HIV can pass HIV to her child during pregnancy, delivery, or breastfeeding. Preventive antiretroviral (ARV) therapy (prophylaxis) given to the mother during pregnancy and labor can greatly reduce the chances that the baby will be infected while developing in the uterus or during delivery. During breastfeeding, ARV therapy for the mother, for the HIV-exposed infant, or for both also can significantly reduce the chances of HIV transmission through breast milk.

How can family planning providers help prevent mother-to-child transmission of HIV? [First four bullets remain the same.]

- Encourage appropriate infant feeding: Counsel women with HIV on safer infant feeding practices
 to reduce the risk of transmission, and help them develop a feeding plan. If possible, refer them
 to someone trained to counsel on infant feeding.
 - For all women, including women with HIV, breastfeeding, and especially early and exclusive breastfeeding, is an important way to promote the child's survival.
 - HIV-infected mothers and/or their infants should receive the appropriate ARV therapy, and mothers should exclusively breastfeed their infants for the first 6 months of life, then

- introduce appropriate complementary foods and continue breastfeeding for the first 12 months of life.
- Breastfeeding should then stop only once a nutritionally adequate and safe diet without breast milk can be provided. When mothers decide to stop breastfeeding, they should stop gradually within one month, and infants should be given safe and adequate replacement feeds to enable normal growth and development. Stopping breastfeeding abruptly is not advised.
- Even when ARV therapy is not available, breastfeeding (exclusive breastfeeding in the first 6 months of life and continued breastfeeding for the first 12 months of life) may still give infants born to mothers infected with HIV a greater chance of survival while still avoiding HIV infection than not breastfeeding at all.
- In some well-resourced countries with low infant and child mortality rates, however, avoiding all breastfeeding will be appropriate. A woman with HIV should be advised of the national recommendation for infant feeding by HIV-infected mothers and counseled and supported in the feeding practice that best suits her situation.
- An HIV-infected mother should consider replacement feeding if—and only if—all the following conditions are met:
 - safe water and sanitation are assured in the household and community;
 - the mother or caregiver can reliably provide infant formula:
 - o sufficient for normal growth and development of the infant
 - o cleanly and frequently, to avoid diarrhea and malnutrition, and
 - o exclusively in the first 6 months;
 - · the family is supportive of this practice; and
 - the mother or caregiver can obtain health care that offers comprehensive child health services.
- If infants and young children are known to be HIV-infected, mothers should be strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding up to 2 years or beyond.
- If a woman is temporarily unable to breastfeed—for example, she or the infant is sick, she is weaning, or her supply of ARVs has run out—she may express and heat-treat breast milk to destroy the HIV before feeding it to the infant. Milk should be heated to the boiling point in a small pot and then cooled by letting the milk stand or by placing the pot in a container of cool water. This should be used only short-term, not throughout breastfeeding.
- Women with HIV who are breastfeeding need advice on keeping their nutrition adequate and their breasts healthy. Infection of the milk ducts in the breast (mastitis), a pocket of pus under the skin (breast abscess), and cracked nipples increase the risk of HIV transmission. If a problem does occur, prompt and appropriate care is important (see Sore or cracked nipples, p. 296).

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