

## U.S. Selected Practice Recommendations for Contraceptive Use, 2016

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

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The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

**Suggested citation:** [Author names; first three, then et al., if more than six.] [Title]. *MMWR Recomm Rep* 2016;65(No. RR-#):[inclusive page numbers].

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# U.S. Selected Practice Recommendations for Contraceptive Use, 2016

Kathryn M. Curtis, PhD<sup>1</sup>  
 Tara C. Jattaoui, MD<sup>1</sup>  
 Naomi K. Tepper, MD<sup>1</sup>  
 Lauren B. Zapata, PhD<sup>1</sup>  
 Leah G. Horton, MSPH<sup>1</sup>  
 Denise J. Jamieson, MD<sup>1</sup>  
 Maura K. Whiteman, PhD<sup>1</sup>

<sup>1</sup>Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion

## Summary

*The 2016 U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR) addresses a select group of common, yet sometimes controversial or complex, issues regarding initiation and use of specific contraceptive methods. These recommendations for health care providers were updated by CDC after review of the scientific evidence and consultation with national experts who met in Atlanta, Georgia, during August 26–28, 2015. The information in this report updates the 2013 U.S. SPR (CDC. U.S. selected practice recommendations for contraceptive use, 2013. MMWR 2013;62[No. RR-5]). Major updates include 1) revised recommendations for starting regular contraception after the use of emergency contraceptive pills and 2) new recommendations for the use of medications to ease insertion of intrauterine devices. The recommendations in this report are intended to serve as a source of clinical guidance for health care providers and provide evidence-based guidance to reduce medical barriers to contraception access and use. 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 45% 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 2010, resulted in U.S. government health care expenditures of \$21 billion (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). Strategies to prevent unintended pregnancy include assisting women at risk for unintended pregnancy and their partners with choosing appropriate contraceptive methods and helping them use methods correctly and consistently to prevent pregnancy.

In 2013, CDC published the first *U.S. Selected Practice Recommendations for Contraceptive Use* (U.S. SPR), adapted from global guidance developed by the World Health Organization (WHO SPR), which provided evidence-based guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate.

U.S. SPR is a companion document to *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) (<http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>), which provides recommendations on safe use of contraceptive methods for women with various medical conditions and other characteristics (5). WHO intended for the global guidance to be used by local or national policy makers, family planning program managers, and the scientific community as a reference when they develop family planning guidance at the country or program level. During 2012–2013, CDC went through a formal process to adapt the global guidance for best implementation in the United States, which included rigorous identification and critical appraisal of the scientific evidence through systematic reviews, and input from national experts on how to translate that evidence into recommendations for U.S. health care providers (6). At that time, CDC committed to keeping this guidance up to date and based on the best available evidence, with full review every few years (6).

This document updates the 2013 U.S. SPR (6) with new evidence and input from experts. Major updates include 1) revised recommendations for starting regular contraception after the use of emergency contraceptive pills and 2) new recommendations for the use of medications to ease insertion of intrauterine devices (IUDs). Recommendations are provided for health care providers on the safe and effective use of contraceptive methods and address provision of contraceptive methods and management of side effects and other problems

**Corresponding author:** Kathryn M. Curtis, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Telephone: 770-488-5200; E-mail: [kmc6@cdc.gov](mailto:kmc6@cdc.gov).

with contraceptive method use, within the framework of removing unnecessary medical barriers to accessing and using contraception. 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, who should seek advice from their health care providers when considering family planning options.

## Summary of Changes from the 2013 U.S. SPR

### Updated Recommendations

Recommendations have been updated regarding when to start regular contraception after ulipristal acetate (UPA) emergency contraceptive pills:

- Advise the woman to start or resume hormonal contraception no sooner than 5 days after use of UPA, and provide or prescribe the regular contraceptive method as needed. For methods requiring a visit to a health care provider, such as depo-medroxyprogesterone acetate (DMPA), implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.
- The woman needs to abstain from sexual intercourse or use barrier contraception for the next 7 days after starting or resuming regular contraception or until her next menses, whichever comes first.
- Any nonhormonal contraceptive method can be started immediately after the use of UPA.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

### New Recommendations

New recommendations have been made for medications to ease IUD insertion:

- Misoprostol is not recommended for routine use before IUD insertion. Misoprostol might be helpful in select circumstances (e.g., in women with a recent failed insertion).
- Paracervical block with lidocaine might reduce patient pain during IUD insertion.

## Methods

Since publication of the 2013 U.S. SPR, CDC has monitored the literature for new evidence relevant to the recommendations through the WHO/CDC continuous identification of research evidence (CIRE) system (7). This system identifies new evidence as it is published and allows WHO and CDC to update systematic reviews and facilitate updates to recommendations as new evidence warrants. Automated searches are run in PubMed weekly, and the results are reviewed. Abstracts that meet specific criteria are added to the web-based CIRE system, which facilitates coordination and peer review of systematic reviews for both WHO and CDC. In 2014, CDC reviewed all of the existing recommendations in the 2013 U.S. SPR for new evidence identified by CIRE that had the potential to lead to a changed recommendation. During August 27–28, 2014, CDC held a meeting in Atlanta, Georgia, of 11 family planning experts and representatives from partner organizations to solicit their input on the scope of and process for updating both the 2010 U.S. MEC and the 2013 U.S. SPR. The participants were experts in family planning and represented different provider types and organizations that represent health care providers. A list of participants is provided at the end of this report. The meeting related to topics to be addressed in the update of U.S. SPR based on new scientific evidence published since 2013 (identified through the CIRE system), topics addressed at a 2014 WHO meeting to update global guidance, and suggestions CDC received from providers for the addition of recommendations not included in the 2013 U.S. SPR (e.g., from provider feedback through e-mail, public inquiry, and questions received at conferences). CDC identified one topic to consider adding to the guidance: the use of medications to ease IUD insertion (evidence question: “Among women of reproductive age, does use of medications before IUD insertion improve the safety or effectiveness of the procedure [ease of insertion, need for adjunctive insertion measures, or insertion success] or affect patient outcomes [pain or side effects] compared with nonuse of these medications?”). CDC also identified one topic for which new evidence warranted a review of an existing recommendation: initiation of regular contraception after emergency contraceptive pills (evidence question: “Does ulipristal acetate for emergency contraception interact with regular use of hormonal contraception leading to decreased effectiveness of either contraceptive method?”). CDC determined that all other recommendations in the 2013 U.S. SPR were up to date and consistent with the current body of evidence for that recommendation.

In preparation for a subsequent expert meeting August 26–28, 2015, to review the scientific evidence

for potential recommendations, CDC staff conducted independent systematic reviews for each of the topics being considered. The purpose of these systematic reviews was to identify direct evidence related to the common clinical challenges associated with the recommendations. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews (8,9), and strength and quality of the evidence were assigned using the system of the U.S. Preventive Services Task Force (10). When direct evidence was limited or not available, indirect evidence (e.g., evidence on surrogate outcomes) and theoretical issues were considered and either added to direct evidence within a systematic review or separately compiled for presentation to the meeting participants. Completed systematic reviews were peer reviewed by two or three experts and then provided to participants before the expert meeting. Reviews are referenced throughout this document; the full reviews have been published and contain the details of each review, including systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessment. CDC staff continued to monitor new evidence identified through the CIRE system during the preparation for the August 2015 meeting.

During August 26–28, 2015, CDC held a meeting in Atlanta, Georgia, of 29 participants who were invited to provide their individual perspectives on the scientific evidence presented and to discuss potential recommendations that followed. Participants represented a wide range of expertise in family planning provision and research and included obstetrician/gynecologists, pediatricians, family physicians, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management. Lists of participants and any potential conflicts of interest are provided at the end of this report. During the meeting, the evidence from the systematic review for each topic was presented, including direct evidence and any indirect evidence or theoretical concerns. Participants provided their perspectives on using the evidence to develop the recommendations that would meet the needs of U.S. health care providers. After the meeting, CDC determined the recommendations in this report, taking into consideration the perspectives provided by the meeting participants. Feedback also was received from four external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These providers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. Areas of research that need additional investigation also were considered during the meeting (11).

## 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 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 (7). 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 most cases, U.S. SPR will follow any updates in the WHO guidance, which typically occurs every 5 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 5 years. Updates to the guidance can be found on the U.S. SPR website (<http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm>).

## 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 have been updated in 2016 (5) and are summarized (Appendix A).

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 incorporate 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 comments and a brief summary of the scientific evidence on which the recommendation is based. The level of evidence from the systematic reviews for each evidence summary are provided based on the U.S. Preventive Services Task Force system, which includes ratings for study design (I: randomized controlled trials; II-1: controlled trials without randomization; II-2: observational studies; and II-3: multiple time series or descriptive studies), ratings for internal validity (good, fair, or poor), and categorization of the evidence as direct or indirect for the specific review question (10).

