

## U.S. Selected Practice Recommendations for Contraceptive Use, 2013

Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

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**Front cover photos, left to right:** intrauterine device, oral contraceptive pills, diaphragm, syringe for injectable contraceptives, male condom, transdermal contraceptive patch, etonogestrel implant, vaginal ring.

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Prepared by  
Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion

### Summary

*The U. S. Selected Practice Recommendations for Contraceptive Use 2013 (U.S. SPR), comprises recommendations that address a select group of common, yet sometimes controversial or complex, issues regarding initiation and use of specific contraceptive methods. These recommendations are a companion document to the previously published CDC recommendations U.S. Medical Eligibility Criteria for Contraceptive Use, 2010 (U.S. MEC). U.S. MEC describes who can use various methods of contraception, whereas this report describes how contraceptive methods can be used. CDC based these U.S. SPR guidelines on the global family planning guidance provided by the World Health Organization (WHO). Although many of the recommendations are the same as those provided by WHO, they have been adapted to be more specific to U.S. practices or have been modified because of new evidence. In addition, four new topics are addressed, including the effectiveness of female sterilization, extended use of combined hormonal methods and bleeding problems, starting regular contraception after use of emergency contraception, and determining when contraception is no longer needed. The recommendations in this report are intended to serve as a source of clinical guidance for health-care providers; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients. Persons should seek advice from their health-care providers when considering family planning options.*

### Introduction

Unintended pregnancy rates remain high in the United States; approximately 50% of all pregnancies are unintended, with higher proportions among adolescent and young women, women who are racial/ethnic minorities, and women with lower levels of education and income (1). Unintended pregnancies increase the risk for poor maternal and infant outcomes (2) and in 2002, resulted in \$5 billion in direct medical costs in the United States (3). Approximately half of unintended pregnancies are among women who were not using contraception at the time they became pregnant; the other half are among women who became pregnant despite reported use of contraception (4). Therefore, strategies to prevent unintended pregnancy include assisting women at risk for unintended pregnancy and their partners with choosing appropriate contraceptive methods and helping women use methods correctly and consistently to prevent pregnancy. In 2010, CDC first adapted global guidance from the World Health Organization (WHO) to help health-care providers counsel women, men, and couples

about contraceptive method choice. The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (U.S. MEC), focuses on who can safely use specific methods of contraception and provides recommendations for the safety of contraceptive methods for women with various medical conditions (e.g., hypertension and diabetes) and characteristics (e.g., age, parity, and smoking status) (Appendix A) (5). The recommendations in this new guide, *U.S. Selected Practice Recommendations for Contraceptive Use, 2013* (U.S. SPR), focuses on how contraceptive methods can be used and provides recommendations on optimal use of contraceptive methods for persons of all ages, including adolescents.

During the past 15 years, CDC has contributed to the development and updating of the WHO global family planning guidance. CDC has supported WHO by coordinating the identification, critical appraisal, and synthesis of the scientific evidence on which the WHO guidance is based. In 2002, WHO published the first edition of the *Selected Practice Recommendations for Contraceptive Use* (WHO SPR), which presented evidence-based global guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. Since then, WHO has regularly updated its guidance on the basis of new evidence, and the document is now in its second edition (6), with an additional update in 2008 (7). The WHO global guidance is not intended for use directly by health-care providers; rather, WHO intends for the guidance to be used by local or national policy makers, family planning program managers, and the

The material in this report originated in the National Center for Chronic Disease Prevention and Health Promotion, Ursula Bauer, PhD, Director; Division of Reproductive Health, Wanda Barfield, MD, Director.

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scientific community as a reference when they develop family planning guidance at the country or program level (6). For example, the United Kingdom adapted WHO SPR and in 2002 published the *U.K. Selected Practice Recommendations for Contraceptive Use* for use by U.K. health-care providers (8).

CDC initiated a formal adaptation process to create U.S. SPR, using both the second edition of WHO SPR (6) and the 2008 update (7) as the basis for the U.S. version. Although much of the guidance is the same as the WHO guidance, the recommendations are specific to U.S. family planning practice. In addition, guidance on contraceptive methods not available in the United States has been removed, and four new topics for guidance have been added (the effectiveness of female sterilization, extended use of combined hormonal methods and bleeding problems, starting regular contraception after use of emergency contraception, and determining when contraception is no longer needed). This document contains recommendations for health-care providers for the safe and effective use of contraceptive methods and addresses provision of contraceptive methods and management of side effects and other problems with contraceptive method use. Although the term woman is used throughout this report, these recommendations refer to all females of reproductive age, including adolescents. Adolescents are identified throughout this document as a special population that might benefit from more frequent follow-up. These recommendations are meant to serve as a source of clinical guidance for health-care providers; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients; persons should seek advice from their health-care providers when considering family planning options.

## Methods

CDC initiated a process to adapt WHO SPR for the United States. This adaptation process included four steps: 1) determining the scope of and process for the adaptation, including an October 2010 meeting in which individual feedback was solicited from a small group of partners and experts; 2) preparing the systematic reviews of the evidence during October 2010–September 2011 to be used for the adaptation, including peer review; 3) convening a larger meeting of experts in October 2011 to examine the evidence and receive input on the recommendations; and 4) finalizing recommendations by CDC.

During October 21–22, 2010, CDC convened a meeting of 10 partners and U.S. family planning experts in Atlanta, Georgia, to discuss the scope of and process for a U.S. adaptation of WHO

SPR. A list of participants is provided at the end of this report. CDC identified the specific WHO recommendations that might benefit from modification for the United States. Criteria used to modify the WHO recommendations included the availability of new scientific evidence or the context in which family planning services are provided in the United States. CDC also identified several WHO recommendations that needed additional specificity to be useful for U.S. health-care providers, as well as the need for additional recommendations not currently included in WHO SPR. In addition, the meeting members discussed removing recommendations that provide information about contraceptive methods that are not available in the United States.

Representatives from CDC and WHO conducted systematic reviews of the scientific evidence for each of the WHO recommendations being considered for adaptation and for each new topic being considered for addition to the guidance. The purpose of these systematic reviews was to identify evidence related to the common clinical challenges associated with the recommendations. When no direct evidence was available, indirect evidence and theoretical issues were considered. Standard guidelines were followed for reporting systematic reviews (9,10), and strength and quality of the evidence were graded using the system of the U.S. Preventive Services Task Force (11). Each complete systematic review was peer reviewed by two or three experts before its use in the adaptation process. Peer reviewers, who were identified from the list of persons scheduled to participate in the October 2011 meeting, were asked to comment on the search strategy, list of articles included in the reviews, and the summary of findings. The systematic reviews were finalized and provided to participants before the October 2011 meeting and were published in May 2013 (12–30).

During October 4–7, 2011, CDC convened a meeting in Atlanta, Georgia, of 36 experts who were invited to assist in guideline development and provide their perspective on the scientific evidence presented and the discussions on potential recommendations that followed. The group included obstetrician/gynecologists, pediatricians, family physicians, nurse-midwives, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management. All participants received all of the systematic reviews before the meeting. During the meeting, the evidence from the systematic review for each topic was presented, and participants discussed the evidence and the translation of the scientific evidence into recommendations that would meet the needs of U.S. health-care providers. In particular, participants discussed whether and how the U.S. context might be different from the global context and whether these differences suggested any need for modifications to the global guidance. CDC gathered the input from the experts during the meeting and finalized the recommendations in this

report. The document was peer reviewed by meeting participants, who were asked to comment on specific issues that were raised during the meeting. Feedback also was received from an external review panel, composed of health-care providers who had not participated in the adaptation meetings. These providers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations, as well as to provide other comments. Areas of research that need additional investigation also were considered during the meeting (31).

## How To Use This Document

The recommendations in this report are intended to help health-care providers address issues related to use of contraceptives, such as how to help a woman initiate use of a contraceptive method, which examinations and tests are needed before initiating use of a contraceptive method, what regular follow-up is needed, and how to address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding. Each recommendation addresses what a woman or health-care provider can do in specific situations. For situations in which certain groups of women might be medically ineligible to follow the recommendations, comments and reference to U.S. MEC are provided (5). The full U.S. MEC recommendations and the evidence supporting those recommendations were published in 2010 (5).

The information in this document is organized by contraceptive method, and the methods generally are presented in order of effectiveness, from highest to lowest. However, the recommendations are not intended to provide guidance on every aspect of provision and management of contraceptive method use. Instead, they use the best available evidence to address specific issues regarding common, yet sometimes complex, clinical issues. Each contraceptive method section generally includes information about initiation of the method, regular follow-up, and management of problems with use (e.g., usage errors and side effects). Each section first provides the recommendation and then includes a comments and evidence section, which includes comments about the recommendations and a brief summary of the scientific evidence on which the recommendation is based.

Recommendations in this document are provided for permanent methods of contraception, such as vasectomy and female sterilization, as well as for reversible methods of contraception, including the copper-containing intrauterine device (Cu-IUD); levonorgestrel-releasing IUD (LNG-IUD); the etonogestrel implant; progestin-only injectables; progestin-only pills (POPs); combined hormonal contraceptive methods

that contain both estrogen and a progestin, including combined oral contraceptives (COCs), a transdermal contraceptive patch, and a vaginal contraceptive ring; and the standard days method (SDM). Recommendations also are provided for emergency use of the Cu-IUD and emergency contraceptive pills (ECPs).

For each contraceptive method, recommendations are provided on the timing for initiation of the method and indications for when and for how long additional contraception, or a back-up method, is needed. Many of these recommendations include guidance that a woman can start a contraceptive method at any time during her menstrual cycle if it is reasonably certain that the woman is not pregnant. Guidance for health-care providers on how to be reasonably certain that a woman is not pregnant is provided.

For each contraceptive method, recommendations include the examinations and tests needed before initiation of the method. These recommendations apply to persons who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (5). Most women need no or very few examinations or tests before initiating a contraceptive method. The following classification system was developed by WHO and adopted by CDC to categorize the applicability of the various examinations or tests before initiation of contraceptive methods (6):

**Class A:** These tests and examinations are essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

**Class B:** These tests and examinations contribute substantially to safe and effective use, although implementation can be considered within the public health context, service context, or both. The risk for not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

**Class C:** These tests and examinations do not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relation of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions. Systematic reviews were conducted for several different types of examinations and tests to assess whether a screening test was associated with safe use of contraceptive methods. Because no single convention exists for screening panels for certain diseases, including diabetes,

lipid disorders, and liver diseases, the search strategies included broad terms for the tests and diseases of interest.

Summary charts and clinical algorithms that summarize the guidance for the various contraceptive methods have been developed for many of the recommendations, including when to start using specific contraceptive methods (Appendix B), examinations and tests needed before initiating the various contraceptive methods (Appendix C), routine follow-up after initiating contraception (Appendix D), management of bleeding irregularities (Appendix E), and management of IUDs when users are found to have pelvic inflammatory disease (PID) (Appendix F). These summaries might be helpful to health-care providers when managing family planning patients. Additional tools are available on the U.S. SPR website (<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>).

## Summary of Changes from WHO SPR

Much of the guidance in U.S. SPR is the same or very similar to the WHO SPR guidance. U.S. SPR includes new guidance on the use of the combined contraceptive patch and vaginal ring, as well as recommendations for four new topics:

- how to start regular contraception after taking ECPs
- management of bleeding irregularities among women using extended or continuous combined hormonal contraceptives (including pills, the patch, and the ring)
- when a woman can rely on female sterilization for contraception
- when a woman can stop using contraceptives and not be at risk for unintended pregnancy

Adaptations to the WHO SPR recommendations include 1) changes to the length of the grace period for depot medroxyprogesterone acetate (DMPA) reinjection, 2) differences in some of the examinations and tests recommended before contraceptive method initiation, 3) differences in some of the recommendations for management of bleeding irregularities because of new data and drug availability in the United States, and 4) a modified missed pill algorithm to respond to concerns of the CDC expert group and other reviewers that simplified algorithms are preferable.

## Contraceptive Method Choice

Many elements need to be considered individually by a woman, man, or couple when choosing the most appropriate contraceptive method. Some of these elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability.

Contraceptive method effectiveness is critically important in minimizing the risk for unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (Table 1). Both consistent and correct use can vary greatly with characteristics such as age, income, desire to prevent or delay pregnancy, and culture. Methods that depend on consistent and correct use by clients have a wide range of effectiveness between typical and perfect users. IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method (Figure 1).

In choosing a method of contraception, the risk for human immunodeficiency virus (HIV) infection and other sexually transmitted diseases (STDs) also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs and HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonorrhea, and trichomoniasis (32). On the basis of a limited number of clinical studies, when a male condom cannot be used properly to prevent infection, a female condom should be considered (32). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (32). Additional information about prevention and treatment of STDs is available from the CDC *Sexually Transmitted Diseases Treatment Guidelines* (32).

## Maintaining Updated Guidance

As with any evidence-based guidance document, a key challenge is keeping the recommendations up to date as new scientific evidence becomes available. Working with WHO, CDC uses the continuous identification of research evidence (CIRE) system to ensure that WHO and CDC guidance is based on the best available evidence and that a mechanism is in place to update guidance when new evidence becomes available (33). CDC will continue to work with WHO to identify and assess all new relevant evidence and determine whether changes in the recommendations are warranted. In

**TABLE 1. Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year — United States**

Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at 1 year <sup>§</sup>
	Typical use*	Perfect use <sup>†</sup>	
No method <sup>¶</sup>	85	85	—
Spermicides**	28	18	42
Fertility awareness–based methods <sup>††</sup>	24	—	47
Standard days method	—	5	—
Two day method	—	4	—
Ovulation method	—	3	—
Symptothermal method	—	0.4	—
Withdrawal	22	4	46
Sponge			
Parous women	24	20	36
Nulliparous women	12	9	—
Condom <sup>§§</sup>			
Female	21	5	41
Male	18	2	43
Diaphragm***	12	6	57
Combined pill and progestin-only pill	9	0.3	67
Evra patch	9	0.3	67
NuvaRing	9	0.3	67
Depo-Provera	6	0.2	56
Intrauterine devices			
Paragard (copper containing)	0.8	0.6	78
Mirena (levonorgestrel releasing)	0.2	0.2	80
Implanon	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100
Lactational amenorrhea method <sup>†††</sup>	—	—	—

**Source:** Adapted from Trussell J. Contraceptive failure in the United States. *Contraception* 2011;83:397–404.

\* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth (NSFG) corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill and Depo-Provera are taken from the 1995 and 2002 NSFG corrected for underreporting of abortion.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

§ Among couples attempting to avoid pregnancy, the percentage who continues to use a method for 1 year.

¶ The percentage becoming pregnant in the second and third columns are based on data from populations where contraception is not used and from women who cease using contraception to become pregnant. Among such populations, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women not relying on reversible methods of contraception if they abandoned contraception altogether.

\*\* Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The ovulation and two day methods are based on evaluation of cervical mucus. The standard days method avoids intercourse on cycle days 8–19. The symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

§§ Without spermicides.

\*\*\* With spermicidal cream or jelly.

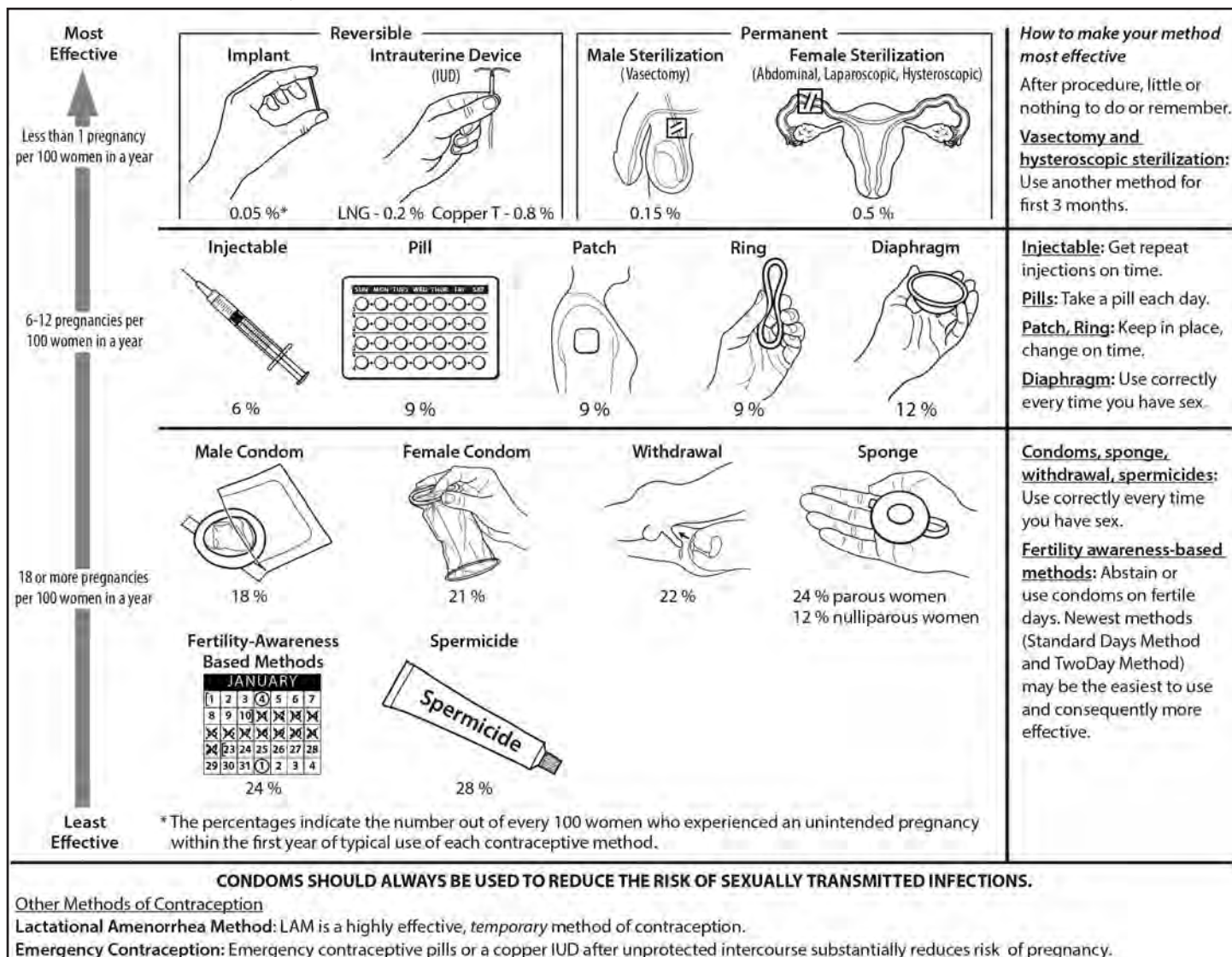
††† This is a highly effective, temporary method of contraception. However, to maintain in effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency of duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches age 6 months.

most cases, U.S. SPR will follow any updates in the WHO guidance, which typically occurs every 3–4 years (or sooner if warranted by new data). In addition, CDC will review any interim WHO updates for their application in the United States. CDC also will identify and assess any new literature for the recommendations that are not included in the WHO guidance and will completely review U.S. SPR every 3–4 years. Updates to the guidance can be found on the U.S. SPR website (<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>).