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 IUDs (LNG-IUDs); 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 she is not pregnant. Guidance for health care providers on how to be reasonably certain that a woman is not pregnant also 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 although they might be needed to address other noncontraceptive health needs (12). Any additional screening needed for preventive health care can be performed at the time of contraception initiation, and initiation should not be delayed for test results. 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 (13):

**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>).

## 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. Although most contraceptive methods are safe for use by most women, U.S. MEC provides recommendations on the safety of specific contraceptive methods for women with certain characteristics and medical conditions (5); a U.S. MEC summary (Appendix A) and the categories of medical eligibility criteria for contraceptive use (Box 1) are provided.

Voluntary informed choice of contraceptive methods is an essential guiding principle, and contraceptive counseling, where applicable, might be an important contributor to the successful use of contraceptive methods.

Contraceptive method effectiveness is critically important in minimizing the risk for unintended pregnancy, particularly

#### BOX 1. 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.

**Source:** Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. medical eligibility criteria for contraceptive use. *MMWR* 2016;65(No. RR-3).

**Abbreviation:** U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use.

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 (Figure 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 use (actual use, including incorrect or inconsistent use) and perfect use (correct and consistent use according to directions) (14). 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.

In choosing a method of contraception, dual protection from the simultaneous risk for human immunodeficiency virus (HIV) 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, including HIV. Consistent and correct use of the male latex condom reduces the risk for HIV

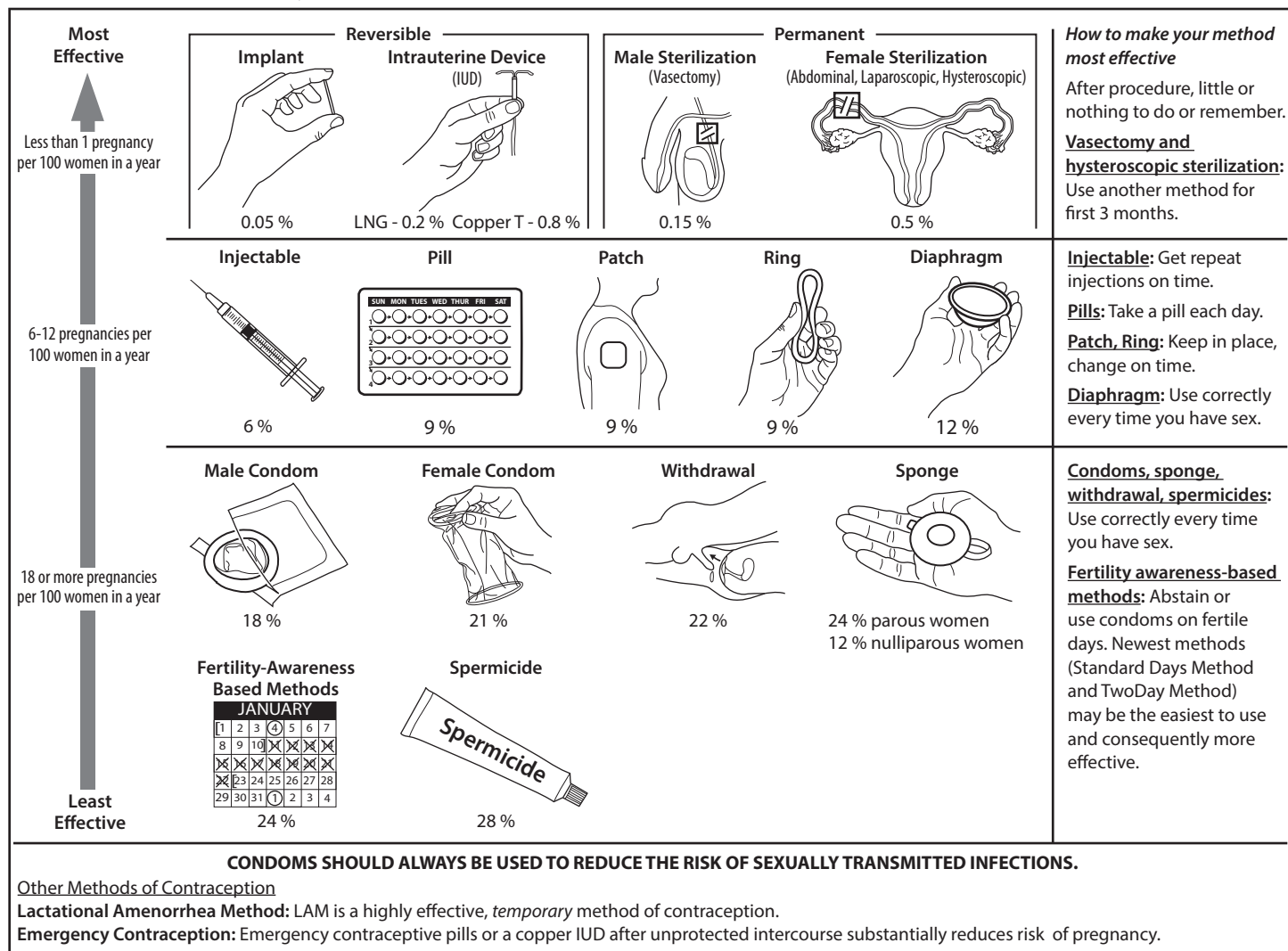
infection and other STDs, including chlamydial infection, gonococcal infection, and trichomoniasis (15). Although evidence is limited, use of female condoms can provide protection from acquisition and transmission of STDs (15). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (15). Additional information about prevention and treatment of STDs is available from the CDC *Sexually Transmitted Diseases Treatment Guidelines* (<http://www.cdc.gov/std/treatment>) (15).

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 assistance in 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 cycle 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.

## 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 (16–19). Therefore, CDC recommends that health care providers use these criteria to assess pregnancy status in a woman who is about to start using contraceptives (Box 2). 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

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.

\* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

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 (20). In addition, the likelihood of ovulation is low from days 1-7 of the menstrual cycle (21). 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 ≤7 days after



**BOX 2. 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

an abortion (22–24). A systematic review reported that the mean day of first ovulation among postpartum nonlactating women occurred 45–94 days after delivery (25). 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 (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds), and are amenorrheic, the risk for pregnancy is  $< 2\%$  (26,27).

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 (28–31). However, pregnancy detection rates can vary widely because of differences in test sensitivity and the timing of testing relative to missed menses (30,32). 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 (29). 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) (33–35).

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 (36–38). Studies also have shown no increased risk for neonatal or infant death or developmental abnormalities among infants exposed in utero to DMPA (37,39,40).

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 (41).

A systematic review identified four analyses of data from three diagnostic accuracy studies that evaluated the performance of the listed criteria (Box 2) through use of a pregnancy checklist compared with a urine pregnancy test conducted concurrently (42). 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 (16) (Level of evidence: Diagnostic accuracy studies, fair, direct).

## Intrauterine Contraception

Four IUDs are available in the United States, the copper-containing IUD and three levonorgestrel-releasing 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) (14). IUDs are long-acting, are reversible, and can be used by women of all ages, including adolescents, and 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 2).
- 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 2).
- **Need for back-up contraception:** No additional contraceptive protection is needed.

#### Postpartum (Including After Cesarean Delivery)

- **Timing:** The Cu-IUD can be inserted at any time postpartum, including immediately postpartum (U.S. MEC 1 or 2) (Box 1), if it is reasonably certain that the woman is not pregnant (Box 2). The Cu-IUD should not be inserted in a woman with postpartum sepsis (e.g., chorioamnionitis or endometritis) (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 a 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 2). Waiting for her next menstrual cycle 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 non-postpartum 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) (43) (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 2).

### 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 2).
- **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 Delivery)

- **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 2). The LNG-IUD should not be inserted in a woman with postpartum sepsis (e.g., chorioamnionitis or endometritis) (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) (27), 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 2). Waiting for her next menstrual cycle 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 may consider providing any type of 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 (43).

## 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 1). 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

**TABLE 1. Classification of examinations and tests needed before IUD insertion**

Examination or test	Class*	
	Copper-containing IUD	Levonorgestrel-releasing IUD
<b>Examination</b>		
Blood pressure	C	C
Weight (BMI) (weight [kg] / height [m] <sup>2</sup> )	— <sup>†</sup>	— <sup>†</sup>
Clinical breast examination	C	C
Bimanual examination and cervical inspection	A	A
<b>Laboratory test</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	— <sup>§</sup>	— <sup>§</sup>
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.

\* **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 1). 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.

<sup>§</sup> Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's *STD Treatment Guidelines* (<http://www.cdc.gov/std/treatment>), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

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 (44,45).