## How To Be Reasonably Certain that a Woman Is Not Pregnant

In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman who is about to start using a contraceptive method. Several criteria for assessing pregnancy risk are listed in the recommendation that follows. These criteria are highly accurate (i.e., a negative predictive value of 99%–100%) in ruling out pregnancy among women who are not pregnant (34–37). Therefore, CDC recommends that health-care providers use these criteria to assess pregnancy

FIGURE 1. Effectiveness of family planning methods



Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397-404.

status in a woman who is about to start using contraceptives (Box 1). If a woman meets one of these criteria (and therefore the health-care provider can be reasonably certain that she is not pregnant), a urine pregnancy test might be considered in addition to these criteria (based on clinical judgment), bearing in mind the limitations of the accuracy of pregnancy testing. If a woman does not meet any of these criteria, then the health-care provider cannot be reasonably certain that she is not pregnant, even with a negative pregnancy test. Routine pregnancy testing for every woman is not necessary.

On the basis of clinical judgment, health-care providers might consider the addition of a urine pregnancy test; however, they should be aware of the limitations, including accuracy

of the test relative to the time of last sexual intercourse, recent delivery, or spontaneous or induced abortion. Routine pregnancy testing for every woman is not necessary. If a woman has had recent (i.e., within the last 5 days) unprotected sexual intercourse, consider offering emergency contraception (either a Cu-IUD or ECPs), if pregnancy is not desired.

**Comments and Evidence Summary.** The criteria for determining whether a woman is pregnant depend on the assurance that she has not ovulated within a certain amount of time after her last menses, spontaneous or induced abortion, or delivery. Among menstruating women, the timing of ovulation can vary widely. During an average 28-day cycle, ovulation generally occurs during days 9-20 (38). In addition, the



**BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant**

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is  $\leq 7$  days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is  $\leq 7$  days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds),\* amenorrheic, and  $< 6$  months postpartum

\***Source:** Lobbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. *Adv Contracept* 1994;10:93–109.

likelihood of ovulation is low from days 1–7 of the menstrual cycle (39). After a spontaneous or an induced abortion, ovulation can occur within 2–3 weeks and has been found to occur as early as 8–13 days after the end of the pregnancy. Therefore, the likelihood of ovulation is low  $\leq 7$  days after an abortion (40–42). A recent systematic review reported that the mean day of first ovulation among postpartum nonlactating women occurred 45–94 days after delivery (43). In one study, the earliest ovulation was reported at 25 days after delivery. Among women who are within 6 months postpartum, are fully or nearly fully breastfeeding, and are amenorrheic, the risk for pregnancy is  $< 2\%$  (44).

Although pregnancy tests often are performed before initiating contraception, the accuracy of qualitative urine pregnancy tests varies depending on the timing of the test relative to missed menses, recent sexual intercourse, or recent pregnancy. The sensitivity of a pregnancy test is defined as the concentration of human chorionic gonadotropin (hCG) at which 95% of tests are positive. Most qualitative pregnancy tests approved by the U.S. Food and Drug Administration (FDA) report a sensitivity of 20–25 mIU/mL in urine (45–48). However, pregnancy detection rates can vary widely because of differences in test sensitivity and the timing of testing relative to missed menses (47,49). Some studies have shown that an additional 11 days past the day of expected menses are needed to detect 100% of pregnancies using qualitative tests (46). In addition, pregnancy tests cannot detect a pregnancy resulting from recent sexual intercourse. Qualitative tests also might have positive results for several weeks after termination of pregnancy

because hCG can be present for several weeks after delivery or abortion (spontaneous or induced) (50–52).

For contraceptive methods other than IUDs, the benefits of starting to use a contraceptive method likely exceed any risk, even in situations in which the health-care provider is uncertain whether the woman is pregnant. Therefore, the health-care provider can consider having patients start using contraceptive methods other than IUDs at any time, with a follow-up pregnancy test in 2–4 weeks. The risks of not starting to use contraception should be weighed against the risks of initiating contraception use in a woman who might be already pregnant. Most studies have shown no increased risk for adverse outcomes, including congenital anomalies or neonatal or infant death, among infants exposed in utero to COCs (53–55). Studies also have shown no increased risk for neonatal or infant death or developmental abnormalities among infants exposed in utero to DMPA (54,56,57).

In contrast, for women who want to begin using an IUD (Cu-IUD or LNG-IUD), in situations in which the health-care provider is uncertain whether the woman is pregnant, the woman should be provided with another contraceptive method to use until the health-care provider is reasonably certain that she is not pregnant and can insert the IUD. Pregnancies among women with IUDs are at higher risk for complications such as spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis (58).

A systematic review identified four analyses of data from three diagnostic accuracy studies that evaluated the performance of the criteria listed above through use of a pregnancy checklist compared with a urine pregnancy test conducted concurrently (12). The performance of the checklist to diagnose or exclude pregnancy varied, with sensitivity of 55%–100% and specificity of 39%–89%. The negative predictive value was consistent across studies at 99%–100%; the pregnancy checklist correctly ruled out women who were not pregnant. One of the studies assessed the added usefulness of signs and symptoms of pregnancy and found that these criteria did not substantially improve the performance of the pregnancy checklist, although the number of women with signs and symptoms was small (34) (Level of evidence: Diagnostic accuracy studies, fair, direct).

## Intrauterine Contraception

Three IUDs are available in the United States, the Cu-IUD and two LNG-IUDs (containing a total of either 13.5 mg or 52 mg levonorgestrel). Fewer than 1 woman out of 100 becomes pregnant in the first year of using IUDs (with typical use) (59). IUDs are long acting, are reversible, and can be

used by women of all ages, including adolescents, and both by parous and nulliparous women. IUDs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

## Initiation of Cu-IUDs

### Timing

- The Cu-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- The Cu-IUD also can be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive. If the day of ovulation can be estimated, the Cu-IUD also can be inserted >5 days after sexual intercourse as long as insertion does not occur >5 days after ovulation.

### Need for Back-Up Contraception

- No additional contraceptive protection is needed after Cu-IUD insertion.

### Special Considerations

#### Amenorrhea (Not Postpartum)

- **Timing:** The Cu-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

#### Postpartum (Including After Cesarean Section)

- **Timing:** The Cu-IUD can be inserted at any time postpartum, including immediately postpartum (U.S. MEC 1 or 2) (Box 2),

#### BOX 2. Categories of medical eligibility criteria for contraceptive use

U.S. MEC 1 = A condition for which there is no restriction for the use of the contraceptive method.

U.S. MEC 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

U.S. MEC 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

U.S. MEC 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

**Abbreviations:** U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.*

**Source:** CDC. U.S. medical eligibility criteria for contraceptive use. *MMWR* 2010;59(No. RR-4).

if it is reasonably certain that the woman is not pregnant (Box 1). The Cu-IUD should not be inserted in a woman with puerperal sepsis (U.S. MEC 4).

- **Need for back-up contraception:** No additional contraceptive protection is needed.

### Postabortion (Spontaneous or Induced)

- **Timing:** The Cu-IUD can be inserted within the first 7 days, including immediately postabortion (U.S. MEC 1 for first trimester abortion and U.S. MEC 2 for second trimester abortion). The Cu-IUD should not be inserted immediately after septic abortion (U.S. MEC 4).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

### Switching from Another Contraceptive Method

- **Timing:** The Cu-IUD can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** No additional contraceptive protection is needed.

**Comments and Evidence Summary.** In situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the Cu-IUD.

A systematic review identified eight studies that suggested that timing of Cu-IUD insertion in relation to the menstrual cycle in nonpostpartum women had little effect on long-term outcomes (rates of continuation, removal, expulsion, or pregnancy) or on short-term outcomes (pain at insertion, bleeding at insertion, or immediate expulsion) (13) (Level of evidence: II-2, fair, direct).

## Initiation of LNG-IUDs

### Timing of LNG-IUD Insertion

- The LNG-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).

### Need for Back-Up Contraception

- If the LNG-IUD is inserted within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the LNG-IUD is inserted >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

## Special Considerations

### Amenorrhea (Not Postpartum)

- **Timing:** The LNG-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postpartum (Including After Cesarean Section)

- **Timing:** The LNG-IUD can be inserted at any time, including immediately postpartum (U.S. MEC 1 or 2) if it is reasonably certain that the woman is not pregnant (Box 1). The LNG-IUD should not be inserted in a woman with puerperal sepsis (U.S. MEC 4).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds) (60), no additional contraceptive protection is needed. Otherwise, a woman who is  $\geq 21$  days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding began, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postabortion (Spontaneous or Induced)

- **Timing:** The LNG-IUD can be inserted within the first 7 days, including immediately postabortion (U.S. MEC 1 for first-trimester abortion and U.S. MEC 2 for second-trimester abortion). The LNG-IUD should not be inserted immediately after a septic abortion (U.S. MEC 4).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the IUD is placed at the time of a surgical abortion.

### Switching from Another Contraceptive Method

- **Timing:** The LNG-IUD can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >7 days since menstrual bleeding began, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from a Cu-IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started,

theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider can consider providing ECPs at the time of LNG-IUD insertion.

**Comments and Evidence Summary.** In situations in which the health-care provider is uncertain whether the woman might be pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the LNG-IUD. If a woman needs to use additional contraceptive protection when switching to an LNG-IUD from another contraceptive method, consider continuing her previous method for 7 days after LNG-IUD insertion. No direct evidence was found regarding the effects of inserting LNG-IUDs on different days of the cycle on short- or long-term outcomes (13).

## Examinations and Tests Needed Before Initiation of a Cu-IUD or an LNG-IUD

Among healthy women, few examinations or tests are needed before initiation of an IUD (Table 2). Bimanual examination and cervical inspection are necessary before IUD insertion. A baseline weight and BMI measurement might be useful for monitoring IUD users over time. If a woman has not been screened for STDs according to STD screening guidelines, screening can be performed at the time of insertion. Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (5).

**Comments and Evidence Summary. Weight (BMI):** Obese women can use IUDs (U.S. MEC 1) (5); therefore, screening for obesity is not necessary for the safe initiation of IUDs. However, measuring weight and calculating BMI (weight [kg] / height [m]<sup>2</sup>) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

**Bimanual examination and cervical inspection:** Bimanual examination and cervical inspection are necessary before IUD insertion to assess uterine size and position and to detect any cervical or uterine abnormalities that might indicate infection or otherwise prevent IUD insertion (61,62).

**STDs:** Women should be routinely screened for chlamydial infection and gonorrhea according to national screening guidelines. The CDC *Sexually Transmitted Diseases Treatment Guidelines* provide information on screening eligibility, timing, and frequency of screening and on screening for persons

**TABLE 2. Classification of examinations and tests needed before IUD insertion**

Examination or test	Class*	
	Copper-containing IUD	Levonorgestrel-releasing IUD
<b>Examinations</b>		
Blood pressure	C	C
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	—†	—†
Clinical breast examination	C	C
Bimanual examination and cervical inspection	A	A
<b>Laboratory tests</b>		
Glucose	C	C
Lipids	C	C
Liver enzymes	C	C
Hemoglobin	C	C
Thrombogenic mutations	C	C
Cervical cytology (Papanicolaou smear)	C	C
STD screening with laboratory tests	—§	—§
HIV screening with laboratory tests	C	C

**Abbreviations:** BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

\* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occur.

with risk factors (32). If STD screening guidelines have been followed, most women do not need additional STD screening at the time of IUD insertion. If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (5). For these women, IUD insertion should be delayed until appropriate

testing and treatment occur. A systematic review did not identify any evidence regarding women who were screened versus not screened for STDs before IUD insertion (14). Although women with STDs at the time of IUD insertion have a higher risk for PID, the overall rate of PID among all IUD users is low (63,64).

**Hemoglobin:** Women with iron-deficiency anemia can use the LNG-IUD (U.S. MEC 1) (5); therefore, screening for anemia is not necessary for safe initiation of the LNG-IUD. Women with iron-deficiency anemia generally can use the Cu-IUD (U.S. MEC 2). Measurement of hemoglobin before initiation of Cu-IUDs is not necessary because of the minimal change in hemoglobin among women with and without anemia using Cu-IUDs. A systematic review identified four studies that provided direct evidence for changes in hemoglobin among women with anemia who received Cu-IUDs (30). Evidence from one randomized trial (65) and one prospective cohort study (66) showed no significant changes in hemoglobin among Cu-IUD users with anemia, whereas two prospective cohort studies (67,68) showed a statistically significant decrease in hemoglobin levels during 12 months of follow-up; however, the magnitude of the decrease was small and most likely not clinically significant. The systematic review also identified 21 studies that provided indirect evidence by examining changes in hemoglobin among healthy women receiving Cu-IUDs (69–89), which generally showed no clinically significant changes in hemoglobin levels with up to 5 years of follow-up (Level of evidence: I to II-2, fair, direct).

**Liver enzymes:** Women with liver disease can use the Cu-IUD (U.S. MEC 1) (5); therefore, screening for liver disease is not necessary for the safe initiation of the Cu-IUD. Although women with certain liver diseases generally should not use the LNG-IUD (U.S. MEC 3) (5), screening for liver disease before initiation of the LNG-IUD is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptive use (14). The prevalence of liver disorders among women of reproductive age is low. In 2008, among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (90). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (91). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (92). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease

might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (93,94), although evidence is limited, and no evidence exists for the LNG-IUD.

**Clinical breast examination:** Women with breast disease can use the Cu-IUD (U.S. MEC 1) (5); therefore, screening for breast disease is not necessary for the safe initiation of the Cu-IUD. Although women with current breast cancer should not use the LNG-IUD (U.S. MEC 4) (5), screening asymptomatic women with a clinical breast examination before inserting an IUD is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (15). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (95).

**Cervical cytology:** Although women with cervical cancer should not undergo IUD insertion (U.S. MEC 4) (5), screening asymptomatic women with cervical cytology before IUD insertion is not necessary because of the high rates of cervical screening, low incidence of cervical cancer in the United States, and high likelihood that a woman with cervical cancer already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with cervical cytology before initiation of IUDs (14). Cervical cancer is rare in the United States, with an incidence rate of 8.1 per 100,000 women per year during 2004–2008 (95). The incidence and mortality rates from cervical cancer have declined dramatically in the United States, largely because of cervical cytology screening (96). Overall screening rates for cervical cancer in the United States are high; among women aged 22–30 years, approximately 87% reported having cervical cytology screening within the last 3 years (97).

**HIV screening:** Although women with acquired immunodeficiency syndrome (AIDS) who are not clinically well should generally not undergo IUD insertion (U.S. MEC 3) (5), HIV screening is not necessary before IUD insertion because of the high likelihood that a woman in the United States with such an advanced stage of disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened for HIV infection before IUD insertion (14). Limited evidence suggests that IUDs are not associated with disease progression, increased

infection, or other adverse health effects among women with HIV infection (98).

**Other screening:** Women with hypertension, diabetes, hyperlipidemia, or thrombogenic mutations can use (U.S. MEC 1) or generally can use (U.S. MEC 2) IUDs (5). Therefore, screening for these conditions is not necessary for the safe initiation of IUDs.

## Provision of Prophylactic Antibiotics at the Time of IUD Insertion

- Prophylactic antibiotics are generally not recommended for Cu-IUD or LNG-IUD insertion.

**Comments and Evidence Summary.** Theoretically, IUD insertion could induce bacterial spread and lead to complications such as PID or infective endocarditis. A metaanalysis was conducted of randomized controlled trials examining antibiotic prophylaxis versus placebo or no treatment for IUD insertion (99). Use of prophylaxis reduced the frequency of unscheduled return visits but did not significantly reduce the incidence of PID or premature IUD discontinuation. Although the risk for PID was higher within the first 20 days after insertion, the incidence of PID was low among all women who had IUDs inserted (63). In addition, the American Heart Association recommends that the use of prophylactic antibiotics solely to prevent infective endocarditis is not needed for genitourinary procedures (100). Studies have not demonstrated a conclusive link between genitourinary procedures and infective endocarditis or a preventive benefit of prophylactic antibiotics during such procedures (100).

## Routine Follow-Up After IUD Insertion

These recommendations address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, persons with certain medical conditions or characteristics, and persons with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time to remove or replace the contraceptive method. No routine follow-up visit is required.
- At other routine visits, health-care providers who see IUD users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.

- Assess any changes in health status, including medications, that would change the appropriateness of the IUD for safe and effective continued use on the basis of U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
- Consider performing an examination to check for the presence of the IUD strings.
- Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

**Comments and Evidence Summary.** Evidence from a systematic review about the effect of a specific follow-up visit schedule on IUD continuation is very limited and of poor quality. The evidence did not suggest that greater frequency of visits or earlier timing of the first follow-up visit after insertion improves continuation of use (16) (Level of evidence: II-2, poor, direct). Evidence from four studies from a systematic review on the incidence of PID among IUD initiators, or IUD removal as a result of PID, suggested that the incidence of PID did not differ between women using Cu-IUDs and those using DMPA, COCs, or LNG-IUDs (17) (Level of evidence: I to II-2, good, indirect). Evidence on the timing of PID after IUD insertion is mixed. Although the rate of PID was generally low, the largest study suggested that the rate of PID was significantly higher in the first 20 days after insertion (63) (Level of evidence: I to II-3, good to poor, indirect).

### Bleeding Irregularities with Cu-IUD Use

- Before Cu-IUD insertion, provide counseling about potential changes in bleeding patterns during Cu-IUD use. Unscheduled spotting or light bleeding, as well as heavy or prolonged bleeding, is common during the first 3–6 months of Cu-IUD use, is generally not harmful, and decreases with continued Cu-IUD use.
- If clinically indicated, consider an underlying gynecological problem, such as Cu-IUD displacement, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids), especially in women who have already been using the Cu-IUD for a few months or longer and who have developed a new onset of heavy or prolonged bleeding. If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecological problem is not found and the woman requests treatment, the following treatment option can be considered during days of bleeding:
  - Nonsteroidal antiinflammatory drugs (NSAIDs) for short-term treatment (5–7 days)

- If bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

**Comments and Evidence Summary.** During contraceptive counseling and before insertion of the Cu-IUD, information about common side effects such as unscheduled spotting or light bleeding or heavy or prolonged menstrual bleeding, especially during the first 3–6 months of use, should be discussed (70). These bleeding irregularities are generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce method discontinuation in clinical trials with other contraceptives (i.e., DMPA) (101,102).

Evidence is limited on specific drugs, doses, and durations of use for effective treatments for bleeding irregularities with Cu-IUD use; therefore, although this document includes general recommendations for treatments to consider, evidence for specific regimens is lacking.

A systematic review identified 11 articles that examined various therapeutic treatments for heavy menstrual bleeding, prolonged menstrual bleeding, or both among women using Cu-IUDs (18). Nine studies examined the use of various oral NSAIDs for the treatment of heavy or prolonged menstrual bleeding among Cu-IUD users and compared them to either a placebo or a baseline cycle. Three of these trials examined the use of indomethacin (103–105), another three examined mefenamic acid (106–108), and another three examined flufenamic acid (103,104,109). Other NSAIDs used in the reported trials included alclufenac (103,104), suprofen (110), and diclofenac sodium (111). All but one NSAID study (107) demonstrated statistically significant or notable reductions in mean total menstrual blood loss with NSAID use. One study among 19 Cu-IUD users with heavy bleeding suggested that treatment with oral tranexamic acid can significantly reduce mean blood loss during treatment compared with placebo (111). Data regarding the overall safety of tranexamic acid are limited; an FDA warning states that tranexamic acid is contraindicated in women with active thromboembolic disease or with a history or intrinsic risk for thrombosis or thromboembolism (112,113). Treatment with aspirin demonstrated no statistically significant change in mean blood loss among women whose pretreatment menstrual blood loss was >80 mL or 60–80 mL; treatment resulted in a significant increase among women whose pretreatment menstrual blood loss was <60 mL (114). One study examined the use of a synthetic form of vasopressin, intranasal desmopressin (300 µg/day), for the first 5 days of menses for three treatment cycles and found a significant reduction in mean blood loss

compared with baseline (106) (Level of evidence: I to II-3, poor to fair, direct). Only one small study examined treatment of spotting with three separate NSAIDs and did not observe improvements in spotting in any of the groups (103) (Level of evidence: I, poor, direct).

### Bleeding Irregularities (Including Amenorrhea) with LNG-IUD Use

- Before LNG-IUD insertion, provide counseling about potential changes in bleeding patterns during LNG-IUD use. Unscheduled spotting or light bleeding is expected during the first 3–6 months of LNG-IUD use, is generally not harmful, and decreases with continued LNG-IUD use. Over time, bleeding generally decreases with LNG-IUD use, and many women experience only light menstrual bleeding or amenorrhea. Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon during LNG-IUD use.

### Irregular Bleeding (Spotting, Light Bleeding, or Heavy or Prolonged Bleeding)

- If clinically indicated, consider an underlying gynecological problem, such as LNG-IUD displacement, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

### Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

**Comments and Evidence Summary.** During contraceptive counseling and before insertion of the LNG-IUD, information about common side effects such as unscheduled spotting or light bleeding, especially during the first 3–6 months of use, should be discussed. Approximately half of LNG-IUD users are likely to experience amenorrhea or oligomenorrhea by 2 years of use (115). These bleeding irregularities are generally not harmful. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities

are generally not harmful has been shown to reduce method discontinuation in clinical trials with other hormonal contraceptives (i.e., DMPA) (101,102). No direct evidence was found regarding therapeutic treatments for bleeding irregularities during LNG-IUD use.

### Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have PID

- Treat the PID according to the CDC *Sexually Transmitted Diseases Treatment Guidelines* (32).
- Provide comprehensive management for STDs, including counseling about condom use.
- The IUD does not need to be removed immediately if the woman needs ongoing contraception.
- Reassess the woman in 48–72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of the IUD.
- If the woman wants to discontinue use, remove the IUD sometime after antibiotics have been started to avoid the potential risk for bacterial spread resulting from the removal procedure.
- If the IUD is removed, consider ECPs if appropriate. Counsel the woman on alternative contraceptive methods, and offer another method if it is desired.
- A summary of IUD management in women with PID is provided (Appendix F).

**Comments and Evidence Summary.** Treatment outcomes do not generally differ between women with PID who retain the IUD and those who have the IUD removed; however, appropriate antibiotic treatment and close clinical follow-up are necessary.

A systematic review identified four studies that included women using copper or nonhormonal IUDs who developed PID and compared outcomes between women who had the IUD removed or did not (19). One randomized trial showed that women with IUDs removed had longer hospitalizations than those who did not, although no differences in PID recurrences or subsequent pregnancies were observed (116). Another randomized trial showed no differences in laboratory findings among women who removed the IUD compared with those who did not (117). One prospective cohort study showed no differences in clinical or laboratory findings during hospitalization; however, the IUD removal group had longer hospitalizations (118). One randomized trial showed that the rate of recovery for most clinical signs and symptoms was higher among women who had the IUD removed than among women who did not (119). No evidence was found regarding women using LNG-IUDs (Level of evidence: I to II-2, fair, direct).

## Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Be Pregnant

- Evaluate for possible ectopic pregnancy.
- Advise the woman that she has an increased risk for spontaneous abortion (including septic abortion that might be life threatening) and of preterm delivery if the IUD is left in place. The removal of the IUD reduces these risks but might not decrease the risk to the baseline level of a pregnancy without an IUD.
  - If she does not want to continue the pregnancy, counsel her about options.
  - If she wants continue the pregnancy, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

### IUD Strings Are Visible or Can Be Retrieved Safely from the Cervical Canal

- Advise the woman that the IUD should be removed as soon as possible.
  - If the IUD is to be removed, remove it by pulling on the strings gently.
  - Advise the woman that she should return promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.
- If she chooses to keep the IUD, advise her to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

### IUD Strings Are Not Visible and Cannot Be Retrieved Safely

- If ultrasonography is available, consider performing or referring for ultrasound examination to determine the location of the IUD. If the IUD cannot be located, it might have been expelled or have perforated the uterine wall.
- If ultrasonography is not possible or the IUD is determined by ultrasound to be inside the uterus, advise the woman to seek care promptly if she has heavy bleeding, cramping, pain, abnormal vaginal discharge, or fever.

**Comments and Evidence Summary.** Removing the IUD improves the pregnancy outcome if the IUD strings are visible or the device can be retrieved safely from the cervical canal. Risks for spontaneous abortion, preterm delivery, and infection are substantial if the IUD is left in place.

Theoretically, the fetus might be affected by hormonal exposure from an LNG-IUD; however, whether this exposure increases the risk for fetal abnormalities is unknown.

A systematic review identified nine studies suggesting that women who did not remove their IUDs during pregnancy were at greater risk for adverse pregnancy outcomes (including

spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis) compared with women who had their IUDs removed or who did not have an IUD (58). Cu-IUD removal decreased risks but not to the baseline risk for pregnancies without an IUD. One case series examined LNG-IUDs. When they were not removed, eight in 10 pregnancies ended in spontaneous abortions (Level of evidence: II-2, fair, direct).

## Implants

The etonogestrel implant, a single rod with 68 mg of etonogestrel, is available in the United States. Fewer than 1 woman out of 100 become pregnant in the first year of use of the etonogestrel implant with typical use (59). The implant is long acting, is reversible, and can be used by women of all ages, including adolescents. The implant does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

## Initiation of Implants

### Timing

- The implant can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).

### Need for Back-Up Contraception

- If the implant is inserted within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the implant is inserted >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Special Considerations

#### Amenorrhea (Not Postpartum)

- **Timing:** The implant can be inserted at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

#### Postpartum (Breastfeeding)

- **Timing:** The implant can be inserted at any time (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds



are breastfeeds) (60), no additional contraceptive protection is needed. Otherwise, a woman who is  $\geq 21$  days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been  $>5$  days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postpartum (Not Breastfeeding)

- **Timing:** The implant can be inserted at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** A woman who is  $\geq 21$  days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been  $>5$  days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postabortion (Spontaneous or Induced)

- **Timing:** The implant can be inserted within the first 7 days, including immediately after the abortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the implant is placed at the time of a surgical abortion.

### Switching from Another Contraceptive Method

- **Timing:** The implant can be inserted immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been  $>5$  days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days after insertion.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been  $>5$  days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the woman to retain the IUD for at least 7 days after the implant is inserted and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

**Comments and Evidence Summary.** In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant likely exceed any risk; therefore, starting the implant should be considered at any time, with a follow-up pregnancy test in 2–4 weeks.

If a woman needs to use additional contraceptive protection when switching to an implant from another contraceptive method, consider continuing her previous method for 7 days after implant insertion. No direct evidence was found regarding the effects of starting the etonogestrel implant at different times of the cycle.

## Examinations and Tests Needed Before Implant Insertion

Among healthy women, no examinations or tests are needed before initiation of an implant, although a baseline weight and BMI measurement might be useful for monitoring implant users over time (Table 3). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (5).

**TABLE 3. Classification of examinations and tests needed before implant insertion**

Examination or test	Class*
<b>Examination</b>	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	— <sup>†</sup>
Clinical breast examination	C
Bimanual examination and cervical inspection	C
<b>Laboratory test</b>	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

**Abbreviations:** BMI = body mass index; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

\* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

<sup>†</sup> Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

**Comments and Evidence Summary. Weight (BMI):** Obese women can use implants (U.S. MEC 1) (5); therefore, screening for obesity is not necessary for the safe initiation of implants. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

**Bimanual examination and cervical inspection:** A pelvic examination is not necessary before initiation of implants because it would not facilitate detection of conditions for which implant use would be unsafe. Women with current breast cancer should not use implants (U.S. MEC 4); women with certain liver diseases generally should not use implants (U.S. MEC 3) (5). However, none of these conditions are likely to be detected by pelvic examination (120). A systematic review identified two case-control studies that compared delayed and immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (15). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed. No evidence was found regarding implants (Level of evidence: II-2 fair, direct).

**Liver enzymes:** Although women with certain liver diseases generally should not use implants (U.S. MEC 3) (5), screening for liver disease before initiation of implants is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (14). The prevalence of liver disorders among women of reproductive age is low. In 2008, the percentage of adults aged 18–44 years with liver disease (not further specified) was 1.0% (90). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (91). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (92). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (93,94), although evidence is limited and no evidence exists for implants.

**Clinical breast examination:** Although women with current breast cancer should not use implants (U.S. MEC 4) (5), screening asymptomatic women with a clinical breast

examination before initiating an implant is not necessary because of the low prevalence of breast cancer among women of reproductive age (15–49 years). A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (15). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (95).

**Other screening:** Women with hypertension, diabetes, hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, STDs, or HIV infection can use (U.S. MEC 1) or generally can use (U.S. MEC 2) implants (5); therefore, screening for these conditions is not necessary for the safe initiation of implants.

## Routine Follow-Up After Implant Insertion

These recommendations address when routine follow-up is needed for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time to remove or replace the contraceptive method. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing implant users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of the implant for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

**Comments and Evidence Summary.** A systematic review did not identify any evidence regarding whether a routine follow-up visit after initiating an implant improves correct or continued use (16).

## Bleeding Irregularities (Including Amenorrhea) During Implant Use

- Before implant insertion, provide counseling about potential changes in bleeding patterns during implant use. Unscheduled spotting or light bleeding is common with implant use, and some women experience amenorrhea. These bleeding changes are generally not harmful and might or might not decrease with continued implant use. Heavy or prolonged bleeding, unscheduled or menstrual, is uncommon during implant use.

### Irregular Bleeding (Spotting, Light Bleeding, or Heavy or Prolonged Bleeding)

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment options during days of bleeding can be considered:
  - NSAIDs for short-term treatment (5–7 days)
  - Hormonal treatment (if medically eligible) with low-dose COCs or estrogen for short-term treatment (10–20 days)
- If irregular bleeding persists and the woman finds it unacceptable, counsel her on alternative methods, and offer another method if it is desired.

### Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

**Comments and Evidence Summary.** During contraceptive counseling and before insertion of the implant, information about common side effects, such as unscheduled spotting or light bleeding and amenorrhea, especially during the first year of use should be discussed. A pooled analysis of data from 11 clinical trials indicate that a significant proportion of etonogestrel implant users had relatively little bleeding: 22% of women experienced amenorrhea and 34% experienced infrequent spotting, although 7% reported frequent bleeding and 18% reported prolonged bleeding (121). Unscheduled bleeding or amenorrhea is generally not harmful. Enhanced

counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce discontinuation in clinical trials with other hormonal contraceptives (i.e., DMPA) (101,102).

A systematic review and four newly published studies examined several medications for the treatment of bleeding irregularities with primarily LNG contraceptive implants (122–126). Two small studies found significant cessation of bleeding within 7 days of start of treatment among women taking oral celecoxib (200 mg) daily for 5 days or oral mefenamic acid (500 mg) 3 times daily for 5 days compared with placebo (124,125). Differences in bleeding cessation were not found among women with etonogestrel implants taking mifepristone but were found when women with the implants combined mifepristone with either ethinyl estradiol or doxycycline (126,127). Doxycycline alone or in combination with ethinyl estradiol did not improve bleeding cessation among etonogestrel implant users (126). Among LNG implant users, mifepristone reduced the number of bleeding or spotting days but only after 6 months of treatment (128). Evidence also suggests that estrogen (129–131), daily COCs (129), levonorgestrel pills (130), tamoxifen (132), or tranexamic acid (133) can reduce the number of bleeding or spotting days during treatment among levonorgestrel implant users. In one small study, vitamin E was found to significantly reduce the mean number of bleeding days after the first treatment cycle; however, another larger study reported no significant differences in length of bleeding and spotting episodes with vitamin E treatment (134,135). Use of aspirin did not result in a significant difference in median length of bleeding or bleeding and spotting episodes after treatment (134). One study among implant users reported a reduction in number of bleeding days after initiating ibuprofen; however, another trial did not demonstrate any significant differences in the number of spotting and bleeding episodes with ibuprofen compared with placebo (123,130).

## Injectables

Progestin-only injectable contraceptives (DMPA, 150 mg intramuscularly or 104 mg subcutaneously) are available in the United States; the only difference between these two formulations is the route of administration. Approximately 6 out of 100 women will become pregnant in the first year of use of DMPA with typical use (59). DMPA is reversible and can be used by women of all ages, including adolescents. DMPA does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

## Initiation of Injectables

### Timing

- The first DMPA injection can be given at any time if it is reasonably certain that the woman is not pregnant (Box 1).

### Need for Back-Up Contraception

- If DMPA is started within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If DMPA is started >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Special Considerations

#### Amenorrhea (Not Postpartum)

- **Timing:** The first DMPA injection can be given at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

#### Postpartum (Breastfeeding)

- **Timing:** The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (60), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

#### Postpartum (Not Breastfeeding)

- **Timing:** The first DMPA injection can be given at any time, including immediately postpartum (U.S. MEC 1) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** A woman who is ≥21 days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual

intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >7 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postabortion (Spontaneous or Induced)

- **Timing:** The first DMPA injection can be given within the first 7 days, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless the injection is given at the time of a surgical abortion.

### Switching from Another Contraceptive Method

- **Timing:** The first DMPA injection can be given immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >7 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 7 days after the injection and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

**Comments and Evidence Summary.** In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting DMPA likely exceed any risk; therefore, starting DMPA should be considered at any time, with a follow-up pregnancy test in 2–4 weeks. If a woman needs to use additional contraceptive protection when switching to DMPA from another contraceptive method, consider continuing her previous method for 7 days after DMPA injection.

A systematic review identified eight articles examining DMPA initiation on different days of the menstrual cycle (20). Evidence from two studies with small samples indicated that DMPA injections given up to day 7 of the menstrual cycle inhibited ovulation; when DMPA was administered after

day 7, ovulation occurred in some women. Cervical mucus was of poor quality (i.e., not favorable for sperm penetration) in 90% of women within 24 hours of the injection (Level of evidence: II-2, fair) (136–138). Studies found that use of another contraceptive method until DMPA could be initiated (bridging option) did not help women initiate DMPA and was associated with more unintended pregnancies than immediate receipt of DMPA (139–143) (Level of evidence: I to II-3, fair to poor, indirect).

### Examinations and Tests Needed Before Initiation of an Injectable

Among healthy women, no examinations or tests are needed before initiation of DMPA, although a baseline weight and BMI measurement might be useful for monitoring DMPA users over time (Table 4). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (5).

**Comments and Evidence Summary. Weight (BMI):** Obese women can use (U.S. MEC 1) or generally can use (U.S. MEC 2) DMPA (5); therefore, screening for obesity is not necessary for

the safe initiation of DMPA. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method. (See guidance on follow-up for DMPA users for evidence on weight gain with DMPA use.)

**Bimanual examination and cervical inspection:** Pelvic examination is not necessary before initiation of DMPA because it does not facilitate detection of conditions for which DMPA would be unsafe. Although women with current breast cancer should not use DMPA (U.S. MEC 4), and women with severe hypertension, heart disease, vascular disease, migraine headaches with aura, or certain liver diseases generally should not use DMPA (U.S. MEC 3) (5), none of these conditions are likely to be detected by pelvic examination (120). A systematic review identified two case-control studies that compared delayed versus immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (15). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed (Level of evidence: II-2, fair, direct).

**Blood pressure:** Women with hypertension generally can use DMPA (U.S. MEC 2), with the exception of women with severe hypertension or vascular disease, who generally should not use DMPA (U.S. MEC 3) (5). Screening for hypertension before initiation of DMPA is not necessary because of the low prevalence of undiagnosed severe hypertension and the high likelihood that women with these conditions already would have had them diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a blood pressure measurement before initiation of progestin-only contraceptives (21). The prevalence of undiagnosed hypertension among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, the percentage with diagnosed hypertension was 7.8%, and the percentage with undiagnosed hypertension was 1.9% (144).