**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 with risk factors (15) (<http://www.cdc.gov/std/treatment>). If STD screening guidelines have been followed, most women do not need additional STD screening at the time of IUD insertion, and insertion should not be delayed. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC STD treatment guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4). A systematic review identified two studies that demonstrated no differences in PID rates among women who screened positive for gonorrhea or chlamydia and underwent concurrent IUD insertion compared with women who screened positive and initiated other contraceptive methods (46). Indirect evidence demonstrates women who undergo same-day STD screening and IUD insertion have similar PID rates compared with women who have delayed IUD insertion. Women who undergo same-day STD screening and IUD insertion have low incidence rates of PID. Algorithms for predicting PID among women with risk factors for STDs have poor predictive value. Risk for PID among women with risk factors for STDs is low (15,47–57). 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 (51,54).

**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 Cu-IUDs (U.S. MEC 2) (5). 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 (58). Evidence from one randomized trial (59)

and one prospective cohort study (60) showed no significant changes in hemoglobin among Cu-IUD users with anemia, whereas two prospective cohort studies (61,62) 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 (63–83), 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).

**Lipids:** Screening for dyslipidemias is not necessary for the safe initiation of Cu-IUD or LNG-IUD 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 (57). During 2009–2012 among women aged 20–44 years in the United States, 7.6% had high cholesterol, defined as total serum cholesterol  $\geq 240$  mg/dL (84). During 1999–2008, the prevalence of undiagnosed hypercholesterolemia among women aged 20–44 years was approximately 2% (85). Studies have shown mixed results about the effects of hormonal methods on lipid levels among both healthy women and women with baseline lipid abnormalities, and the clinical significance of these changes is unclear (86–89).

**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 (57). In 2012, among U.S. women, the percentage with liver disease (not further specified) was 1.3% (90). In 2013, the incidence of acute hepatitis A, B, or C was  $\leq 1$  per 100,000 U.S. population (91). During 2002–2011, the incidence of liver carcinoma among U.S. women was approximately 3.7 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 (95). The incidence of breast cancer among women of reproductive age in the United States is low. In 2012, the incidence of breast cancer among women aged 20–49 years was approximately 70.7 per 100,000 women (96).

**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 (57). Cervical cancer is rare in the United States, with an incidence rate of 9.8 per 100,000 women during 2012 (96). The incidence and mortality rates from cervical cancer have declined dramatically in the United States, largely because of cervical cytology screening (97). Overall screening rates for cervical cancer in the United States are high; in 2013 among women aged 18–44 years, approximately 77% reported having cervical cytology screening within the last 3 years (98).

**HIV screening:** Women with HIV infection can use (U.S. MEC 1) or generally can use (U.S. MEC 2) IUDs (5). Therefore, HIV screening is not necessary before IUD insertion. A systematic review did not identify any evidence regarding outcomes among women who were screened versus not screened for HIV infection before IUD insertion (57). Limited evidence suggests that IUDs are not associated with disease progression, increased infection, or other adverse health effects among women with HIV infection (99–114).

**Other screening:** Women with hypertension, diabetes, 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 Medications to Ease IUD Insertion

- Misoprostol is not recommended for routine use before IUD insertion. Misoprostol might be helpful in select circumstances (e.g., in women with a recent failed insertion).
- Paracervical block with lidocaine might reduce patient pain during IUD insertion.

**Comments and Evidence Summary.** Potential barriers to IUD use include anticipated pain with insertion and provider concerns about difficult insertion. Identifying effective approaches to ease IUD insertion might increase IUD initiation.

Evidence for misoprostol from two systematic reviews, including a total of 10 randomized controlled trials, suggests that misoprostol does not improve provider ease of insertion, reduce the need for adjunctive insertion measures, or improve insertion success (Level of evidence: I, good to fair, direct) and might increase patient pain and side effects (Level of evidence: I, high quality) (115,116). However, one randomized controlled trial examined women with a recent failed IUD insertion and found significantly higher insertion success with second insertion attempt among women pretreated with misoprostol versus placebo (Level of evidence: I, good, direct) (117).

Limited evidence for paracervical block with lidocaine from one systematic review suggests that it might reduce patient pain (115). In this review, two randomized controlled trials found significantly reduced pain at either tenaculum placement or IUD insertion among women receiving paracervical block with 1% lidocaine 3–5 minutes before IUD insertion (118,119). Neither trial found differences in side effects among women receiving paracervical block compared with controls (Level of evidence: I, moderate to low quality) (118,119).

Limited evidence on nonsteroidal antiinflammatory drugs (NSAIDs) and nitric oxide donors generally suggested no positive effect; evidence on lidocaine with administration other than paracervical block was limited and inconclusive (Level of evidence for provider ease of insertion: I, good to poor, direct; Level of evidence for need for adjunctive insertion measures: I, fair, direct; Level of evidence for patient pain: I, high to low quality; Level of evidence for side effects: I, high to low quality) (115,116).

## 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 (120). 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 (51). In addition, the American Heart Association recommends that the use of prophylactic antibiotics solely to prevent infective endocarditis is not needed for genitourinary procedures (121). Studies have not demonstrated a conclusive link between genitourinary procedures and infective endocarditis or a preventive benefit of prophylactic antibiotics during such procedures (121).

### 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 who might benefit from more frequent follow-up visits include adolescents, persons with certain medical conditions or characteristics, and persons with multiple medical conditions.

- Advise the 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 (122) (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 (123) (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 generally was low, the largest study suggested that the rate of PID was significantly higher in the first 20 days after insertion (51) (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:
  - 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 (64). 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) (124,125).

Evidence is limited on specific drugs, doses, and durations of use for effective treatments for bleeding irregularities with Cu-IUD use. Therefore, although this report includes general

recommendations for treatments to consider, evidence for specific regimens is lacking.

A systematic review identified 11 studies that examined various therapeutic treatments for heavy menstrual bleeding, prolonged menstrual bleeding, or both among women using Cu-IUDs (126). 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 with either a placebo or a baseline cycle. Three of these trials examined the use of indomethacin (127–129), three examined mefenamic acid (130–132), and three examined flufenamic acid (127,128,133). Other NSAIDs used in the reported trials included alclofenac (127,128), suprofen (134), and diclofenac sodium (135). All but one NSAID study (131) 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 (135). 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 (136,137). 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 (138). 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 (130) (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 (127) (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 (139). 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) (124,125). 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* (15).
- 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 (140). 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 (141). Another randomized trial showed no differences in laboratory findings among women who removed the IUD compared with those who did not (142). One prospective cohort study showed no differences in clinical or laboratory findings during hospitalization; however, the IUD removal group had longer hospitalizations (143). 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 (144). 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 for 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 to 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 Safely Retrieved

- 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 (41). 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, 8 out of 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 (14). 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 2).

### 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 2).
- **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 2).
- **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) (27), 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 >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 2).
- **Need for back-up contraception:** If a woman is <21 days postpartum, no additional contraceptive protection is needed. 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 >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 2). Waiting for her next menstrual cycle 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.
  - If the woman cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the woman to use ECPs (with the exception of UPA) 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 2). 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 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 (U.S. MEC 3) use implants (5). However, none of these conditions are likely to be detected

by pelvic examination (145). 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 (95). 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).

**Lipids:** Screening for dyslipidemias is not necessary for the safe initiation of implants 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 (57). During 2009–2012 among women aged 20–44 years in the United States, 7.6% had high cholesterol, defined as total serum cholesterol  $\geq 240$  mg/dL (84). During 1999–2008, the prevalence of undiagnosed hypercholesterolemia among women aged 20–44 years was approximately 2% (85). Studies have shown mixed results regarding the effects of hormonal methods on lipid levels among both healthy women and women with baseline lipid abnormalities, and the clinical significance of these changes is unclear (86–89).

**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 (57). In 2012, the percentage of U.S. women with liver disease (not further specified) was 1.3% (90). In 2013, the incidence of acute hepatitis A, B, or C was  $\leq 1$  per 100,000 U.S. population (91). During 2002–2011, the incidence of liver carcinoma among U.S. women was approximately 3.7 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

**TABLE 2. 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> )	—†
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.

\* **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 1). 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.

examination before initiation of implants 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 (95). The incidence of breast cancer among women of reproductive age in the United States is low. In 2012, the incidence of breast cancer among women aged 20–49 years was approximately 70.7 per 100,000 women (96).

**Other screening:** Women with hypertension, diabetes, 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 who might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise the 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 change 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 (122).

## 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 indicates 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 (146). 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) (124,125).

A systematic review and four newly published studies examined several medications for the treatment of bleeding irregularities with primarily levonorgestrel contraceptive implants (147–151). 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 (149,150). 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 (151,152). Doxycycline alone or in combination with ethinyl estradiol did not improve bleeding cessation among etonogestrel implant users (151). Among LNG implant users, mifepristone reduced the number of bleeding or spotting days but only after 6 months of treatment (153). Evidence also suggests that estrogen (154–156), daily COCs (154), LNG pills (155), tamoxifen (157), or tranexamic acid (158) can reduce the number of bleeding or spotting days during treatment among LNG 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 (159,160). Use of aspirin did not result in a significant difference in median length of bleeding or bleeding and spotting episodes after treatment (159). 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 (148,155).