**Glucose:** Although women with complicated diabetes generally should not use DMPA (U.S. MEC 3) (5), screening for diabetes before initiation of DMPA is not necessary because of the low prevalence of undiagnosed diabetes and the high likelihood that women with complicated diabetes would already have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with glucose measurement before initiation of hormonal contraceptives (14). The prevalence of diabetes among women of reproductive age is low. During 1999–2008 among women aged 20–44 years

**TABLE 4. Classification of examinations and tests needed before DMPA initiation**

Examination or test	Class*
<b>Examination</b>	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	—†
Clinical breast examination	C
Bimanual examination and cervical inspection	C
<b>Laboratory test</b>	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

**Abbreviations:** BMI = body mass index; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

\* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

in the United States, the percentage with diagnosed diabetes was 3% and the percentage with undiagnosed diabetes was 0.5% (144). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (145–151).

**Liver enzymes:** Although women with certain liver diseases generally should not use DMPA (U.S. MEC 3) (5), screening for liver disease before initiation of DMPA is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (14). The prevalence of liver disorders among women of reproductive age is low. In 2008 among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (90). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (91). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (92). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (93,94), although evidence is limited and no evidence exists for DMPA.

**Clinical breast examination:** Although women with current breast cancer should not use DMPA (U.S. MEC 4) (5), screening asymptomatic women with a clinical breast examination before initiating DMPA is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a clinical breast examination before initiation of hormonal contraceptives (15). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (95).

**Other screening:** Women with hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, HIV infection, or other STDs can use (U.S. MEC 1) or generally can use (U.S. MEC 2) DMPA (5); therefore, screening for these conditions is not necessary for the safe initiation of DMPA.

## Routine Follow-Up After Injectable Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems, if she wants to change the method being used, and when it is time for reinjection. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing injectable users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of the injectable for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

**Comments and Evidence Summary.** Although no evidence exists regarding whether a routine follow-up visit after initiating DMPA improves correct or continued use, monitoring weight or BMI change over time is important for DMPA users.

A systematic review identified a limited body of evidence that examined whether weight gain in the few months after DMPA initiation predicted future weight gain (17). Two studies found significant differences in weight gain or BMI at follow-up periods ranging from 12 to 36 months between early weight gainers (i.e., those who gained >5% of their baseline body weight within 6 months after initiation) and those who were not early weight gainers (152,153). The differences between groups were more pronounced at 18, 24, and 36 months than at 12 months. One study found that most adolescent DMPA users who had gained >5% of their baseline weight by 3 months gained even more weight by 12 months (154) (Level of evidence: II-2, fair, to II-3, fair, direct).

## Timing of Repeat Injections

### Reinjection Interval

- Provide repeat DMPA injections every 3 months (13 weeks).

## Special Considerations

### Early Injection

- The repeat DMPA injection can be given early when necessary.

### Late Injection

- The repeat DMPA injection can be given up to 2 weeks late (15 weeks from the last injection) without requiring additional contraceptive protection.
- If the woman is >2 weeks late (>15 weeks from the last injection) for a repeat DMPA injection, she can have the injection if it is reasonably certain that she is not pregnant (Box 1). She needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. She might consider the use of emergency contraception if appropriate.

**Comments and Evidence Summary.** There are no time limits on early injections; injections can be given when necessary (e.g., when a woman cannot return at the routine interval). WHO has extended the time that a woman can have a late reinjection (i.e., grace period) for DMPA use from 2 weeks to 4 weeks on the basis of data from one study showing low pregnancy rates through 4 weeks; however, the CDC expert group did not consider the data to be generalizable to the United States because a large proportion of women in the study were breastfeeding. Therefore, U.S. SPR recommends a grace period of 2 weeks.

A systematic review identified 12 studies evaluating time to pregnancy or ovulation after the last injection of DMPA (155). Although pregnancy rates were low during the 2-week interval following the reinjection date and for 4 weeks following the reinjection date, data were sparse and one study included a large proportion of breastfeeding women (156–158). Studies also indicated a wide variation in time to ovulation after the last DMPA injection, with the majority ranging from 15 to 49 weeks from the last injection (159–167) (Level of evidence: II-2, fair, direct).

## Bleeding Irregularities (Including Amenorrhea) During Injectable Use

- Before DMPA initiation, provide counseling about potential changes in bleeding patterns during DMPA use. Amenorrhea and unscheduled spotting or light bleeding is common with DMPA use, and heavy or prolonged bleeding can occur with DMPA use. These bleeding irregularities are generally not harmful and might decrease with continued DMPA use.

## Unscheduled Spotting or Light Bleeding

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment option during days of bleeding can be considered:
  - NSAIDs for short-term treatment (5–7 days)
- If unscheduled spotting or light bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

## Heavy or Prolonged Bleeding

- If clinically indicated, consider an underlying gynecological problem, such as interactions with other medications, an STD, pregnancy, or new pathologic uterine conditions (such as fibroids or polyps). If an underlying gynecologic problem is identified, treat the condition or refer for care.
- If an underlying gynecologic problem is not found and the woman wants treatment, the following treatment options during days of bleeding can be considered:
  - NSAIDs for short-term treatment (5–7 days)
  - Hormonal treatment (if medically eligible) with low-dose COCs or estrogen for short-term treatment (10–20 days)
- If heavy or prolonged bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

## Amenorrhea

- Amenorrhea does not require any medical treatment. Provide reassurance.
  - If a woman's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated.
- If amenorrhea persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

**Comments and Evidence Summary.** During contraceptive counseling and before initiation of DMPA, information about common side effects such as irregular bleeding should be discussed. Unscheduled bleeding or spotting is common with DMPA use (168). Additionally, amenorrhea is common after ≥1 years of continuous use (168,169). These bleeding irregularities are generally not harmful. Enhanced counseling among DMPA users detailing expected bleeding patterns and

reassurance that these irregularities generally are not harmful has been shown to reduce DMPA discontinuation in clinical trials (101,102).

A systematic review, as well as two additional studies, examined the treatment of bleeding irregularities during DMPA use (122,170,171). Two small studies found significant cessation of bleeding within 7 days of starting treatment among women taking valdecoxib for 5 days or mefenamic acid for 5 days compared with placebo (172,173). Treatment with ethinyl estradiol was found to stop bleeding better than placebo during the treatment period, although rates of discontinuation were high, and safety outcomes were not examined (174). In one small study among DMPA users who had been experiencing amenorrhea for 2 months, treatment with COCs was found to alleviate amenorrhea better than placebo (175). No studies examined the effects of aspirin on bleeding irregularities among DMPA users.

## Combined Hormonal Contraceptives

Combined hormonal contraceptives contain both estrogen and a progestin and include 1) COCs (various formulations), 2) a transdermal contraceptive patch (which releases 150  $\mu\text{g}$  of norelgestromin and 20  $\mu\text{g}$  ethinyl estradiol daily), and 3) a vaginal contraceptive ring (which releases 120  $\mu\text{g}$  etonogestrel and 15  $\mu\text{g}$  ethinyl estradiol daily). Approximately 9 out of 100 women become pregnant in the first year of use with combined hormonal contraceptives with typical use (59). These methods are reversible and can be used by women of all ages. Combined hormonal contraceptives are generally used for 21–24 consecutive days, followed by 4–7 hormone-free days (either no use or placebo pills). These methods are sometimes used for an extended period with infrequent or no hormone-free days. Combined hormonal contraceptives do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

### Initiation of Combined Hormonal Contraceptives

#### Timing

- Combined hormonal contraceptives can be initiated at any time if it is reasonably certain that the woman is not pregnant (Box 1).

#### Need for Back-Up Contraception

- If combined hormonal contraceptives are started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.

- If combined hormonal contraceptives are started >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

## Special Considerations

### Amenorrhea (Not Postpartum)

- **Timing:** Combined hormonal contraceptives can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postpartum (Breastfeeding)

- **Timing:** Combined hormonal contraceptives can be started when the woman is medically eligible to use the method (176) and if it is reasonably certain that she is not pregnant. (Box 1).
  - Postpartum women who are breastfeeding should not use combined hormonal contraceptives during the first 3 weeks after delivery (U.S. MEC 4) because of concerns about increased risk for venous thromboembolism and generally should not use combined hormonal contraceptives during the fourth week postpartum (U.S. MEC 3) because of concerns about potential effects on breastfeeding performance. Postpartum, breastfeeding women with other risk factors for venous thromboembolism generally should not use combined hormonal contraceptives 4–6 weeks after delivery (U.S. MEC 3).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds) (60), no additional contraceptive protection is needed. Otherwise, a woman who is  $\geq 21$  days postpartum and has not experienced return of her menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postpartum (Not Breastfeeding)

- **Timing:** Combined hormonal contraceptives can be started when the woman is medically eligible (176) and if it is reasonably certain that she is not pregnant (Box 1).
  - Postpartum women should not use combined hormonal contraceptives during the first 3 weeks after delivery (U.S. MEC 4) because of concerns about increased risk



for venous thromboembolism. Postpartum women with other risk factors for venous thromboembolism generally should not use combined hormonal contraceptives 3–6 weeks after delivery (U.S. MEC 3).

- **Need for back-up contraception:** A woman who is  $\geq 21$  days postpartum and whose menstrual cycles have not returned needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days. If her menstrual cycles have returned and it has been  $>5$  days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

### Postabortion (Spontaneous or Induced)

- **Timing:** Combined hormonal contraceptives can be started within the first 7 days after first or second trimester abortion, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** She needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless combined hormonal contraceptives are started at the time of a surgical abortion.

### Switching from Another Contraceptive Method

- **Timing:** Combined hormonal contraceptives can be started immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been  $>5$  days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been  $>5$  days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 7 days after combined hormonal contraceptives are initiated and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

**Comments and Evidence Summary.** In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting combined hormonal contraceptives likely exceed any risk; therefore, starting combined hormonal contraceptives should be considered at any time, with a follow-up pregnancy test in 2–4 weeks. If a

woman needs to use additional contraceptive protection when switching to combined hormonal contraceptives from another contraceptive method, consider continuing her previous method for 7 days after starting combined hormonal contraceptives.

A systematic review of 18 studies examined the effects of starting combined hormonal contraceptives on different days of the menstrual cycle (22). Overall, the evidence suggested that pregnancy rates did not differ by the timing of combined hormonal contraceptive initiation (143,177–179) (Level of evidence: I to II-3, fair, indirect). The more follicular activity that occurred before starting COCs, the more likely ovulation was to occur; however, no ovulations occurred when COCs were started at a follicle diameter of 10 mm (mean cycle day 7.6) or when the ring was started at 13 mm (median cycle day 11) (180–189) (Level of evidence: I to II-3, fair, indirect). Bleeding patterns and other side effects did not vary with the timing of combined hormonal contraceptive initiation (177,178,190–194) (Level of evidence: I to II-2, good to poor, direct). Although continuation rates of combined hormonal contraceptives were initially improved by the “quick start” approach (i.e., starting on the day of the visit), the advantage disappeared over time (178,179,190–195) (Level of evidence: I to II-2, good to poor, direct).

## Examinations and Tests Needed Before Initiation of Combined Hormonal Contraceptives

Among healthy women, few examinations or tests are needed before initiation of combined hormonal contraceptives (Table 5). Blood pressure should be measured before initiation of combined hormonal contraceptives. Baseline weight and BMI measurements might be useful for monitoring combined hormonal contraceptive users over time. Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. U.S. MEC might be useful in such circumstances (5).

**Comments and Evidence Summary. Blood pressure:** Women who have more severe hypertension (systolic pressure of  $\geq 160$  mm Hg or diastolic pressure of  $\geq 100$  mm Hg) or vascular disease should not use combined hormonal contraceptives (U.S. MEC 4), and women who have less severe hypertension (systolic pressure of 140–159 mm Hg or diastolic pressure of 90–99 mm Hg) or adequately controlled hypertension generally should not use combined hormonal contraceptives (U.S. MEC 3) (5). Therefore, blood pressure should be measured before initiating combined hormonal contraceptives. If access to health care is limited, blood pressure measurements may be obtained in nonclinical settings, such as

**TABLE 5. Classification of examinations and tests needed before combined hormonal contraceptive initiation**

Examination or laboratory test	Class*
<b>Examination</b>	
Blood pressure	A <sup>†</sup>
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	— <sup>§</sup>
Clinical breast examination	C
Bimanual examination and cervical inspection	C
<b>Laboratory test</b>	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

**Abbreviations:** BMI = body mass index; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

\* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

<sup>†</sup> In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

<sup>§</sup> Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

pharmacies or fire stations, and reported by the woman to her provider. Evidence suggests that cardiovascular outcomes are worse among women who did not have their blood pressure measured before initiating COCs.

A systematic review identified six articles from three studies that reported cardiovascular outcomes among women who had blood pressure measurements and women who did not have blood pressure measurements before initiating COCs (21). Three case-control studies showed that women who did not have blood pressure measurements before initiating COCs had a higher risk for acute myocardial infarction than women who did have blood pressure measurements (196–198). Two case-control studies showed that women who did not have blood pressure measurements before initiating COCs had a higher risk for ischemic stroke than women who did have blood pressure measurements (199,200). One case-control study showed no difference in the risk for hemorrhagic stroke among women who initiated COCs regardless of whether their blood pressure was measured (201). Studies that examined hormonal contraceptive methods other than COCs were not identified (Level of evidence: II-2, fair, direct).

**Weight (BMI):** Obese women generally can use combined hormonal contraceptives (U.S. MEC 2) (5); therefore, screening for obesity is not necessary for the safe initiation of combined hormonal contraceptives. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

**Bimanual examination and cervical inspection:** Pelvic examination is not necessary before initiation of combined hormonal contraceptives because it does not facilitate detection of conditions for which hormonal contraceptives would be unsafe. Women with certain conditions such as current breast cancer, severe hypertension or vascular disease, heart disease, migraine headaches with aura, and certain liver diseases, as well as women aged  $\geq 35$  years who smoke  $\geq 15$  cigarettes per day, should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives (5); however, none of these conditions are likely to be detected by pelvic examination (120). A systematic review identified two case-control studies that compared delayed and immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (15). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were found (Level of evidence: II-2 fair, direct).

**Glucose:** Although women with complicated diabetes should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives, depending on the severity of the condition (5), screening for diabetes before initiation of hormonal contraceptives is not necessary because of the low prevalence of undiagnosed diabetes and the high likelihood that women with complicated diabetes already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with glucose measurement before initiation of hormonal contraceptives (14). The prevalence of diabetes among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, the percentage with diagnosed diabetes was 3% and the percentage with undiagnosed diabetes was 0.5% (144). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (145–151).

**Lipids:** Although some women with hyperlipidemias generally should not use combined hormonal contraceptives (U.S. MEC 2/3, depending on the type and severity of the hyperlipidemia and presence of other cardiovascular risk factors) (5), screening for hyperlipidemia before initiation of

hormonal contraceptives is not necessary because of the low prevalence of undiagnosed disease in women of reproductive age and the low likelihood of clinically significant changes with use of hormonal contraceptives. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with lipid measurement before initiation of hormonal contraceptives (14). The prevalence of hyperlipidemia among women of reproductive age is low. During 1999–2008 among women aged 20–44 years in the United States, approximately 10% had hypercholesterolemia, defined as total cholesterol  $\geq$  240 mg/dL or currently taking lipid-lowering medications, and the prevalence of undiagnosed hypercholesterolemia was approximately 2% (144). Studies have shown mixed results about the effects of hormonal methods on lipid levels, and the clinical significance of these changes is unclear (202–204). In addition, women with abnormal lipid levels at baseline were not found to have increased risk for adverse changes to their lipid profile when using hormonal methods (202).

**Liver enzymes:** Although women with certain liver diseases should not use (U.S. MEC 4) or generally should not use (U.S. MEC 3) combined hormonal contraceptives (5), screening for liver disease before initiation of combined hormonal contraceptives is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (14). The prevalence of liver disorders among women of reproductive age is low. In 2008 among adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (90). In 2009, the incidence of acute hepatitis A, B, or C among women was  $<$ 1 per 100,000 population (91). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (92). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (93,94), although evidence is limited; no evidence exists for other types of combined hormonal contraceptives.

**Thrombogenic mutations:** Women with thrombogenic mutations should not use combined hormonal contraceptives (U.S. MEC 4) (5) because of the increased risk for venous thromboembolism (205). However, studies have shown that universal screening for thrombogenic mutations before

initiating COCs is not cost-effective because of the rarity of the conditions and the high cost of screening (206–208).

**Clinical breast examination:** Although women with current breast cancer should not use combined hormonal contraceptives (U.S. MEC 4) (5), screening asymptomatic women with a clinical breast examination before initiating combined hormonal contraceptives is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a breast examination before initiation of hormonal contraceptives (15). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women aged 20–49 years was approximately 72 per 100,000 women (95).

**Other screening:** Women with anemia, cervical intraepithelial neoplasia, cervical cancer, HIV infection, or other STDs can use (U.S. MEC 1) or generally can use (U.S. MEC 2) combined hormonal contraceptives (5); therefore, screening for these conditions is not necessary for the safe initiation of combined hormonal contraceptives.

## Number of Pill Packs that Should Be Provided at Initial and Return Visits

- At the initial and return visits, provide or prescribe up to a 1-year supply of COCs (e.g., 13 28-day pill packs), depending on the woman's preferences and anticipated use.
- A woman should be able to obtain COCs easily in the amount and at the time she needs them.

**Comments and Evidence Summary.** The more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy.

A systematic review of the evidence suggested that providing a greater number of pill packs was associated with increased continuation (23). Studies that compared provision of one versus 12 packs, one versus 12 or 13 packs, or three versus seven packs found increased continuation of pill use among women provided with more pill packs (209–211). However, one study found that there was no difference in continuation when patients were provided one and then three packs versus four packs all at once (212). In addition to continuation, a greater number of pills packs provided was associated with fewer pregnancy tests, fewer pregnancies, and lower cost per client. However, a greater number of pill packs (i.e., 13 packs versus three packs) also was associated with increased pill wastage in one study (210) (Level of evidence: I to II-2, fair, direct).

## Routine Follow-Up After Combined Hormonal Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems or if she wants to change the method being used. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing combined hormonal contraceptive users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of combined hormonal contraceptives for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Assess blood pressure.
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

**Comments and Evidence Summary.** No evidence exists regarding whether a routine follow-up visit after initiating combined hormonal contraceptives improves correct or continued use. Monitoring blood pressure is important for combined hormonal contraceptive users. Health-care providers might consider recommending women obtain blood pressure measurements in nonclinical settings (e.g., pharmacy or fire station).

A systematic review identified five studies that examined the incidence of hypertension among women who began using a COC versus those who started a nonhormonal method of contraception or a placebo (17). Few women developed hypertension after initiating COCs, and studies examining increases in blood pressure after COC initiation found mixed results. No studies were identified that examined changes in blood pressure among patch or vaginal ring users (Level of evidence: I, fair, to II-2, fair, indirect).

## Late or Missed Doses and Side Effects from Combined Hormonal Contraceptive Use

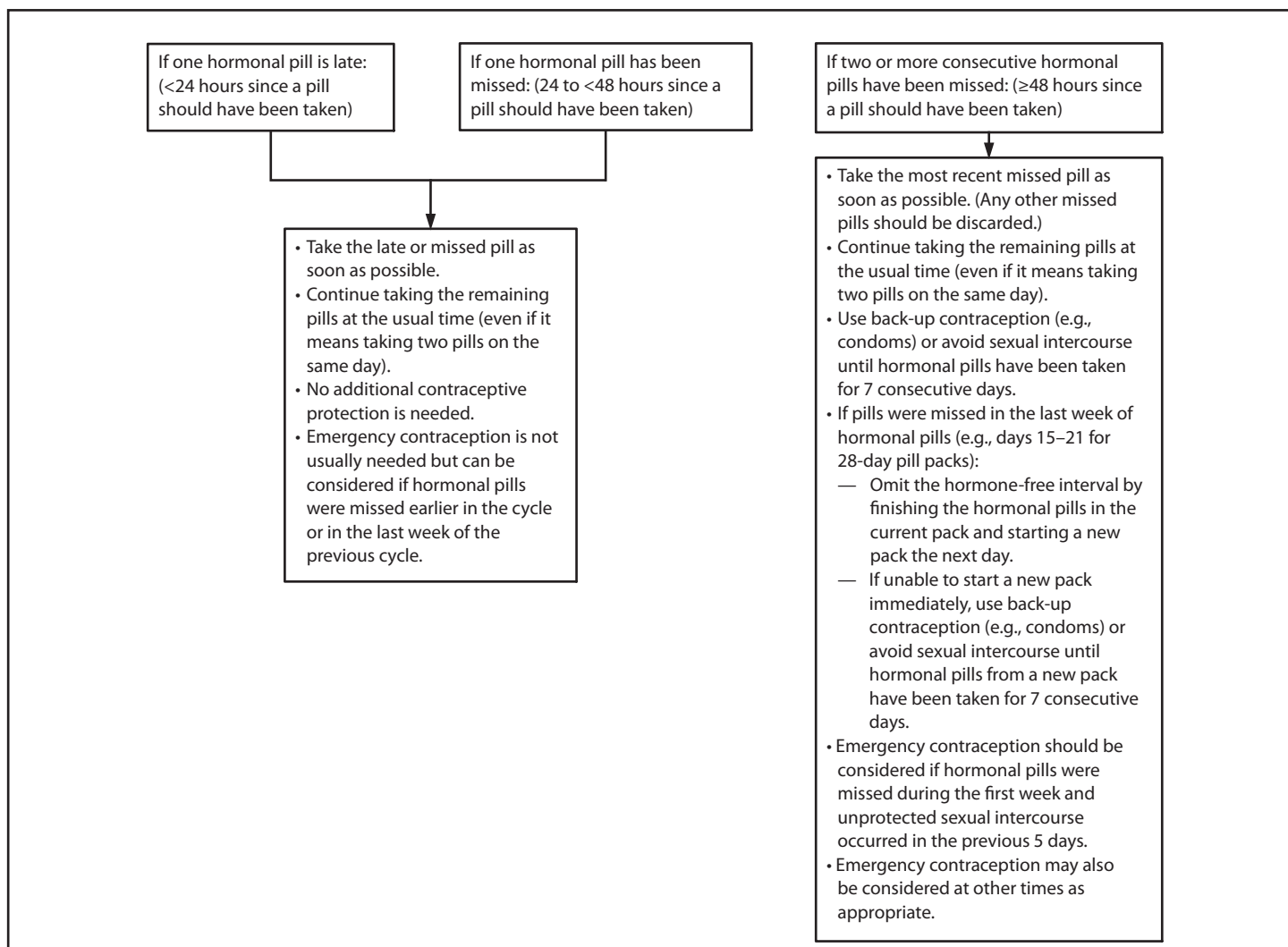
For the following recommendations, a dose is considered late when <24 hours have elapsed since the dose should have

been taken. A dose is considered missed if  $\geq 24$  hours have elapsed since the dose should have been taken. For example, if a COC pill was supposed to have been taken on Monday at 9:00 a.m. and is taken at 11:00 a.m., the pill is late; however, by Tuesday morning at 11:00 a.m., Monday's 9:00 a.m. pill has been missed and Tuesday's 9:00 a.m. pill is late. For COCs, the recommendations only apply to late or missed hormonally active pills and not to placebo pills. Recommendations are provided for late or missed pills (Figure 2), the patch (Figure 3), and the ring (Figure 4).

**Comments and Evidence Summary.** Inconsistent or incorrect use of combined hormonal contraceptives is a major cause of combined hormonal contraceptive failure. Extending the hormone-free interval is considered to be a particularly risky time to miss combined hormonal contraceptives. Seven days of continuous combined hormonal contraceptive use is deemed necessary to reliably prevent ovulation. The recommendations reflect a balance between simplicity and precision of science. Women who frequently miss COCs or experience other usage errors with combined hormonal patch or combined vaginal ring should consider an alternative contraceptive method that is less dependent on the user to be effective (e.g., IUD, implant, or injectable).

A systematic review identified 36 studies that examined measures of contraceptive effectiveness of combined hormonal contraceptives during cycles with extended hormone-free intervals, shortened hormone-free intervals, or deliberate nonadherence on days not adjacent to the hormone-free interval (24). Most of the studies examined COCs (188,213–240), two examined the combined hormonal patch (234,241), and six examined the combined vaginal ring (185,242–246). No direct evidence on the effect of missed pills on the risk for pregnancy was found. Studies of women deliberately extending the hormone-free interval up to 14 days found wide variability in the amount of follicular development and occurrence of ovulation (216,219,221,222,224,225,227–230); in general, the risk for ovulation was low, and among women who did ovulate, cycles were usually abnormal. In studies of women who deliberately missed pills on various days during the cycle not adjacent to the hormone-free interval, ovulation occurred infrequently (214,220–222,230,231,233,234). Studies comparing 7-day hormone-free intervals with shorter hormone-free intervals found lower rates of pregnancy (213,217,226,232) and significantly greater suppression of ovulation (215,225,236–238,240) among women with shorter intervals in all but one study (235), which found no difference. Two studies that compared 30- $\mu\text{g}$  ethinyl estradiol pills with 20- $\mu\text{g}$  ethinyl estradiol pills showed more follicular activity when 20- $\mu\text{g}$  ethinyl estradiol pills were missed (216,219). In

FIGURE 2. Recommended actions after late or missed combined oral contraceptives



studies examining the combined vaginal ring, three studies found that nondeliberate extension of the hormone-free interval for 24 to <48 hours from the scheduled period did not increase the risk for pregnancy (242,243,245); one study found that ring insertion after a deliberately extended hormone-free interval that allowed a 13-mm follicle to develop interrupted ovarian function and further follicular growth (185); and one study found that inhibition of ovulation was maintained after deliberately forgetting to remove the ring for up to 2 weeks after normal ring use (246). In studies examining the combined hormonal patch, one study found that missing 1–3 consecutive days before patch replacement (either wearing one patch 3 days longer before replacement or going 3 days without a patch before replacing the next patch) on days not adjacent to the patch-free interval resulted in little follicular activity and low risk for ovulation (234), and one pharmacokinetic study found that serum levels of

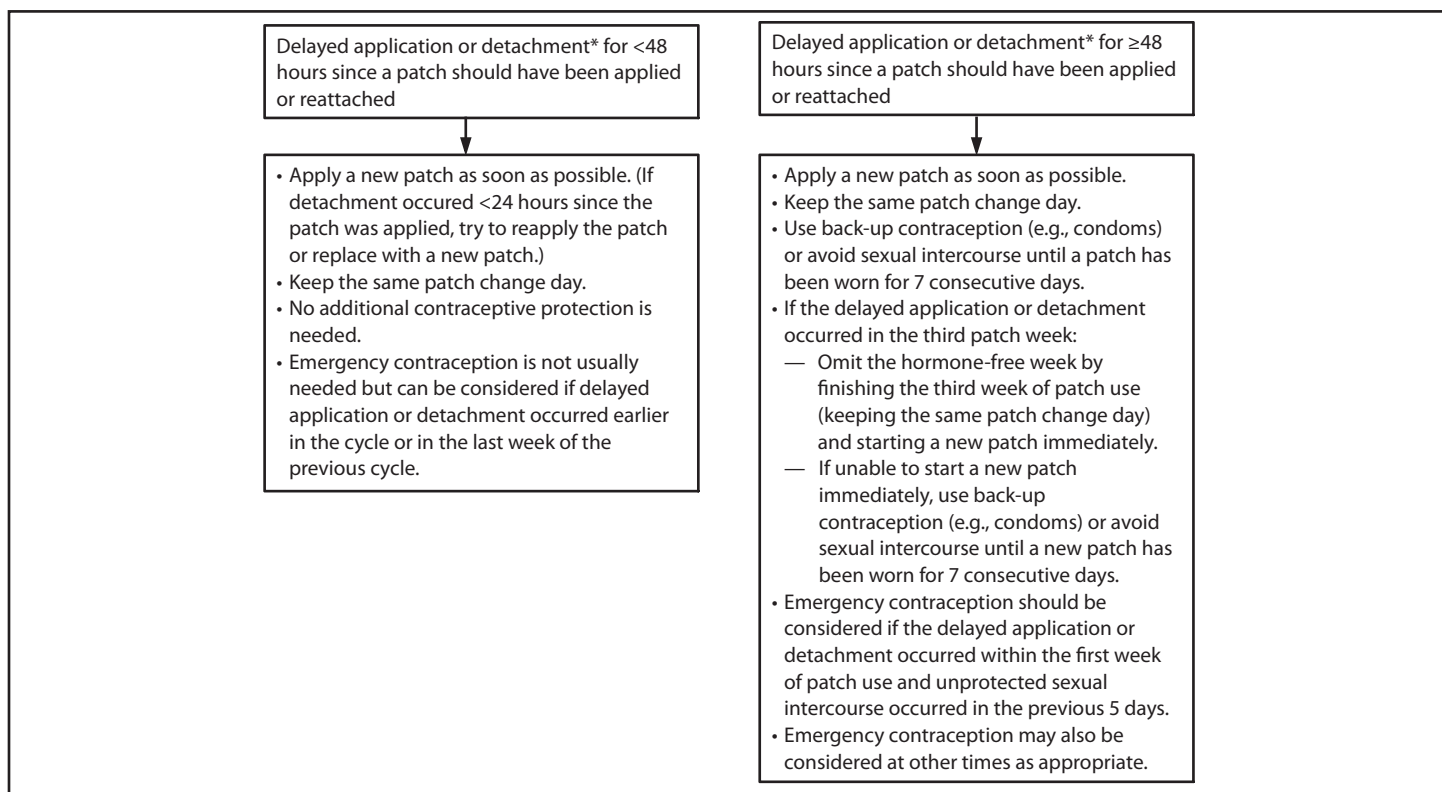
ethinyl estradiol and progestin norelgestromin remained within reference ranges after extending patch wear for 3 days (241). No studies were found on extending the patch-free interval. In studies that provide indirect evidence on the effects of missed combined hormonal contraception on surrogate measures of pregnancy, how differences in surrogate measures correspond to pregnancy risk is unclear (Level of evidence: I, good, indirect to II-3, poor, direct).

### Vomiting or Severe Diarrhea While Using COCs

Certain steps should be taken by women who experience vomiting or severe diarrhea while using COCs (Figure 5).

**Comments and Evidence Summary.** Theoretically, the contraceptive effectiveness of COCs might be decreased because of vomiting or severe diarrhea. Because of the lack of evidence that addresses vomiting or severe diarrhea while using COCs, these recommendations are based on the recommendations

**FIGURE 3. Recommended actions after delayed application or detachment with combined hormonal patch**



\* If detachment takes place but the woman is unsure when the detachment occurred, consider the patch to have been detached for ≥48 hours since a patch should have been applied or reattached.

for missed COCs. No evidence was found on the effects of vomiting or diarrhea on measures of contraceptive effectiveness including pregnancy, follicular development, hormone levels, or cervical mucus quality.

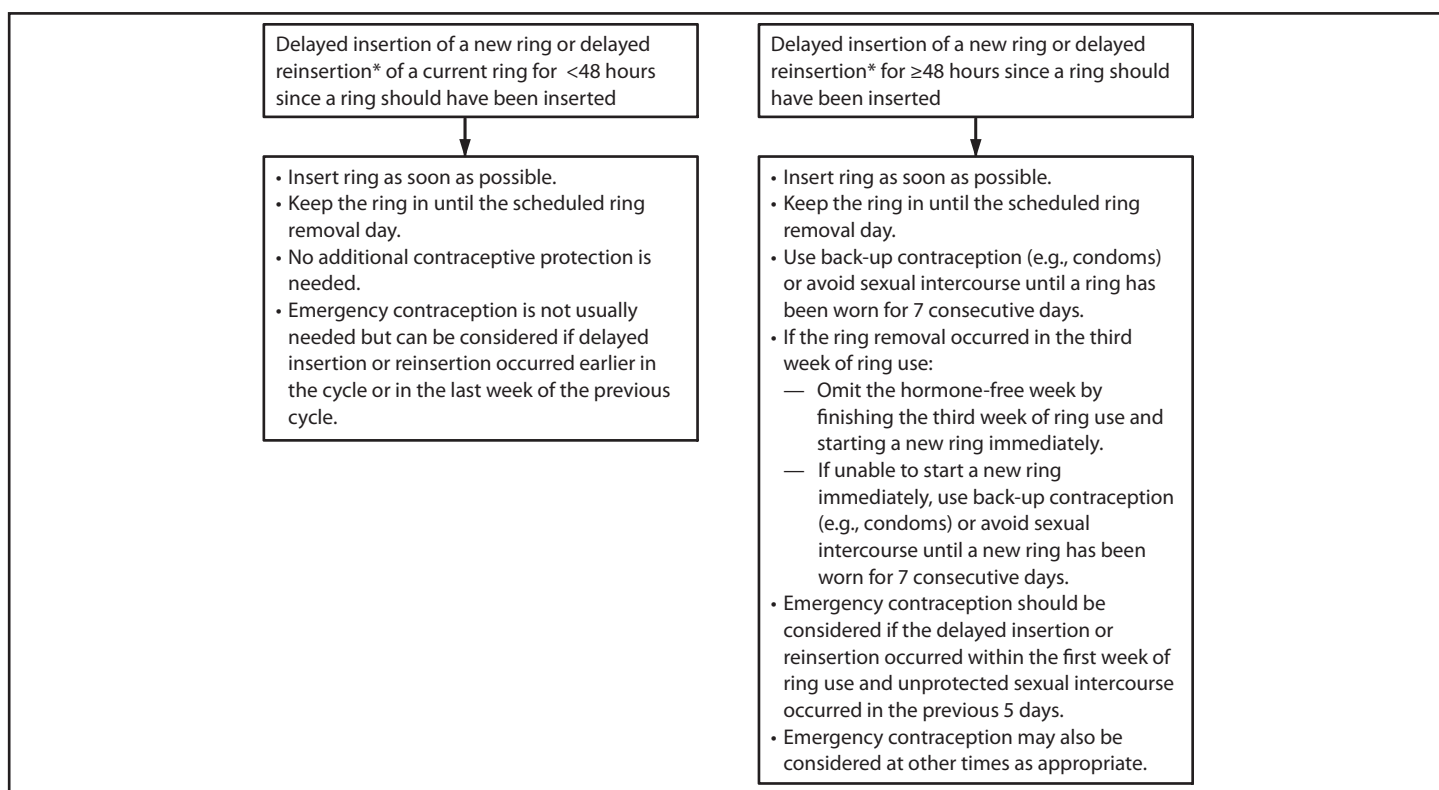
### Unscheduled Bleeding with Extended or Continuous Use of Combined Hormonal Contraceptives

- Before initiation of combined hormonal contraceptives, provide counseling about potential changes in bleeding patterns during extended or continuous combined hormonal contraceptive use. (Extended contraceptive use is defined as a planned hormone-free interval after at least two contiguous cycles. Continuous contraceptive use is defined as uninterrupted use of hormonal contraception without a hormone-free interval [247].)
- Unscheduled spotting or bleeding is common during the first 3–6 months of extended or continuous combined hormonal contraceptive use. It is generally not harmful and decreases with continued combined hormonal contraceptive use.

- If clinically indicated, consider an underlying gynecological problem, such as inconsistent use, interactions with other medications, cigarette smoking, an STD, pregnancy, or new pathologic uterine conditions (e.g., polyps or fibroids). If an underlying gynecological problem is found, treat the condition or refer for care.
- If an underlying gynecological problem is not found and the woman wants treatment, the following treatment option can be considered:
  - Advise the woman to discontinue combined hormonal contraceptive use (i.e., a hormone-free interval) for 3–4 consecutive days; a hormone-free interval is not recommended during the first 21 days of using the continuous or extended combined hormonal contraceptive method. A hormone-free interval also is not recommended more than once per month because contraceptive effectiveness might be reduced.
- If unscheduled spotting or bleeding persists and the woman finds it unacceptable, counsel her on alternative contraceptive methods, and offer another method if it is desired.