## 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 (14). 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 2).

### 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 2).
- **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; U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 2).
- **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) (27), 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 2).
- **Need for back-up contraception:** If a woman is <21 days postpartum, no additional contraceptive protection is needed. 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 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 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 2). Waiting for her next menstrual cycle 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.
  - If the woman cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the woman to use ECPs (with the exception of UPA) 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 (161). Evidence from two studies with small sample sizes 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) (162–164). 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 (165–169) (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 to monitor DMPA 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).

**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, 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 (145). 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 (95). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of

**TABLE 3. Classification of examinations and tests needed before depo-medroxyprogesterone acetate 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; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use.

\* **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 1). 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.

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 (170). The prevalence of undiagnosed hypertension among women of reproductive age is low. During 2009–2012 among women aged 20–44 years in the United States, the prevalence of hypertension was 8.7% (84). During 1999–2008, the percentage of women aged 20–44 years with undiagnosed hypertension was 1.9% (85).

**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 (57). The prevalence of diabetes among women of reproductive age is low. During 2009–2012 among women aged 20–44 years in the United States, the prevalence of diabetes was 3.3% (84). During 1999–2008, the percentage of women aged 20–44 years with undiagnosed diabetes was 0.5% (85). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (171–177).

**Lipids:** Screening for dyslipidemias is not necessary for the safe initiation of injectables 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 (57). During 2009–2012 among women aged 20–44 years in the United States, 7.6% had high cholesterol, defined as total serum cholesterol  $\geq 240$  mg/dL (84). During 1999–2008, the prevalence of undiagnosed hypercholesterolemia among women aged 20–44 years was approximately 2% (85). Studies have shown mixed results about the effects of hormonal methods on lipid levels among both healthy women and women with baseline lipid abnormalities, and the clinical significance of these changes is unclear (86–89).

**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 (57). In 2012, among U.S. women, the percentage with liver disease (not further specified) was 1.3% (90). In 2013, the incidence of acute hepatitis A, B, or C was  $\leq 1$  per 100,000 U.S. population (91). During 2002–2011, the incidence of liver carcinoma among U.S. women was approximately 3.7 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 (95). The incidence of breast cancer among women of reproductive age in the United States is low. In 2012, the incidence of breast cancer among women aged 20–49 years was approximately 70.7 per 100,000 women (96).

**Other screening:** Women with 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 who might benefit from frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise the 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 change 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 (123). 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 (178,179). 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 (180) (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 2). 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 (with the exception of UPA) if appropriate.

**Comments and Evidence Summary.** No time limits exist for 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 (181). 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 (182–184). 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 (185–193) (Level of evidence: level 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 (194). In addition, amenorrhea is common after  $\geq 1$  years of continuous use (194,195). 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 (124,125).

A systematic review, as well as two additional studies, examined the treatment of bleeding irregularities during DMPA use (195–197). 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 (198,199). 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 (200). 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 (201). 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 (14). 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 2).

### 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 2).
- **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 (5) and if it is reasonably certain that she is not pregnant. (Box 2).
- 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) (27), 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 to use the method (5) and if it is reasonably certain that she is not pregnant (Box 2).
- 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:** If a woman is <21 days postpartum, no additional contraceptive protection is needed. 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 following first-trimester or second-trimester abortion, 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 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 2). Waiting for her next menstrual cycle 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.
  - If the woman cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the woman to use ECPs at the time of IUD removal. Combined hormonal contraceptives can be started immediately after use of ECPs (with the exception of UPA). Combined hormonal contraceptives can be started no sooner than 5 days after use of UPA.

**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 (202). Overall, the evidence suggested that pregnancy rates did not differ by the timing of combined hormonal contraceptive initiation (169,203–205) (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) (206–215) (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 (204,205,216–220) (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 (203,204,216–221) (Level of evidence: I to II-2, good to poor, direct).

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

Among healthy women, few examinations or tests are needed before initiation of combined hormonal contraceptives (Table 4). 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  $\geq 160$  mmHg 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 evaluated before initiating combined hormonal contraceptives. In instances in which blood pressure cannot be measured by a provider, blood pressure measured in other settings can be 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 (170). 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 (222–224). 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 (225,226). One case-control study showed no difference in the risk for hemorrhagic stroke among women who initiated COCs regardless of whether their

**TABLE 4. Classification of examinations and tests needed before combined hormonal contraceptive initiation**

Examination or 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.

\* **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 instances in which blood pressure cannot be measured by a provider, blood pressure measured in other settings can be reported by the woman to her 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 1). 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.

blood pressure was measured (227). 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 and 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 (145). 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 (95). 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: Level 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 (57). The prevalence of diabetes among women of reproductive age is low. During 2009–2012 among women aged 20–44 years in the United States, the prevalence of diabetes was 3.3% (84). During 1999–2008, the percentage of women aged 20–44 years with undiagnosed diabetes was 0.5% (85). Although hormonal contraceptives can have some adverse effects on glucose metabolism in healthy and diabetic women, the overall clinical effect is minimal (171–177).

**Lipids:** Screening for dyslipidemias is not necessary for the safe initiation of combined hormonal contraceptives 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 (57). During 2009–2012 among women aged 20–44 years in the United States, 7.6% had high cholesterol, defined as total serum cholesterol  $\geq 240$  mg/dL (84). During 1999–2008, the prevalence of undiagnosed hypercholesterolemia among women aged 20–44 years was approximately 2% (85). A systematic review identified few studies, all of poor quality, that suggest that women with known dyslipidemias using combined hormonal contraceptives might be at increased risk for myocardial infarction, cerebrovascular accident, or venous thromboembolism compared with women without dyslipidemias; no studies were identified that examined risk for pancreatitis among women with known dyslipidemias using combined hormonal contraceptives (89). Studies have shown mixed results regarding the effects of hormonal contraceptives on lipid levels among both healthy women and women with

baseline lipid abnormalities, and the clinical significance of these changes is unclear (86–89).

**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 (57). In 2012, among U.S. women, the percentage with liver disease (not further specified) was 1.3% (90). In 2013, the incidence of acute hepatitis A, B, or C was  $\leq 1$  per 100,000 U.S. population (91). During 2002–2011, the incidence of liver carcinoma among U.S. women was approximately 3.7 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 (228). 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 (229–231).

**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 (95). The incidence of breast cancer among women of reproductive age in the United States is low. In 2012, the incidence of breast cancer among women aged 20–49 years was approximately 70.7 per 100,000 women (96).

**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 (232). 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 (233–235). However, one study found no difference in continuation when patients were provided one and then three packs versus four packs all at once (236). 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 (i.e., 13 packs versus three packs) also was associated with increased pill wastage in one study (234) (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 who might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise the 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 change 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 other settings.

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 (123). 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

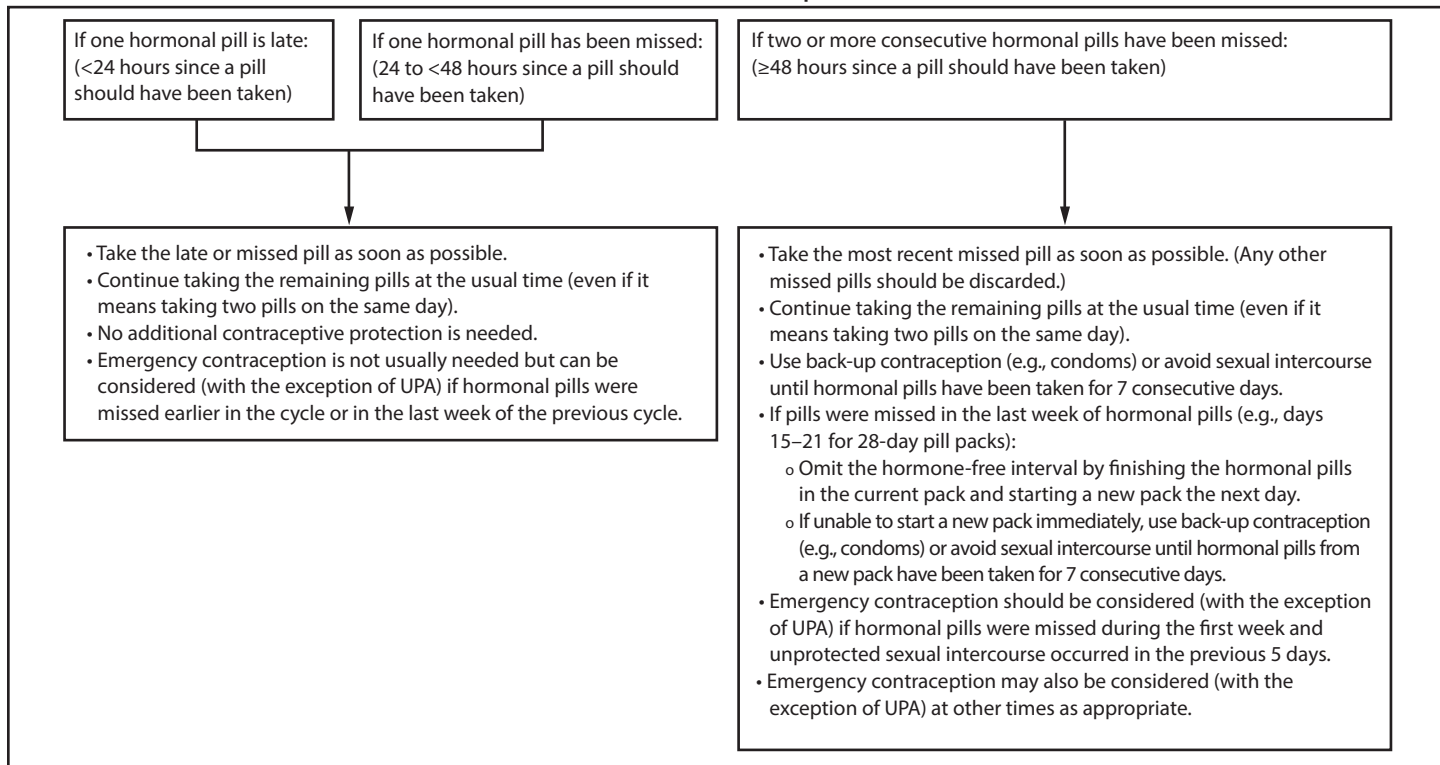
For the following recommendations, a dose is considered late when <24 hours have elapsed since the dose should have been taken. A dose is considered missed if  $\geq$ 24 hours have elapsed since the dose should have been taken. For example, if a COC pill was supposed to have been taken on Monday at 9:00 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).