**Comments and Evidence Summary.** During contraceptive counseling and before initiating extended or continuous

FIGURE 4. Recommended actions after delayed insertion or reinsertion with combined vaginal ring



\* If removal takes place but the woman is unsure of how long the ring has been removed, consider the ring to have been removed for ≥48 hours since a ring should have been inserted or reinserted.

combined hormonal contraceptives, information about common side effects such as unscheduled spotting or bleeding, especially during the first 3–6 months of use, should be discussed (248). These bleeding irregularities are generally not harmful and usually improve with persistent use of the hormonal method. To avoid unscheduled spotting or bleeding, counseling should emphasize the importance of correct use and timing; for users of contraceptive pills, emphasize consistent pill use. Enhanced counseling about expected bleeding patterns and reassurance that bleeding irregularities are generally not harmful has been shown to reduce method discontinuation in clinical trials with DMPA (101,102).

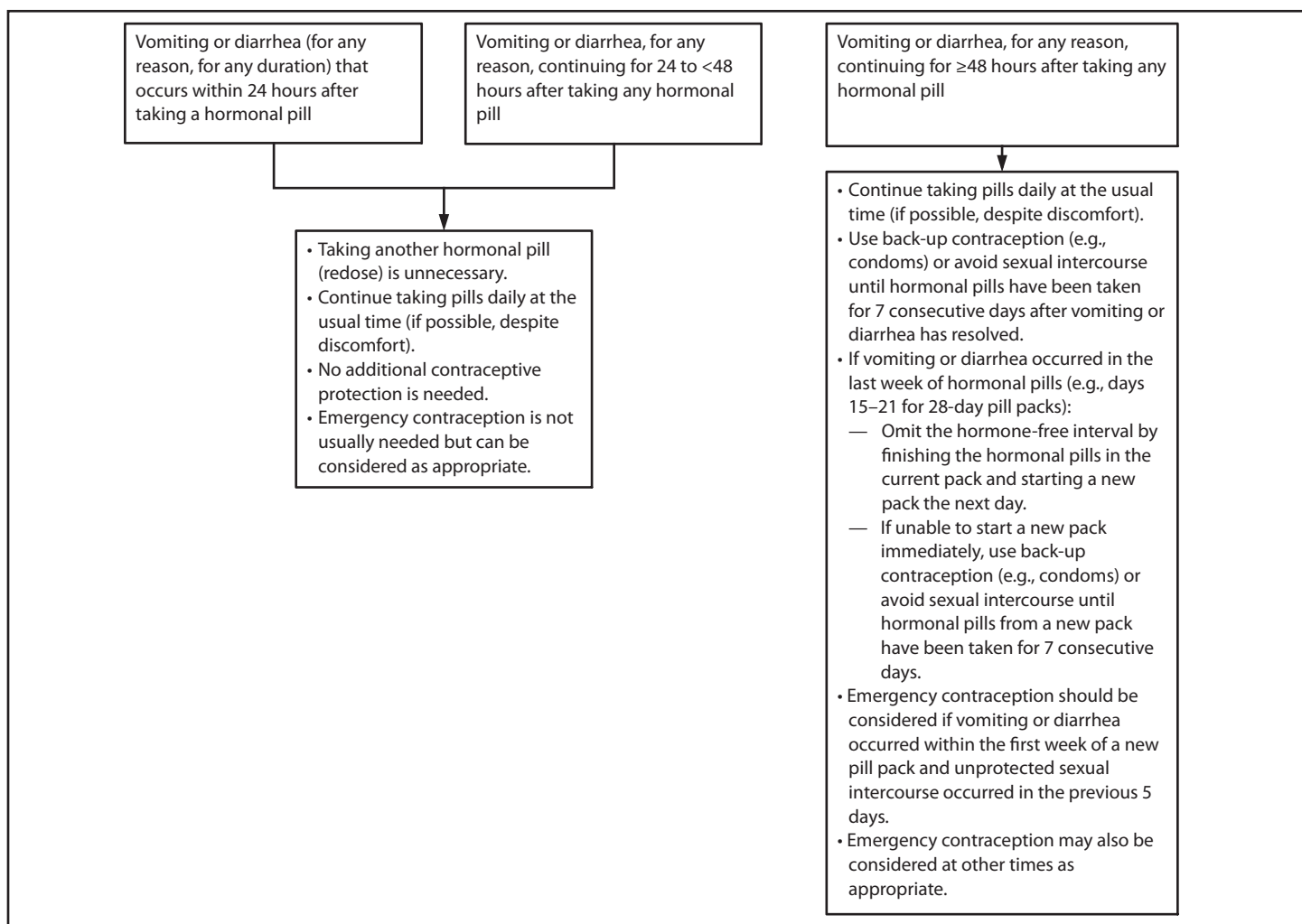
A systematic review identified three studies with small study populations that addressed treatments for unscheduled bleeding among women using extended or continuous combined hormonal contraceptives (25). In two separate randomized clinical trials in which women were taking either contraceptive pills or using the contraceptive ring continuously for 168 days, women assigned to a hormone-free interval of 3 or 4 days reported improved bleeding. Although they noted an initial increase in flow, this was followed by an abrupt decrease 7–8 days later with eventual cessation of flow 11–12 days later.

These findings were compared with women who continued to use their method without a hormone-free interval, in which a greater proportion reported either treatment failure or fewer days of amenorrhea (249,250). In another randomized trial of 66 women with unscheduled bleeding among women using 84 days of hormonally active contraceptive pills, oral doxycycline (100 mg twice daily) initiated the first day of bleeding and taken for 5 days did not result in any improvement in bleeding compared with placebo (251) (Level of evidence: I, fair, direct).

## Progestin-Only Pills

POPs contain only a progestin and no estrogen and are available in the United States. Approximately 9 out of 100 women become pregnant in the first year of use with POPs with typical use (59). POPs are reversible and can be used by women of all ages. POPs do not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

FIGURE 5. Recommended steps after vomiting or diarrhea while using combined oral contraceptives



## Initiation of POPs

### Timing

- POPs can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).

### Need for Back-Up Contraception

- If POPs are started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If POPs are started >5 days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

### Special Considerations

#### Amenorrhea (Not Postpartum)

- **Timing:** POPs can be started at any time if it is reasonably certain that the woman is not pregnant (Box 1).

- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

### Postpartum (Breastfeeding)

- **Timing:** POPs can be started at any time, including immediately postpartum (U.S. MEC 2 if <1 month postpartum and U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** If the woman is <6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds) (60), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycles needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days. If her menstrual cycles have



returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

### Postpartum (Not Breastfeeding)

- **Timing:** POPs can be started at any time, including immediately postpartum (U.S. MEC 1), if it is reasonably certain that the woman is not pregnant (Box 1).
- **Need for back-up contraception:** Women who are ≥21 days postpartum and whose menstrual cycles have not returned need to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days. If her menstrual cycles have returned and it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.

### Postabortion (Spontaneous or Induced)

- **Timing:** POPs can be started within the first 7 days, including immediately postabortion (U.S. MEC 1).
- **Need for back-up contraception:** The woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days unless POPs are started at the time of a surgical abortion.

### Switching from Another Contraceptive Method

- **Timing:** POPs can be started immediately if it is reasonably certain that the woman is not pregnant (Box 1). Waiting for her next menstrual period is unnecessary.
- **Need for back-up contraception:** If it has been >5 days since menstrual bleeding started, she needs to abstain from sexual intercourse or use additional contraceptive protection for the next 2 days.
- **Switching from an IUD:** If the woman has had sexual intercourse since the start of her current menstrual cycle and it has been >5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. A health-care provider may consider any of the following options:
  - Advise the women to retain the IUD for at least 2 days after POPs are initiated and return for IUD removal.
  - Advise the woman to abstain from sexual intercourse or use barrier contraception for 2 days before removing the IUD and switching to the new method.
  - Advise the woman to use ECPs at the time of IUD removal.

**Comments and Evidence Summary.** In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting POPs likely exceed any risk; therefore, starting POPs should be considered at any time, with a follow-up pregnancy test in 2–4 weeks.

Unlike COCs, POPs inhibit ovulation in about half of cycles, although the rates vary widely by individual (252). Peak serum steroid levels are reached about 2 hours after administration, followed by rapid distribution and elimination, such that by 24 hours after administration, serum steroid levels are near baseline (252). Therefore, taking POPs at approximately the same time each day is important. An estimated 48 hours of POP use has been deemed necessary to achieve the contraceptive effects on cervical mucus (252). If a woman needs to use additional contraceptive protection when switching to POPs from another contraceptive method, consider continuing her previous method for 2 days after starting POPs. No direct evidence was found regarding the effects of starting POPs at different times of the cycle.

## Examinations and Tests Needed Before Initiation of POPs

Among healthy women, no examinations or tests are needed before initiation of POPs, although a baseline weight and BMI measurement might be useful for monitoring POP users over time (Table 6). Women with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates

**TABLE 6. Classification of examinations and tests needed before POP initiation**

Examination or laboratory test	Class*
<b>Examination</b>	
Blood pressure	C
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	—†
Clinical breast examination	C
Bimanual examination and cervical inspection	C
<b>Laboratory test</b>	
Glucose	C
Lipids	C
Liver enzymes	C
Hemoglobin	C
Thrombogenic mutations	C
Cervical cytology (Papanicolaou smear)	C
STD screening with laboratory tests	C
HIV screening with laboratory tests	C

**Abbreviations:** BMI = body mass index; HIV = human immunodeficiency virus; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

\* **Class A:** essential and mandatory in all circumstances for safe and effective use of the contraceptive method. **Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available. **Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

for a particular method of contraception. U.S. MEC might be useful in such circumstances (5).

**Comments and Evidence Summary. Weight (BMI):** Obese women can use POPs (U.S. MEC 1) (5); therefore, screening for obesity is not necessary for the safe initiation of POPs. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

**Bimanual examination and cervical inspection:** Pelvic examination is not necessary before initiation of POPs because it does not facilitate detection of conditions for which POPs would be unsafe. Women with current breast cancer should not use POPs (U.S. MEC 4), and women with certain liver diseases generally should not use POPs (U.S. MEC 3) (5); however, neither of these conditions are likely to be detected by pelvic examination (120). A systematic review identified two case-control studies that compared delayed versus immediate pelvic examination before initiation of hormonal contraceptives, specifically oral contraceptives or DMPA (15). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of abnormal wet mounts were observed (Level of evidence: II-2 fair, direct).

**Liver enzymes:** Although women with certain liver diseases generally should not use POPs (U.S. MEC 3) (5), screening for liver disease before initiation of POPs is not necessary because of the low prevalence of these conditions and the high likelihood that women with liver disease already would have had the condition diagnosed. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with liver enzyme tests before initiation of hormonal contraceptives (14). The prevalence of liver disorders among women of reproductive age is low. In 2008 among U.S. adults aged 18–44 years, the percentage with liver disease (not further specified) was 1.0% (90). In 2009, the incidence of acute hepatitis A, B, or C among women was <1 per 100,000 population (91). During 1998–2007, the incidence of liver carcinoma among women was approximately 3 per 100,000 population (92). Because estrogen and progestins are metabolized in the liver, the use of hormonal contraceptives among women with liver disease might, theoretically, be a concern. The use of hormonal contraceptives, specifically COCs and POPs, does not affect disease progression or severity in women with hepatitis, cirrhosis, or benign focal nodular hyperplasia (93,94).

**Clinical breast examination:** Although women with current breast cancer should not use POPs (U.S. MEC 4) (5), screening asymptomatic women with a clinical breast examination

before initiating POPs is not necessary because of the low prevalence of breast cancer among women of reproductive age. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened with a clinical breast examination before initiation of hormonal contraceptives (15). The incidence of breast cancer among women of reproductive age in the United States is low. In 2009, the incidence of breast cancer among women ages 20–49 was approximately 72 per 100,000 women (95).

**Other screening:** Women with hypertension, diabetes, hyperlipidemia, anemia, thrombogenic mutations, cervical intraepithelial neoplasia, cervical cancer, STDs, or HIV infection can use (U.S. MEC 1) or generally can use (U.S. MEC 2) POPs (5); therefore, screening for these conditions is not necessary for the safe initiation of POPs.

## Number of Pill Packs that Should Be Provided at Initial and Return Visits

- At the initial and return visits, provide or prescribe up to a 1-year supply of POPs (e.g., 13 28-day pill packs), depending on the woman's preferences and anticipated use.
- A woman should be able to obtain POPs easily in the amount and at the time she needs them.

**Comments and Evidence Summary.** The more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy.

A systematic review of the evidence suggested that providing a greater number of pill packs was associated with increased continuation (23). Studies that compared provision of one versus 12 packs, one versus 12 or 13 packs, or three versus seven packs found increased continuation of pill use among women provided with more pill packs (209–211). However, one study found that there was no difference in continuation when patients were provided one and then three packs versus four packs all at once (212). In addition to continuation, a greater number of pill packs provided was associated with fewer pregnancy tests, fewer pregnancies, and lower cost per client. However, a greater number of pill packs (13 packs versus three packs) also was associated with increased pill wastage in one study (210) (Level of evidence: I to II-2, fair, direct).

## Routine Follow-Up After POP Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and

different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise a woman to return at any time to discuss side effects or other problems or if she wants to change the method being used. No routine follow-up visit is required.
- At other routine visits, health-care providers seeing POP users should do the following:
  - Assess the woman's satisfaction with her contraceptive method and whether she has any concerns about method use.
  - Assess any changes in health status, including medications, that would change the appropriateness of POPs for safe and effective continued use based on U.S. MEC (e.g., category 3 and 4 conditions and characteristics).
  - Consider assessing weight changes and counseling women who are concerned about weight changes perceived to be associated with their contraceptive method.

**Comments and Evidence Summary.** No evidence was found regarding whether a routine follow-up visit after initiating POPs improves correct or continued use.

### Missed POPs

For the following recommendations, a dose is considered missed if it has been >3 hours since it should have been taken.

- Take one pill as soon as possible.
- Continue taking pills daily, one each day, at the same time each day, even if it means taking two pills on the same day.
- Use back-up contraception (e.g., condoms) or avoid sexual intercourse until pills have been taken correctly, on time, for 2 consecutive days.
- Emergency contraception should be considered if the woman has had unprotected sexual intercourse.

**Comments and Evidence Summary.** Inconsistent or incorrect use of oral contraceptive pills is a major reason for oral contraceptive failure. Unlike COCs, POPs inhibit ovulation in about half of cycles, although this rate varies widely by individual (252). Peak serum steroid levels are reached about 2 hours after administration, followed by rapid distribution and elimination, such that by 24 hours after administration, serum steroid levels are near baseline (252). Therefore, taking POPs at approximately the same time each day is important. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus (252). Women who frequently miss POPs should consider an alternative contraceptive method that is less dependent on the user to be effective (e.g., IUD, implant, or injectable).

No evidence was found regarding the effects of missed POPs available in the United States on measures of contraceptive effectiveness including pregnancy, follicular development, hormone levels, or cervical mucus quality.

### Vomiting or Severe Diarrhea (for any Reason or Duration) that Occurs Within 3 Hours After Taking a Pill

- Take another pill as soon as possible (if possible, despite discomfort).
- Continue taking pills daily, one each day, at the same time each day.
- Use back-up contraception (e.g., condoms) or avoid sexual intercourse until 2 days after vomiting or diarrhea has resolved.
- Emergency contraception should be considered if the woman has had unprotected sexual intercourse.

**Comments and Evidence Summary.** Theoretically, the contraceptive effectiveness of POPs might be decreased because of vomiting or severe diarrhea. Because of the lack of evidence to address this question, these recommendations are based on the recommendations for missed POPs. No evidence was found regarding the effects of vomiting or diarrhea on measures of contraceptive effectiveness, including pregnancy, follicular development, hormone levels, or cervical mucus quality.

### Standard Days Method

SDM is a method based on fertility awareness; users must avoid unprotected sexual intercourse on days 8–19 of the menstrual cycle (253). Approximately 5 out of 100 women become pregnant in the first year of use with perfect (i.e., correct and consistent) use of SDM (253); effectiveness based on typical use is not available for this method but is expected to be lower than that for perfect use. SDM is reversible and can be used by women of all ages. SDM does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

### Use of SDM Among Women with Various Menstrual Cycle Durations

#### Menstrual Cycles of 26–32 Days

- These women may use the method.
- Provide a barrier method of contraception for protection on days 8–19 if she wants one.
- If she has unprotected sexual intercourse during days 8–19, consider the use of emergency contraception if appropriate.

## Two or More Menstrual Cycles of <26 or >32 Days Within Any 1 Year of SDM Use

- Advise the woman that the method might not be appropriate for her because of a higher risk for pregnancy. Help her consider another method.

**Comments and Evidence Summary.** The probability of pregnancy is increased when the menstrual cycle is outside the range of 26–32 days, even if unprotected sexual intercourse is avoided on days 8–19. A study of 7,600 menstrual cycles, including information on cycle length and signs of ovulation, concluded that the theoretical effectiveness of SDM is greatest for women with cycles of 26–32 days, that the method is still effective for women who occasionally have a cycle outside this range, and that it is less effective for women who consistently have cycles outside this range. Information from daily hormonal measurements shows that the timing of the 6-day fertile window varies greatly, even among women with regular cycles (39,254,255).

## Emergency Contraception

Emergency contraception consists of methods that can be used by women after sexual intercourse to prevent pregnancy. Emergency contraception methods have varying ranges of effectiveness depending on the method and timing of administration. Four options are available in the United States: the Cu-IUD and three types of ECPs.

### Types of Emergency Contraception

#### Intrauterine Device

- Cu-IUD

#### ECPs

- Ulipristal acetate (UPA) in a single dose (30 mg)
- Levonorgestrel in a single dose (1.5 mg) or as a split dose (1 dose of 0.75 mg of levonorgestrel followed by a second dose of 0.75 mg of levonorgestrel 12 hours later)
- Combined estrogen and progestin in 2 doses (Yuzpe regimen: 1 dose of 100  $\mu$ g of ethinyl estradiol plus 0.50 mg of levonorgestrel followed by a second dose of 100  $\mu$ g of ethinyl estradiol plus 0.50 mg of levonorgestrel 12 hours later)

### Initiation of Emergency Contraception

#### Timing

##### Cu-IUD

- The Cu-IUD can be inserted within 5 days of the first act of unprotected sexual intercourse as an emergency contraceptive.

- In addition, when the day of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after sexual intercourse, as long as insertion does not occur >5 days after ovulation.

#### ECPs

- ECPs should be taken as soon as possible within 5 days of unprotected sexual intercourse.

**Comments and Evidence Summary.** Cu-IUDs are highly effective as emergency contraception (256) and can be continued as regular contraception. UPA and levonorgestrel ECPs have similar effectiveness when taken within 3 days after unprotected sexual intercourse; however, UPA has been shown to be more effective than the levonorgestrel formulation 3–5 days after unprotected sexual intercourse (257). The combined estrogen and progestin regimen is less effective than UPA or levonorgestrel and also is associated with more frequent occurrence of side effects (nausea and vomiting) (258). The levonorgestrel formulation might be less effective than UPA among obese women (257).

Two studies of UPA use found consistent decreases in pregnancy rates when administered within 120 hours of unprotected sexual intercourse (257,259). Five studies found that the levonorgestrel and combined regimens decreased risk for pregnancy through the fifth day after unprotected sexual intercourse; however, rates of pregnancy were slightly higher when ECPs were taken after 3 days (260–264). A meta-analysis of levonorgestrel ECPs found that pregnancy rates were low when administered within 4 days after unprotected sexual intercourse but increased at 4–5 days (265) (Level of evidence: I to II-2, good to poor, direct).

### Advance Provision of ECPs

- An advance supply of ECPs may be provided so that ECPs will be available when needed and can be taken as soon as possible after unprotected sexual intercourse.

**Comments and Evidence Summary.** A systematic review identified 17 studies that reported on safety or effectiveness of advance ECPs in adult or adolescent women (26). Any use of ECPs was two to seven times greater among women who received an advance supply of ECPs. However, a summary estimate (relative risk = 0.97; 95% confidence interval = 0.77–1.22) of five randomized controlled trials did not indicate a significant reduction in unintended pregnancies at 12 months with advance provision of ECPs. In the majority of studies among adults or adolescents, patterns of regular contraceptive use, pregnancy rates, and incidence of STDs did not vary between those who received advance ECPs and those who did not. Although available evidence supports the safety of advance

provision of ECPs, effectiveness of advance provision of ECPs in reducing pregnancy rates at the population level has not been demonstrated (Level of evidence: I to II-3, good to poor, direct).

## Initiation of Regular Contraception After ECPs

### UPA

- Any regular contraceptive method can be started immediately after the use of UPA.
- The woman needs to abstain from sexual intercourse or use barrier contraception for 14 days or until her next menses, whichever comes first.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

### Levonorgestrel and Combined Estrogen and Progestin ECPs

- Any regular contraceptive method can be started immediately after the use of levonorgestrel or combined estrogen and progestin ECPs.
- The woman needs to abstain from sexual intercourse or use barrier contraception for 7 days.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

**Comments and Evidence Summary.** Data on when a woman can start regular contraception after ECPs are limited to expert opinion and product labeling (27). Theoretically, the effectiveness of systemic hormonal contraception might be decreased when administered concurrently or in close succession because of the antiprogestin properties of UPA (266,267); these theoretical concerns do not exist for combined estrogen and progestin or levonorgestrel formulations of ECPs. The resumption or initiation of regular hormonal contraception after ECP use involves consideration of the risk for pregnancy if ECPs fail and the risks for unintended pregnancy if contraception initiation is delayed until the subsequent menstrual cycle. If a woman is planning to initiate contraception after the next menstrual period after ECP use, the cycle in which ECPs are used might be shortened, prolonged, or involve unscheduled bleeding.

## Prevention and Management of Nausea and Vomiting with ECP Use

### Nausea and Vomiting

- Levonorgestrel and UPA ECPs cause less nausea and vomiting than combined estrogen and progestin ECPs.

- Routine use of antiemetics before taking ECPs is not recommended. Pretreatment with antiemetics may be considered depending on availability and clinical judgment.

### Vomiting Within 3 Hours of Taking ECPs

- Another dose of ECP should be taken as soon as possible. Use of an antiemetic should be considered.

**Comments and Evidence Summary.** Many women do not experience nausea or vomiting when taking ECPs, and predicting which women will experience nausea or vomiting is difficult. Although routine use of antiemetics before taking ECPs is not recommended, antiemetics are effective in some women and can be offered when appropriate. Health-care providers who are deciding whether to offer antiemetics to women taking ECPs should consider the following: 1) women taking combined estrogen and progestin ECPs are more likely to experience nausea and vomiting than those who take levonorgestrel or UPA ECPs; 2) evidence indicates that antiemetics reduce the occurrence of nausea and vomiting in women taking combined estrogen and progestin ECPs; and 3) women who take antiemetics might experience other side effects from the antiemetics.

A systematic review examined incidence of nausea and vomiting with different ECP regimens and effectiveness of antinausea drugs in reducing nausea and vomiting with ECP use (28). The levonorgestrel regimen was associated with significantly less nausea than a nonstandard dose of UPA (50 mg) and the standard combined estrogen and progestin regimen (268–270). Use of the split-dose levonorgestrel showed no differences in nausea and vomiting compared with the single-dose levonorgestrel (260,261,263,271) (Level of evidence: I, good-fair, indirect). Two trials of antinausea drugs, meclizine and metoclopramide, taken before combined estrogen and progestin ECPs, reduced the severity of nausea (272,273). Significantly less vomiting occurred with meclizine but not metoclopramide (Level of evidence: I, good-fair, direct). No direct evidence was found regarding the effects of vomiting after taking ECPs.

## Female Sterilization

Laparoscopic, abdominal, and hysteroscopic methods of female sterilization are available in the United States, and some of these procedures can be performed in an outpatient procedure or office setting. Fewer than 1 out of 100 women become pregnant in the first year after female sterilization (59). Because these methods are intended to be irreversible, all women should be appropriately counseled about the permanency of sterilization and the availability of highly

effective, long-acting, reversible methods of contraception. Female sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

### When Hysteroscopic Sterilization Is Reliable for Contraception

- Before a woman can rely on hysteroscopic sterilization for contraception, a hysterosalpingogram (HSG) must be performed 3 months after the sterilization procedure to confirm bilateral tubal occlusion.
- The woman should be advised that she needs to abstain from sexual intercourse or use additional contraceptive protection until she has confirmed bilateral tubal occlusion.

### When Laparoscopic and Abdominal Approaches Are Reliable for Contraception

- A woman can rely on sterilization for contraception immediately after laparoscopic and abdominal approaches. No additional contraceptive protection is needed.

**Comments and Evidence Summary.** HSG confirmation is necessary to confirm bilateral tubal occlusion after hysteroscopic sterilization. The inserts for the hysteroscopic sterilization system available in the United States are placed bilaterally into the fallopian tubes and require 3 months for adequate fibrosis and scarring leading to bilateral tubal occlusion. After hysteroscopic sterilization, advise the woman to correctly and consistently use an effective method of contraception while awaiting confirmation. If compliance with another method might be a problem, a woman and her health-care provider may consider DMPA injection at the time of sterilization to ensure adequate contraception for 3 months. Unlike laparoscopic and abdominal sterilizations, pregnancy risk beyond 7 years of follow-up has not been studied among women who received hysteroscopic sterilization.

Pregnancy risk with at least 10 years of follow-up has been studied among women who received laparoscopic and abdominal sterilizations (274,275). Although these methods are highly effective, pregnancies can occur many years after the procedure, and the risk for pregnancy is higher among younger women (274,276).

A systematic review was conducted to identify studies that reported whether pregnancies occurred after hysteroscopic sterilization (29). Twenty-four studies were identified that reported whether pregnancies occurred after hysteroscopic sterilization and found that very few pregnancies occurred among women with confirmed bilateral tubal occlusion; however, few studies include long-term follow-up, and

none with follow-up for >7 years. Among women who had successful bilateral placement, most pregnancies that occurred after hysteroscopic sterilization were in women who did not have confirmed bilateral tubal occlusion at 3 months, either because of lack of follow up or misinterpretation of HSG results (277–279). Some pregnancies occurred within 3 months of placement, including among women who were already pregnant at the time of the procedure, women who did not use alternative contraception, or women who had failures of alternative contraception (277,278,280–283). Although these studies generally demonstrated high rates of bilateral placement, some pregnancies occurred as a result of lack of bilateral placement identified on later imaging (277,278,280,281,283,284). Most pregnancies occurred after deviations from FDA directions, which include placement in the early follicular phase of the menstrual cycle, imaging at 3 months to document proper placement, and use of effective alternative contraception until documented occlusion (Level of evidence: II-3, fair, direct).

## Male Sterilization

Male sterilization, or vasectomy, is one of the few contraceptive methods available to men and can be performed in an outpatient procedure or office setting. Fewer than 1 woman out of 100 becomes pregnant in the first year after her male partner undergoes sterilization (59). Because male sterilization is intended to be irreversible, all men should be appropriately counseled about the permanency of sterilization and the availability of highly effective, long-acting, reversible methods of contraception for women. Male sterilization does not protect against STDs; consistent and correct use of male latex condoms reduces the risk for STDs, including HIV.

### When Vasectomy Is Reliable for Contraception

- A semen analysis should be performed 8–16 weeks after a vasectomy to ensure the procedure was successful.
- The man should be advised that he should use additional contraceptive protection or abstain from sexual intercourse until he has confirmation of vasectomy success by postvasectomy semen analysis.

### Other Postprocedure Recommendations

- The man should refrain from ejaculation for approximately 1 week after the vasectomy to allow for healing of surgical sites and, after certain methods of vasectomy, occlusion of the vas.

**Comments and Evidence Summary.** The Vasectomy Guideline Panel of the American Urological Association performed a systematic review of key issues concerning the practice of vasectomy (285). All English-language publications on vasectomy published during 1949–2011 were reviewed. For more information, see the American Urological Association *Vasectomy Guidelines* (available at <http://www.auanet.org/education/vasectomy.cfm>).

Motile sperm disappear within a few weeks after vasectomy (286–289). The time to azoospermia varies widely in different studies; however, by 12 weeks after the vasectomy, 80% of men have azoospermia, and almost all others have rare nonmotile sperm (defined as  $\leq 100,000$  nonmotile sperm per milliliter) (285). The number of ejaculations after vasectomy is not a reliable indicator of when azoospermia or rare nonmotile sperm will be achieved (285). Once azoospermia or rare nonmotile sperm has been achieved, patients can rely on the vasectomy for contraception, although not with 100% certainty. The risk for pregnancy after a man has achieved postvasectomy azoospermia is approximately one in 2,000 (290–294).

A median of 78% (range 33%–100%) of men return for a single postvasectomy semen analysis (285). In the largest cohorts that appear typical of North American vasectomy practice, approximately two thirds of men (55%–71%) return for at least one postvasectomy semen analysis (291,295–299). Assigning men an appointment after their vasectomy might improve compliance with follow-up (300).

## When Women Can Stop Using Contraceptives

- Contraceptive protection is still needed for women aged  $>44$  years if the woman wants to avoid pregnancy.

**Comments and Evidence Summary.** The age at which a woman is no longer at risk for pregnancy is not known. Although uncommon, spontaneous pregnancies occur among women aged  $>44$  years. Both the American College of Obstetricians and Gynecologists and the North American Menopause Society recommend that women continue contraceptive use until menopause or age 50–55 years (301,302). The median age of menopause is approximately 51 years in North America (301) but can vary from ages 40 to 60 years (303). The median age of definitive loss of natural fertility is 41 years but can range up to age 51 years (304,305). No reliable laboratory tests are available to confirm definitive loss of fertility in a woman. The assessment of follicle-stimulating hormone levels to determine when a woman is no longer fertile might not be accurate (301).

Health-care providers should consider the risks for becoming pregnant in a woman of advanced reproductive age, as well as any risks of continuing contraception until menopause. Pregnancies among women of advanced reproductive age are at higher risk for maternal complications, such as hemorrhage, venous thromboembolism, and death, and fetal complications, such as spontaneous abortion, stillbirth, and congenital anomalies (306–308). Risks associated with continuing contraception, in particular risks for acute cardiovascular events (venous thromboembolism, myocardial infarction, or stroke) or breast cancer, also are important to consider. U.S. MEC states that on the basis of age alone, women aged  $>45$  years can use POPs, implants, the LNG-IUD, or the Cu-IUD (U.S. MEC 1) (5). Women aged  $>45$  years generally can use combined hormonal contraceptives and DMPA (U.S. MEC 2) (5). However, women in this age group might have chronic conditions or other risk factors that might render use of hormonal contraceptive methods unsafe; U.S. MEC might be helpful in guiding the safe use of contraceptives in these women.

The incidence of venous thromboembolism was higher among oral contraceptive users aged  $\geq 45$  years compared with younger oral contraceptive users in two studies (309–311); however, an interaction between hormonal contraception and increased age compared with baseline risk was not demonstrated (309,310) or was not examined (311). The relative risk for myocardial infarction was higher among all oral contraceptive users than in nonusers, although a trend of increased relative risk with increasing age was not demonstrated (312,313). No studies were found regarding the risk for stroke in COC users aged  $\geq 45$  years (Level of evidence: II-2, good to poor, direct).

A pooled analysis by the Collaborative Group on Hormonal Factors and Breast Cancer in 1996 (314) found small increased relative risks for breast cancer among women aged  $\geq 45$  years whose last use of combined hormonal contraceptives was  $<5$  years previously and for those whose last use was 5–9 years previously. Seven more recent studies suggested small but nonsignificant increased relative risks for breast carcinoma in situ or breast cancer among women who had used oral contraceptives or DMPA when they were aged  $\geq 40$  years compared with those who had never used either method (315–321) (Level of evidence: II-2, fair, direct).

## Conclusion

Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including LARC methods such as IUDs and implants, to reduce the risk for unintended pregnancy. However, with these expanded options

comes the need for evidence-based guidance to help health-care providers offer quality family planning care to their patients, including choosing the most appropriate contraceptive method for individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness. Removing unnecessary barriers can help patients access and successfully use contraceptive methods. Several medical barriers to initiating and continuing contraceptive methods might exist, such as unnecessary screening examinations and tests before starting the method (e.g., a pelvic examination before initiation of COCs), inability to receive the contraceptive on the same day as the visit (e.g., waiting for test results that might not be needed or waiting until the woman's next menstrual period to start use), and difficulty obtaining continued contraceptive supplies (e.g., restrictions on number of pill packs dispensed at one time). Removing unnecessary steps, such as providing prophylactic antibiotics at the time of IUD insertion or requiring unnecessary follow-up procedures, also can help patients access and successfully use contraception.

Most women can start most contraceptive methods at any time, and few examinations or tests, if any, are needed before starting a contraceptive method. Routine follow-up for most women includes assessment of her satisfaction with the contraceptive method, concerns about method use, and changes in health status or medications that could affect medical eligibility for continued use of the method. Because changes in bleeding patterns are one of the major reasons for discontinuation of contraception, recommendations are provided for the management of bleeding irregularities with various contraceptive methods. In addition, because women and health-care providers can be confused about the procedures for missed pills and dosing errors with the contraceptive patch and ring, the instructions are streamlined for easier use. ECPs and emergency use of the Cu-IUD are important options for women, and recommendations on using these methods, as well as starting regular contraception after use of emergency contraception, are provided. Male and female sterilization are highly effective methods of contraception for men, women, and couples who have completed childbearing; for men undergoing vasectomy and women undergoing a hysteroscopic sterilization procedure, additional contraceptive protection is needed until the success of the procedure can be confirmed.

CDC is committed to working with partners at the federal, national, and local levels to disseminate, implement, and evaluate the recommendations in U.S. SPR so that the information reaches health-care providers. Strategies for dissemination and implementation include collaborating with other federal agencies and professional and service organizations to widely distribute the recommendations through presentations, electronic distribution, newsletters, and

other publications; development of provider tools and job aids to assist providers in implementing the new recommendations; and training activities for students, as well as for continuing education. CDC will conduct a survey of family planning health-care providers before and after release of this report to assess attitudes and practices related to contraceptive use. Results from this survey will assist CDC in evaluating the impact of these recommendations on the provision of contraceptives in the United States. Finally, CDC will continually monitor new scientific evidence and will update these recommendations as warranted by new evidence. Updates to the recommendations, as well as provider tools and other resources, are available on the CDC U.S. SPR website (<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>).

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## Appendix A

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010



**Key:**

1. No restriction (method can be used)
2. Advantages generally outweigh theoretical or proven risks
3. Theoretical or proven risks usually outweigh the advantages
4. Unacceptable health risk (method not to be used)

**Updated June 2012.** This summary sheet only contains a subset of the recommendations from the US MEC. For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>.



Most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the male latex condom reduces the risk of STIs and HIV.