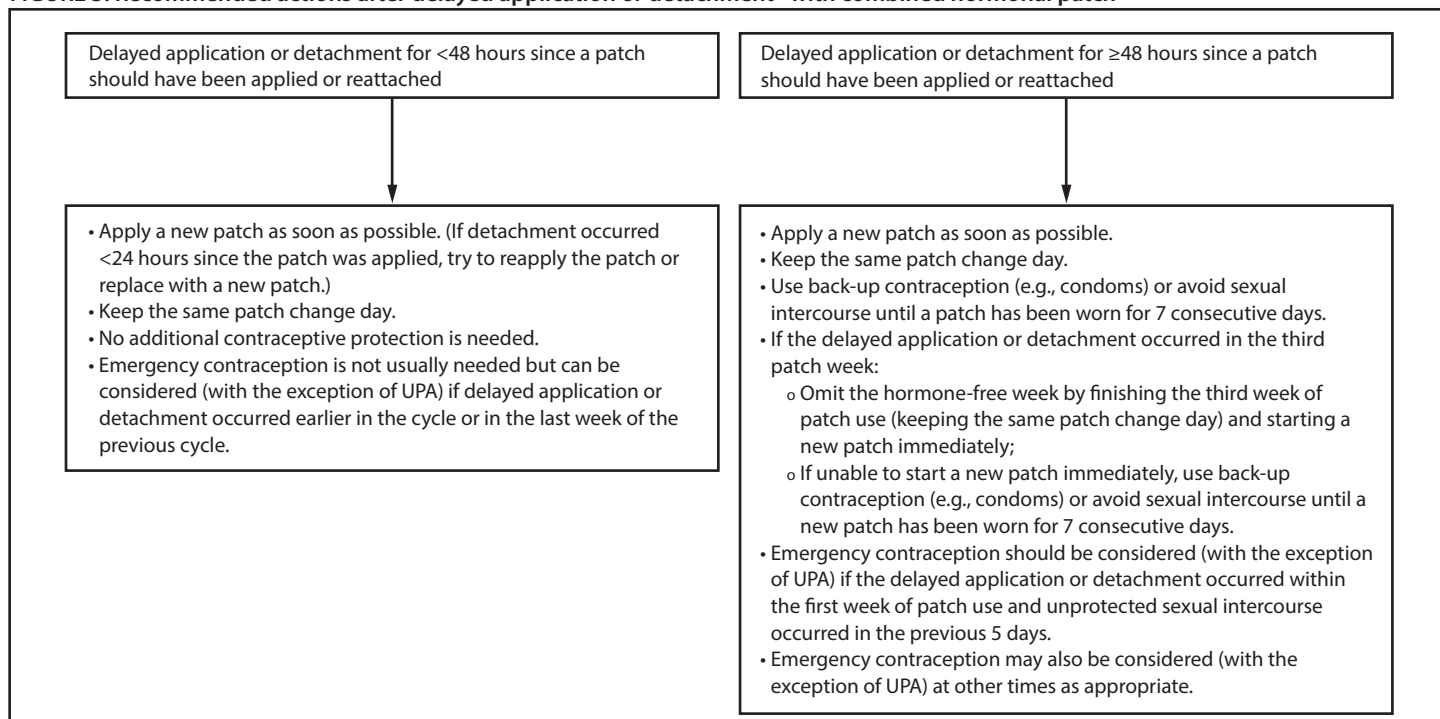
A systematic review identified 36 studies that examined measures of contraceptive effectiveness of combined hormonal contraceptives during cycles with extended hormone-free intervals, shortened hormone-free intervals, or deliberate nonadherence on days not adjacent to the hormone-free interval (237). Most of the studies examined COCs (215,238–265), two examined the combined hormonal patch (259,266), and six examined the combined vaginal ring (211,267–271). 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 (241,244,246,247,249,250,252–255); 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 (239,245–247,255,256,258,259). Studies comparing 7-day hormone-free intervals with shorter hormone-free intervals found lower rates of pregnancy (238,242,251,257) and significantly greater suppression of ovulation (240,250,261–263,265) among women with shorter intervals in all but one study (260), which found no difference. Two studies that compared 30- $\mu$ g ethinyl estradiol pills with 20- $\mu$ g ethinyl estradiol pills showed more follicular activity when 20- $\mu$ g ethinyl estradiol pills were missed (241,244). In 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 (267,268,270); 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 (211); 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 (271). 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 (259), and one pharmacokinetic study found that serum levels of

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



Abbreviation: UPA = ulipristal acetate.

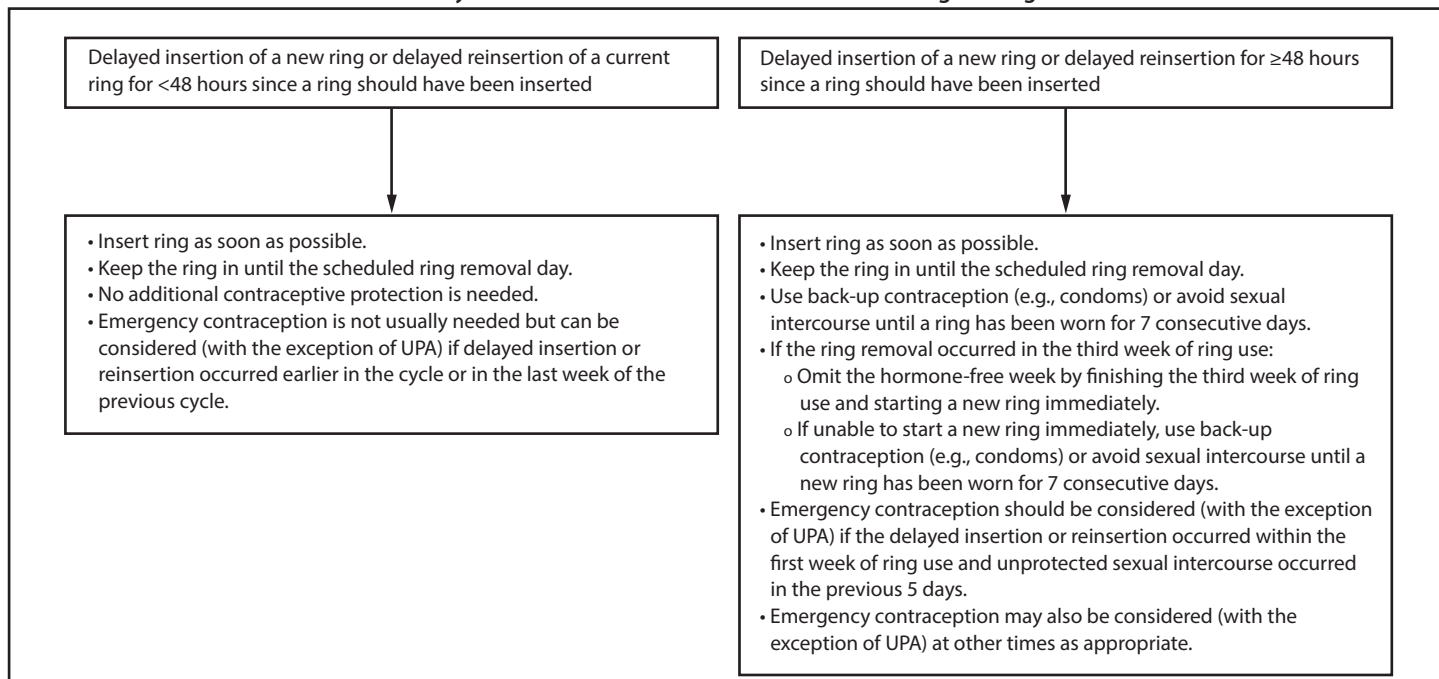
**FIGURE 3. Recommended actions after delayed application or detachment\* with combined hormonal patch**



Abbreviation: UPA = ulipristal acetate.

\* 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.

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



**Abbreviation:** UPA = ulipristal acetate.

\* 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.

ethinyl estradiol and progestin norelgestromin remained within reference ranges after extending patch wear for 3 days (266). 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

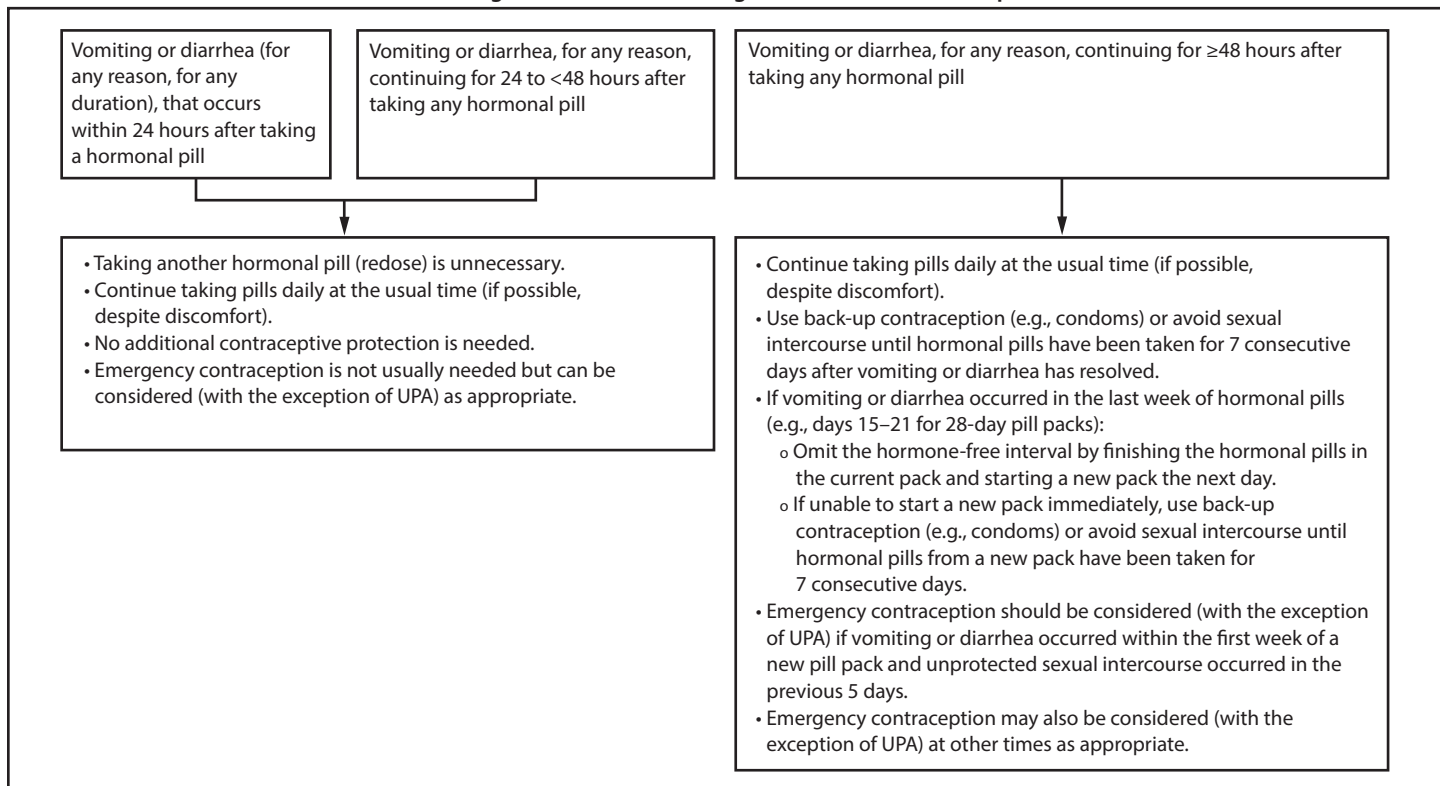
Certain steps should be taken by women who experience vomiting or severe diarrhea while using COCs (Figure 5).

**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 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) (272).
- 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:

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



Abbreviation: UPA = ulipristal acetate.

- 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 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 (273). 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 (124,125,274).

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 (275). 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 (276,277). 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 (278) (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 (14). 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.

### Initiation of POPs

#### Timing

- POPs can be started at any time if it is reasonably certain that the woman is not pregnant (Box 2).

#### 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 2).
- **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; U.S. MEC 1 if ≥1 month postpartum) if it is reasonably certain that the woman is not pregnant (Box 2).
- **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) (27), no additional contraceptive protection is needed. Otherwise, a woman who is ≥21 days postpartum and has not experienced return of her menstrual cycles, she 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 2).
- **Need for back-up contraception:** If a woman is <21 days postpartum, no additional contraceptive protection is needed. 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 2). Waiting for her next menstrual cycle 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 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 7 days before removing the IUD and switching to the new method.
  - If the woman cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the woman to use ECPs at the time of IUD removal. POPs can be started immediately after use of ECPs (with the exception of UPA). POPs can be started no sooner than 5 days after use of UPA.

**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 (279). 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 (279). 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 (279). 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 5). 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. The 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 (145). 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 (95). No differences in risk factors for cervical neoplasia, incidence of STDs, incidence of abnormal Papanicolaou smears, or incidence of

**TABLE 5. Classification of examinations and tests needed before progestin-only pill 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; HIV = human immunodeficiency virus; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use.

\* **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 1). 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.

abnormal findings from wet mounts were observed (Level of evidence: II-2 fair, direct).

**Lipids:** Screening for dyslipidemias is not necessary for the safe initiation of POPs 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 (57). During 2009–2012 among women aged 20–44 years in the United States, 7.6% had high cholesterol, defined as total serum cholesterol  $\geq 240$  mg/dL (84). During 1999–2008, the prevalence of undiagnosed hypercholesterolemia among women aged 20–44 years was approximately 2% (85). Studies have shown mixed results about the effects of hormonal methods on lipid levels among both healthy women and women with baseline lipid abnormalities, and the clinical significance of these changes is unclear (86–89).

**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 (57). In 2012, among U.S. women, the percentage with liver disease (not further specified) was 1.3% (90). In 2013, the incidence of acute hepatitis A, B, or C was  $\leq 1$  per 100,000 U.S. population (91). During 2002–2011, the incidence of liver carcinoma among U.S. women was approximately 3.7 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 (95). The incidence of breast cancer among women of reproductive age in the United States is low. In 2012, the incidence of breast cancer among women aged 20–49 years was approximately 70.7 per 100,000 women (96).

**Other screening:** Women with hypertension, diabetes, 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 visit, 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 (232). 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 (233–235). However, one study found no difference in continuation when patients were provided one and then three packs versus four packs all at once (236). 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 (234) (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 who might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

- Advise the 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 change 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 and 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 (with the exception of UPA) 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 (279). 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 (279). 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 (279). 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 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 (with the exception of UPA) 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 (280). Approximately 5 out of 100 women

become pregnant in the first year of use with perfect (i.e., correct and consistent) use of SDM (280); 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 Durations of the Menstrual Cycle

#### Menstrual Cycles of 26–32 Days

- The woman 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 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 (21,281,282).

### 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

- 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 µg of ethinyl estradiol plus 0.50 mg of levonorgestrel followed by a second dose of 100 µg 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 (283) 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 (284). 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) (285). The levonorgestrel formulation might be less effective than UPA among obese women (286).

Two studies of UPA use found consistent decreases in pregnancy rates when administered within 120 hours of unprotected sexual intercourse (284,287). 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 (288–292). 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 (293) (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 (294). 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

- Advise the woman to start or resume hormonal contraception no sooner than 5 days after use of UPA, and provide or prescribe the regular contraceptive method as needed. For methods requiring a visit to a health care provider, such as DMPA, implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.
- The woman needs to abstain from sexual intercourse or use barrier contraception for the next 7 days after starting or resuming regular contraception or until her next menses, whichever comes first.
- Any nonhormonal contraceptive method can be started immediately after the use of UPA.
- 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.** 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. A health care provider may provide or prescribe pills, the patch, or the ring for a woman to start no sooner than 5 days after use of UPA. For methods requiring a visit to a health care provider, such as DMPA, implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.