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <40=1		Menarche to <18=1		Menarche to <18=2		Menarche to <18=1		Menarche to <20=2		Menarche to <20=2	
		≥40=2		18-45=1		18-45=1		18-45=1		≥20=1		≥20=1	
				>45=1		>45=2		>45=1					
Anatomic abnormalities	a) Distorted uterine cavity									4		4	
	b) Other abnormalities									2		2	
Anemias	a) Thalassemia	1		1		1		1		1		2	
	b) Sickle cell disease <sup>†</sup>	2		1		1		1		1		2	
	c) Iron-deficiency anemia	1		1		1		1		1		2	
Benign ovarian tumors	(including cysts)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	2*		2*		2*		2*		2		1	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer <sup>†</sup>												
	i) current	4		4		4		4		4		1	
	ii) past and no evidence of current disease for 5 years	3		3		3		3		3		1	
Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3*		2*		2*		2*					
	b) 1 month or more postpartum	2*		1*		1*		1*					
Cervical cancer	Awaiting treatment	2		1		2		2		4	2	4	2
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		2		1		2		2		2		1	

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Cirrhosis	a) Mild (compensated)	1		1		1		1		1		1	
	b) Severe† (decompensated)	4		3		3		3		3		1	
DVT/PE	a) History of DVT/PE, not on anticoagulant therapy												
	i) higher risk for recurrent DVT/PE	4		2		2		2		2		1	
	ii) lower risk for recurrent DVT/PE	3		2		2		2		2		1	
	b) Acute DVT/PE	4		2		2		2		2		2	
	c) DVT/PE and established on anticoagulant therapy for at least 3 months												
	i) higher risk for recurrent DVT/PE	4*		2		2		2		2		2	
	ii) lower risk for recurrent DVT/PE	3*		2		2		2		2		2	
	d) Family history (first-degree relatives)	2		1		1		1		1		1	
	e) Major surgery												
	(i) with prolonged immobilization	4		2		2		2		2		1	
	(ii) without prolonged immobilization	2		1		1		1		1		1	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes mellitus	a) History of gestational diabetes mellitus only	1		1		1		1		1		1	
	b) Non-vascular disease												
	(i) non-insulin dependent	2		2		2		2		2		1	
	(ii) insulin dependent†	2		2		2		2		2		1	
	c) Nephropathy/retinopathy/neuropathy†	3/4*		2		3		2		2		1	
	d) Other vascular disease or diabetes of >20 years' duration†	3/4*		2		3		2		2		1	
Endometrial cancer†		1		1		1		1		4   2		4   2	
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		1		1		1		1		1		2	
Epilepsy†	(see also Drug Interactions)	1*		1*		1*		1*		1		1	
Gallbladder disease	a) Symptomatic												
	(i) treated by cholecystectomy	2		2		2		2		2		1	
	(ii) medically treated	3		2		2		2		2		1	
	(iii) current	3		2		2		2		2		1	
	b) Asymptomatic	2		2		2		2		2		1	
Gestational trophoblastic disease	a) Decreasing or undetectable β-hCG levels	1		1		1		1		3		3	
	b) Persistently elevated β-hCG levels or malignant disease†	1		1		1		1		4		4	
Headaches	a) Non-migrainous	1*	2*	1*	1*	1*	1*	1*	1*	1*	1*	1*	
	b) Migraine												
	i) without aura, age <35	2*	3*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	ii) without aura, age ≥35	3*	4*	1*	2*	2*	2*	2*	2*	2*	2*	1*	
	iii) with aura, any age	4*	4*	2*	3*	2*	3*	2*	3*	2*	3*	1*	

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD		
		I	C	I	C	I	C	I	C	I	C	I	C	
History of bariatric surgery <sup>†</sup>	a) Restrictive procedures	1		1		1		1		1		1		
	b) Malabsorptive procedures	COCs: 3		3		1		1		1		1		
P/R: 1														
History of cholestasis	a) Pregnancy-related	2		1		1		1		1		1		
	b) Past COC-related	3		2		2		2		2		1		
History of high blood pressure during pregnancy		2		1		1		1		1		1		
History of pelvic surgery		1		1		1		1		1		1		
HIV	High risk	1		1		1*		1		2		2		
	HIV infected (see also Drug Interactions) <sup>†</sup>	1*		1*		1*		1*		2		2		
	AIDS (see also Drug Interactions) <sup>†</sup>	1*		1*		1*		1*		3		2*		
	Clinically well on therapy	If on treatment, see Drug Interactions										2		2
Hyperlipidemias		2/3*		2*		2*		2*		2*		1*		
Hypertension	a) Adequately controlled hypertension	3*		1*		2*		1*		1		1		
	b) Elevated blood pressure levels (properly taken measurements)													
	(i) systolic 140-159 or diastolic 90-99	3		1		2		1		1		1		
	(ii) systolic ≥160 or diastolic ≥100 <sup>†</sup>	4		2		3		2		2		1		
	c) Vascular disease	4		2		3		2		2		1		
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		2		1		1		1		
Ischemic heart disease <sup>†</sup>	Current and history of	4		2		3		2		3		1		
Liver tumors	a) Benign													
	i) Focal nodular hyperplasia	2		2		2		2		2		1		
	ii) Hepatocellular adenoma <sup>†</sup>	4		3		3		3		3		1		
	b) Malignant <sup>†</sup>	4		3		3		3		3		1		
Malaria		1		1		1		1		1		1		

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*		2*		3*		2*		2		1	
Obesity	a) $\geq 30$ kg/m <sup>2</sup> BMI	2		1		1		1		1		1	
	b) Menarche to <18 years and $\geq 30$ kg/m <sup>2</sup> BMI	2		1		2		1		1		1	
Ovarian cancer <sup>†</sup>		1		1		1		1		1		1	
Parity	a) Nulliparous	1		1		1		1		2		2	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		2		1		1		1		1	
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)												
	(i) with subsequent pregnancy	1		1		1		1		1		1	
	(ii) without subsequent pregnancy	1		1		1		1		2		2	
	b) Current	1		1		1		1		4		2*	
Peripartum cardiomyopathy <sup>†</sup>	a) Normal or mildly impaired cardiac function												
	(i) <6 months	4		1		1		1		2		2	
	(ii) $\geq 6$ months	3		1		1		1		2		2	
	b) Moderately or severely impaired cardiac function	4		2		2		2		2		2	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	1*		1*		1*		1*		2		2	
	c) Immediately post-septic abortion	1*		1*		1*		1*		4		4	
Postpartum (see also Breastfeeding)	a) <21 days	4		1		1		1					
	b) 21 days to 42 days												
	(i) with other risk factors for VTE	3*		1		1		1					
	(ii) without other risk factors for VTE	2		1		1		1					
	c) >42 days	1		1		1		1					

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)	a) <10 minutes after delivery of the placenta									2			1
	b) 10 minutes after delivery of the placenta to < 4 weeks									2			2
	c) ≥4 weeks									1			1
	d) Puerperal sepsis									4			4
Pregnancy		NA*		NA*		NA*		NA*		4*			4*
Rheumatoid arthritis	a) On immunosuppressive therapy	2		1		2/3*		1		2	1	2	1
	b) Not on immunosuppressive therapy	2		1		2		1		1		1	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver <sup>†</sup>	1		1		1		1		1		1	
Severe dysmenorrhea		1		1		1		1		1		2	
STIs	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1		1		1		1		4	2*	4	2*
	b) Other STIs (excluding HIV and hepatitis)	1		1		1		1		2	2	2	2
	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1		1		1		1		2	2	2	2
	d) Increased risk of STIs	1		1		1		1		2/3*	2	2/3*	2
Smoking	a) Age <35	2		1		1		1		1		1	
	b) Age ≥35, <15 cigarettes/day	3		1		1		1		1		1	
	c) Age ≥35, ≥15 cigarettes/day	4		1		1		1		1		1	
Solid organ transplantation <sup>†</sup>	a) Complicated	4		2		2		2		3	2	3	2
	b) Uncomplicated	2*		2		2		2		2		2	
Stroke <sup>†</sup>	History of cerebrovascular accident	4		2	3	3		2	3	2		1	

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
Superficial venous thrombosis	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial thrombophlebitis	2		1		1		1		1		1	
Systemic lupus erythematosus <sup>†</sup>	a) Positive (or unknown) antiphospholipid antibodies	4		3		3	3	3		3		1	1
	b) Severe thrombocytopenia	2		2		3	2	2		2*		3*	2*
	c) Immunosuppressive treatment	2		2		2	2	2		2		2	1
	d) None of the above	2		2		2	2	2		2		1	1
Thrombogenic mutations <sup>†</sup>		4*		2*		2*		2*		2*		1*	
Thyroid disorders	Simple goiter/hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis <sup>†</sup> (see also Drug Interactions)	a) Non-pelvic	1*		1*		1*		1*		1		1	
	b) Pelvic	1*		1*		1*		1*		4	3	4	3
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	2*		2*		3*		3*		4*	2*	4*	2*
Uterine fibroids		1		1		1		1		2		2	
Valvular heart disease	a) Uncomplicated	2		1		1		1		1		1	
	b) Complicated <sup>†</sup>	4		1		1		1		1		1	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		2		2		2		1	1	1	
	b) Heavy or prolonged bleeding	1*		2*		2*		2*		1*	2*	2*	
Viral hepatitis	a) Acute or flare	3/4*	2	1		1		1		1		1	
	b) Carrier/Chronic	1	1	1		1		1		1		1	

See table footnotes on page 54.

## Appendix A (Continued)

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		LNG-IUD		Copper-IUD	
		I	C	I	C	I	C	I	C	I	C	I	C
<b>Drug Interactions</b>													
Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*		1		1		1		2/3*		2*	
	b) Non-nucleoside reverse transcriptase inhibitors	2*		2*		1		2*		2/3*		2*	
	c) Ritonavir-boosted protease inhibitors	3*		3*		1		2*		2/3*		2*	
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*		3*		1		2*		1		1	
	b) Lamotrigine	3*		1		1		1		1		1	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampicin or rifabutin therapy	3*		3*		1		2*		1		1	

**Abbreviations:** AIDS = acquired immunodeficiency syndrome; BMI = body mass index; C = continuation of contraceptive method; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; I = initiation of contraceptive method; LNG-IUD = levonorgestrel-releasing intrauterine device; NA = not applicable; PE = pulmonary embolism; STI = sexually transmitted infection; VTE = venous thromboembolism.

**Source:** Modified from CDC. Summary chart of U.S. medical eligibility criteria for contraceptive use. Atlanta, GA: CDC; 2012. (Available at <http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm>.)

\* Please see the complete guidance for a clarification to this classification: [www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm](http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm).

† Condition that exposes a woman to increased risk as a result of unintended pregnancy.



## Appendix B

### When To Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back-up) needed	Examinations or tests needed before initiation*
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection <sup>†</sup>
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection <sup>†</sup>
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

**Abbreviations:** BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

\* Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI (weight [kg]/height [m]<sup>2</sup>) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

<sup>†</sup> Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (Box 2). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

## Appendix C

### Examinations and Tests Needed Before Initiation of Contraceptive Methods

The examinations or tests noted apply to women who are presumed to be healthy. Those with known medical problems or other special conditions might need additional examinations or tests before being determined to be appropriate candidates for a particular method of contraception. The *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* (U.S. MEC), might be useful in such circumstances (5). The following classification was considered useful in differentiating the applicability of the various examinations or tests:

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

**Class B:** contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

**Class C:** does not contribute substantially to safe and effective use of the contraceptive method.

These classifications focus on the relationship of the examinations or tests to safe initiation of a contraceptive method. They are not intended to address the appropriateness of these examinations or tests in other circumstances. For example, some of the examinations or tests that are not deemed necessary for safe and effective contraceptive use might be appropriate for good preventive health care or for diagnosing or assessing suspected medical conditions.

No examinations or tests are needed before initiating condoms or spermicides. A bimanual examination is necessary for diaphragm fitting. A bimanual examination and cervical inspection are needed for cervical cap fitting.

**TABLE. Examinations and tests needed before initiation of contraceptive methods**

Examination or test	Contraceptive method and class							
	Cu-IUD and LNG-IUD	Implant	Injectable	CHC	POP	Condom	Diaphragm or cervical cap	Spermicide
<b>Examination</b>								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/height [m] <sup>2</sup> )	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
<b>Laboratory test</b>								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

**Abbreviations:** BMI = body mass index; CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

\* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

## Appendix D

### Routine Follow-Up After Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and

different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

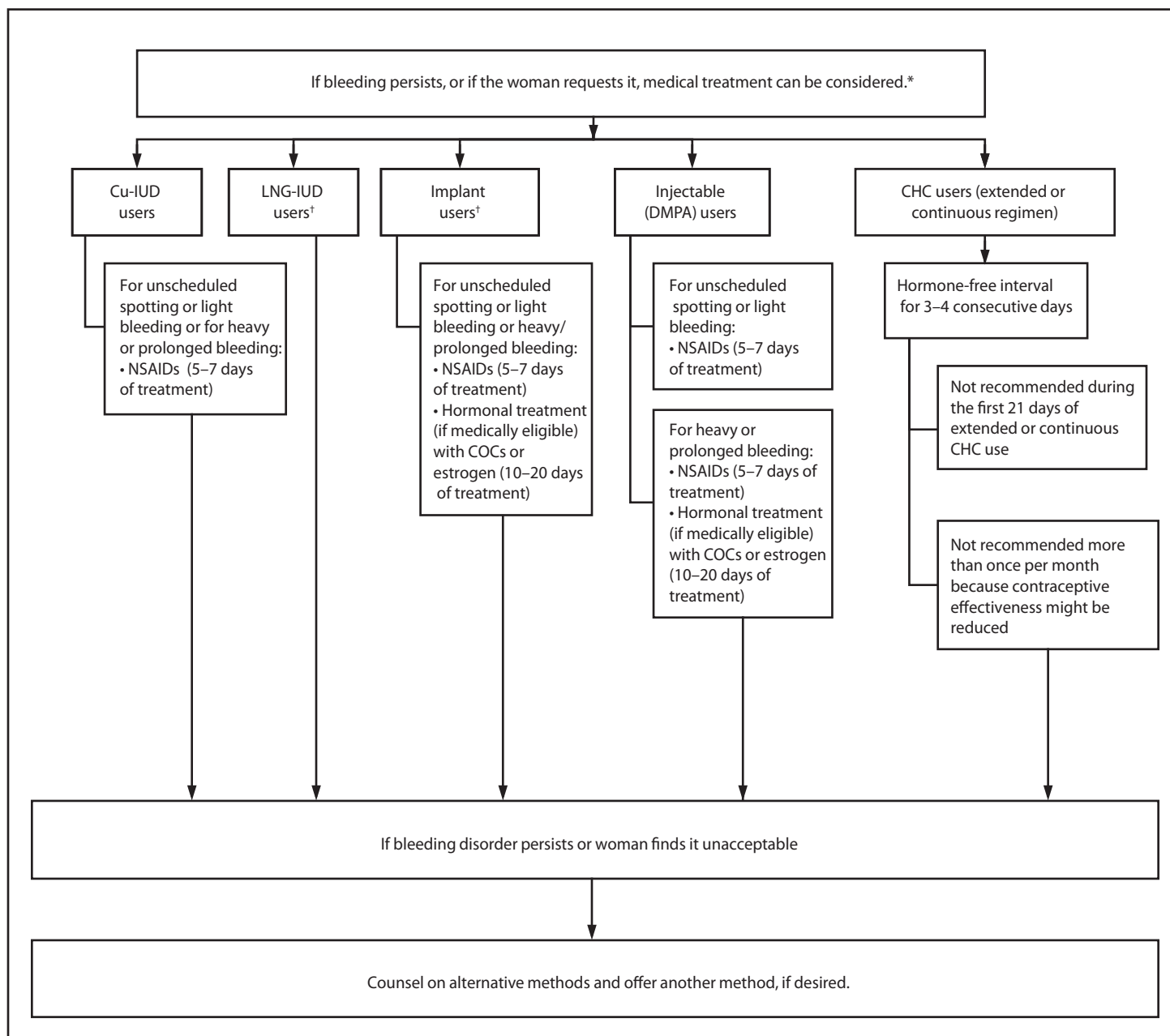
**TABLE. Routine follow-up after contraceptive initiation**

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
<b>General follow-up</b>					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
<b>Other routine visits</b>					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 2).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

**Abbreviations:** CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

## Appendix E

### Management of Women with Bleeding Irregularities While Using Contraception



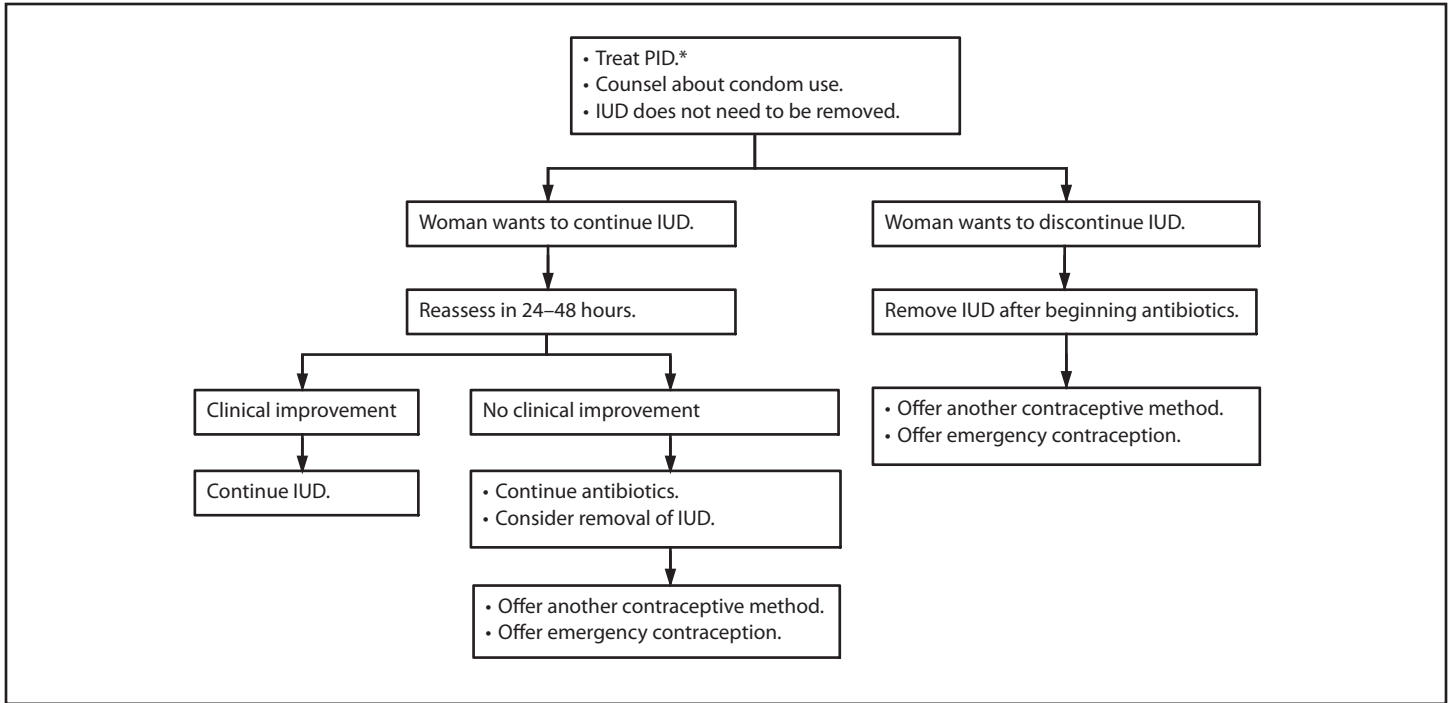
**Abbreviations:** CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

\* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.

† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

## Appendix F

### Management of the IUD when a Cu-IUD or an LNG-IUD User Is Found To Have Pelvic Inflammatory Disease



**Abbreviations:** Cu-IUD = copper-containing IUD; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing IUD; PID = pelvic inflammatory disease.  
\* Treat according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>).

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