Data on when a woman can start regular contraception after ECPs are limited to pharmacodynamic data and expert opinion (295–297). In one pharmacodynamic study of women who were randomly assigned to either UPA or placebo groups mid-cycle followed by a 21-day course of combined hormonal contraception found no difference between UPA and placebo groups in the time for women's ovaries to reach quiescence by ultrasound and serum estradiol (296); this finding suggests that UPA did not have an effect on the combined hormonal contraception. In another pharmacodynamic study with a crossover design, women were randomly assigned to one of three groups: 1) UPA followed by desogestrel for 20 days started 1 day later; 2) UPA plus placebo; or 3) placebo plus desogestrel for 20 days (295). Among women taking UPA followed by desogestrel, a higher incidence of ovulation in the first 5 days was found compared with UPA alone (45% versus 3%, respectively), suggesting desogestrel might decrease the effectiveness of UPA. No concern exists that administering combined estrogen and progestin or levonorgestrel formulations of ECPs concurrently with systemic hormonal contraception decreases the effectiveness of either emergency or regular contraceptive methods because these formulations do not have antiprogestin properties like UPA. If a woman is planning to initiate contraception after the next menstrual bleeding 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 (298). 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 (299–301). Use of the split-dose levonorgestrel showed no differences in nausea and vomiting compared with the single-dose levonorgestrel (288,290,292,302) (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 (303,304). 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 (14). 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 (305,306). Although these methods are highly effective, pregnancies can occur many years after the procedure, and the risk for pregnancy is higher among younger women (306,307).

A systematic review was conducted to identify studies that reported whether pregnancies occurred after hysteroscopic sterilization (308). 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 (309–311). 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 (310–315). 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 (310,311,313–316). 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 (14). 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 (317). All English-language publications on vasectomy published during 1949–2011 were reviewed. For more information, see the American Urological Association *Vasectomy Guidelines* (<https://www.auanet.org/common/pdf/education/clinical-guidance/Vasectomy.pdf>).

Motile sperm disappear within a few weeks after vasectomy (318–321). 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) (317). The number of ejaculations after vasectomy is not a reliable indicator of when azoospermia or rare nonmotile sperm will be achieved (317). 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 (322–326).

A median of 78% (range 33%–100%) of men return for a single postvasectomy semen analysis (317). 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 (322,327–331). Assigning men an appointment after their vasectomy might improve compliance with follow-up (332).

## 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 (333,334). The median age of menopause is approximately 51 years in North America (333)

but can vary from ages 40–60 years (335). The median age of definitive loss of natural fertility is 41 years but can range up to age 51 years (336,337). 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 (333).

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 (338–340). 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.

In two studies, the incidence of venous thromboembolism was higher among oral contraceptive users aged  $\geq 45$  years compared with younger oral contraceptive users (341–343); however, an interaction between hormonal contraception and increased age compared with baseline risk was not demonstrated (341,342) or was not examined (343). 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 (344,345). 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 (346) 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 (347–353) (Level of evidence: II-2, fair, direct).



## Conclusion

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 U.S. SPR recommendations 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 conducts surveys of family planning health care providers to assess attitudes and practices related to contraceptive use. Results from these surveys 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>.

### Acknowledgments

This report is based, in part, on the work of the Promoting Family Planning Team, Department of Reproductive Health and Research, World Health Organization, and its development of the *Selected Practice Recommendations for Contraceptive Use, 3rd edition*.

### U.S. Selected Practice Recommendations for Contraceptive Use Participants

#### CDC Guideline Development Group for U.S. Medical Eligibility Criteria for Contraceptive Use and U.S. Selected Practice Recommendations for Contraceptive Use

Kathryn M. Curtis, PhD (Chair), Erin Berry-Bibee, MD, Suzanne G. Folger, PhD, Leah G. Horton, MSPH, Denise J. Jamieson, MD, Tara C. Jatlaoui, MD, Polly A. Marchbanks, PhD, H. Pamela Pagano, MPH, Halley E.M. Riley, MPH, Mirelys Rodriguez, Katharine B. Simmons, MD, Naomi K. Tepper, MD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia.

#### Invited Meeting Participants

##### August 27–28, 2014, Atlanta, Georgia

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Gale Burstein, MD, Erie County Department of Health, Buffalo, New York; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, WA; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360 and American College of Obstetricians and Gynecologists, Durham, NC; Deborah Nucatola, MD, Planned Parenthood Federation of America, New York, New York; Michael Policar, MD, University of California, San Francisco, California; Carolyn Westhoff, MD, Columbia University, New York, New York.

#### Systematic Review Presenters and Authors

##### Meeting, August 26–28, 2015, Atlanta, Georgia

Kathryn M. Curtis, PhD, Tara C. Jatlaoui, MD, Polly A. Marchbanks, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia; Nathalie Kapp, MD, HRA Pharma, Paris, France.

**Invited Meeting Participants****August 26–28, 2015, Atlanta, Georgia**

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Rebecca Allen, MD, American Society for Reproductive Medicine and Women and Infants Hospital, Providence, Rhode Island; Abbey Berenson, MD, University of Texas Medical Branch, Galveston, Texas; Amanda Black, MD, University of Ottawa, Ontario, Canada; Cora Collette Breuner, MD, American Academy of Pediatrics and Seattle Children's Hospital, Seattle, Washington; Gale Burstein, MD, Erie County Department of Health, Buffalo, New York; Alicia Christy, MD, National Institutes of Health, Rockville, Maryland; Mitchell D. Creinin, MD, University of California, Davis, California; Linda Dominguez, Southwest Women's Health, Albuquerque, New Mexico; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, WA; Marji Gold, MD, Albert Einstein College of Medicine, Bronx, New York; Robert Hatcher, MD, Emory University, Atlanta, Georgia; Mark Hathaway, MD, JHPIEGO and Unity Healthcare, Washington, DC; Stephen Heartwell, MD, Susan Thompson Buffett Foundation, Omaha, Nebraska; Paula Hillard, MD, Stanford University, Palo Alto, California; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Reagan McDonald-Mosley, MD, Planned Parenthood Federation of America, New York, New York; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360, Durham, North Carolina; Jeffrey Peipert, MD, Washington University, St. Louis, Missouri; Michael Policar, MD, University of California, San Francisco, California; Sarah Prager, MD, University of Washington, Seattle Washington; David Soper, MD, Medical University of South Carolina, Charleston, South Carolina; Lisa Soule, MD, Food and Drug Administration, Rockville, Maryland; James Trussell, PhD, Princeton University, Princeton, New Jersey; Carolyn Westhoff, MD, Columbia University, New York, New York; Christopher Zahn, MD, American College of Obstetricians and Gynecologists, Washington, DC.

**CDC Attendees**

Wanda D. Barfield, MD, Peter Briss, MD, W. Craig Hooper, PhD, Jill Huppert, MD, Caroline King, PhD, Michele Mandel, Titilope Oduyebo, MD, Cria Perrine, MD, Sam Posner, PhD.

**External Reviewers**

Claude Burnett, MD, Northeast Health District, Georgia Department of Public Health, Athens, Georgia; Carrie Cwiak, MD, Emory University, Atlanta, Georgia; David Klein, MD, Uniformed Services University, Bethesda, Maryland; Seema Menon, MD, Medical College of Wisconsin, Milwaukee, Wisconsin.

**Conflicts of Interest for Invited Meeting Participants****August 26–28, 2015, Atlanta, Georgia**

Rebecca Allen, Nexplanon trainer for Merck and Liletta trainer for Actavis, consultant, advisory board, and education grant from Bayer; Mitchell D. Creinin, Nexplanon trainer for Merck, litigation consultant for Bayer, advisory board for Merck and Teva Pharmaceutical Industries Ltd., consultant for Lemonaid — PolkaDoc app, research support to University of California, Davis from Medicines360, ContraMed, Merck, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and Society of Family Planning; Linda Dominguez, speaker for Bayer, Merck, and Actavis; Alison Edelman, royalties from Up to Date, Inc., consultant for Genzyme, grant support from National Institutes of Health and Gates Foundation, travel funds from World Health Organization, grant support and honorarium from Society of Family Planning, honorarium and travel funds from Contemporary Forum, trainer for Merck, consultant for Gynuity Health Projects, honorarium from CDC, Projects In Knowledge, and American Congress of Obstetricians and Gynecologists, advisory board for Agile Therapeutics; Eve Espey, travel funds from the American Congress of Obstetricians and Gynecologists, Society for Family Planning, and U.S. Food and Drug Administration, Reproductive and Drug Advisory Committee for U.S. Food and Drug Administration, travel funds and honoraria from Wayne State University, Telluride Conference, New Mexico Department of Health Clinician Conference, Planned Parenthood National Medical Conference and Society of Family Planning, British Columbia Contraception Access Research Team Conference, and American Congress of Obstetricians and Gynecologists annual meeting; Emily Godfrey, research funding from Bayer Women's Health, Prima-Temp, and Teva Pharmaceutical Industries Ltd., trainer for Merck and Upstream USA, grant reviewer for Fellowship of Family Planning and Society of Family Planning Research Fund; Mark Hathaway, Liletta trainer and speaker for Actavis and Medicines360, Nexplanon trainer for Merck, advisory board for ContraMed LLC and Afaxys Pharmaceuticals; Paula Hillard consultant for American Civil Liberties Union, Advanced Health Media, CMEology, National Sleep Foundation, and Planned Parenthood Federation of America, honoraria from National Sleep Foundation, Dignity Health, CMEology, Advance Health Media, and Medscape, editorial board for Advanstar — Contemporary OB/GYN, board examiner for the American Board of Obstetrics and Gynecology, contract reviewer for the Department of Health and Human Services, editorial board for EBSCO — PEMSof, Nexplanon trainer for Merck, scientific advisor to Proctor and Gamble, publication royalties from Wiley Blackwell Publishing; Nathalie Kapp, employee of HRA Pharma; Andrew Kaunitz, advisory board participant of Allergan, Bayer, Merck, and Pfizer, clinical trial funding to University of Florida from Agile Therapeutics, Bayer, Merck; Jeffrey Peipert, research funding from Bayer and Teva Pharmaceutical Industries Ltd., advisory board for Perrigo; Michael Policar, litigation consultant for Bayer; James Trussell, advisory board for Merck and Teva Pharmaceutical Industries Ltd., consultant for Bayer; Carolyn Westhoff, data and safety monitoring board for Merck and Bayer, advisory board for Agile Therapeutics, MicroChips Biotech, and Actavis, research support to Columbia University from Medicines360, León Farma, and ContraMed.

## Handling Conflict of Interest

To promote transparency, all participants were asked to disclose any potential conflicts of interest to CDC prior to the expert meeting and to report any potential conflicts of interest during the introductory portion of the expert meeting. All potential conflicts of interest are listed above. No participants were excluded from discussion based on potential conflicts of interest. One presenter was an employee of a pharmaceutical company and participated by teleconference; after the presentation and questions related to the presentation, the presenter was excused from the discussion. CDC staff who ultimately decided and developed these recommendations have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters relevant to these recommendations.

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## Recommendations and Reports

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## Appendix A

### Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

Health-care providers can use the summary table as a quick reference guide to the classifications for hormonal contraceptive methods and intrauterine contraception to compare classifications across these methods (Box A1) (Table A1). For

complete guidance, see the 2016 *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) (Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep* 2016;65[No. RR-3]) for clarifications to the numeric categories, as well as for summaries of the evidence and additional comments. Hormonal contraceptives and intrauterine devices do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

#### BOX A1. Categories for classifying hormonal contraceptives and intrauterine devices

- 1 = A condition for which there is no restriction for the use of the contraceptive method.
- 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE A1. Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
<b>Personal Characteristics and Reproductive History</b>						
Pregnancy	4*	4*	NA*	NA*	NA*	NA*
Age	Menarche to <20 years: 2 ≥20 years: 1	Menarche to <20 years: 2 ≥20 years: 1	Menarche to <18 years: 1 18–45 years: 1 >45 years: 1	Menarche to <18 years: 2 18–45 years: 1 >45 years: 2	Menarche to <18 years: 1 18–45 years: 1 >45 years: 1	Menarche to <40 years: 1 ≥40 years: 2
<b>Parity</b>						
a. Nulliparous	2	2	1	1	1	1
b. Parous	1	1	1	1	1	1
<b>Breastfeeding</b>						
a. <21 days postpartum	—	—	2*	2*	2*	4*
b. 21 to <30 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	2*	2*	2*	3*
ii. Without other risk factors for VTE	—	—	2*	2*	2*	3*
c. 30–42 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	1*	1*	1*	3*

See table footnotes on page 61.

TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
ii. Without other risk factors for VTE	—	—	1*	1*	1*	2*
d. >42 days postpartum	—	—	1*	1*	1*	2*
<b>Postpartum</b> (nonbreastfeeding women)						
a. <21 days postpartum	—	—	1	1	1	4
b. 21–42 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	—	—	1	1	1	3*
ii. Without other risk factors for VTE	—	—	1	1	1	2
c. >42 days postpartum	—	—	1	1	1	1
<b>Postpartum</b> (including cesarean delivery)						
a. <10 minutes after delivery of the placenta						
i. Breastfeeding	1*	2*	—	—	—	—
ii. Nonbreastfeeding	1*	1*	—	—	—	—
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2*	2*	—	—	—	—
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1*	1*	—	—	—	—
d. Postpartum sepsis	4	4	—	—	—	—
<b>Postabortion</b>						
a. First trimester	1*	1*	1*	1*	1*	1*
b. Second trimester	2*	2*	1*	1*	1*	1*
c. Immediate postseptic abortion	4	4	1*	1*	1*	1*
<b>Past ectopic pregnancy</b>	1	1	1	1	2	1
<b>History of pelvic surgery</b> (see Postpartum [Including Cesarean Delivery] section)	1	1	1	1	1	1
<b>Smoking</b>						
a. Age <35 years	1	1	1	1	1	2
b. Age ≥35 years						
i. <15 cigarettes/day	1	1	1	1	1	3
ii. ≥15 cigarettes/day	1	1	1	1	1	4
<b>Obesity</b>						
a. BMI ≥30 kg/m <sup>2</sup>	1	1	1	1	1	2
b. Menarche to <18 years and BMI ≥30 kg/m <sup>2</sup>	1	1	1	2	1	2
<b>History of bariatric surgery</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.						
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	1	1
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	3	COCs: 3 Patch and ring: 1

See table footnotes on page 61.



**TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices**

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
<b>Cardiovascular Disease</b>						
<b>Multiple risk factors for atherosclerotic cardiovascular disease</b> (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	2	2*	3*	2*	3/4*
<b>Hypertension</b> Systolic blood pressure $\geq$ 160 mm Hg or diastolic blood pressure $\geq$ 100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy.						
a. Adequately controlled hypertension	1*	1*	1*	2*	1*	3*
b. Elevated blood pressure levels (properly taken measurements)						
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1*	1*	1*	2*	1*	3*
ii. Systolic $\geq$ 160 mm Hg or diastolic $\geq$ 100 mm Hg	1*	2*	2*	3*	2*	4*
c. Vascular disease	1*	2*	2*	3*	2*	4*
<b>History of high blood pressure during pregnancy</b> (when current blood pressure is measurable and normal)	1	1	1	1	1	2
<b>Deep venous thrombosis/ Pulmonary embolism</b>						
a. History of DVT/PE, not receiving anticoagulant therapy						
i. Higher risk for recurrent DVT/PE (one or more risk factors)	1	2	2	2	2	4
• History of estrogen-associated DVT/PE						
• Pregnancy-associated DVT/PE						
• Idiopathic DVT/PE						
• Known thrombophilia, including antiphospholipid syndrome						
• Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer						
• History of recurrent DVT/PE						
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	2	2	2	2	3
b. Acute DVT/PE	2	2	2	2	2	4
c. DVT/PE and established receiving anticoagulant therapy for at least 3 months						
i. Higher risk for recurrent DVT/PE (one or more risk factors)	2	2	2	2	2	4*
• Known thrombophilia, including antiphospholipid syndrome						
• Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer						
• History of recurrent DVT/PE						
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	2	2	3*

See table footnotes on page 61.

TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD		Implants		DMPA	POP		CHCs
d. Family history (first-degree relatives)	1	1		1		1	1		2
e. Major surgery									
i. With prolonged immobilization	1	2		2		2	2		4
ii. Without prolonged immobilization	1	1		1		1	1		2
f. Minor surgery without immobilization	1	1		1		1	1		1
<b>Known thrombogenic mutations</b> (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy.	1*	2*		2*		2*	2*		4*
<b>Superficial venous disorders</b>									
a. Varicose veins	1	1		1		1	1		1
b. Superficial venous thrombosis (acute or history)	1	1		1		1	1		3*
<b>Current and history of ischemic heart disease</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.	1	Initiation 2	Continuation 3	Initiation 2	Continuation 3	3	Initiation 2	Continuation 3	4
<b>Stroke</b> (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy.	1	2		Initiation 2	Continuation 3	3	Initiation 2	Continuation 3	4
<b>Valvular heart disease</b> Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy.									
a. Uncomplicated	1	1		1		1	1		2
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1	1		1		1	1		4
<b>Peripartum cardiomyopathy</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.									
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II; patients with no limitation of activities or patients with slight, mild limitation of activity) (2)									
i. <6 months	2	2		1		1	1		4
ii. ≥6 months	2	2		1		1	1		3
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV; patients with marked limitation of activity or patients who should be at complete rest) (2).	2	2		2		2	2		4
<b>Rheumatic Diseases</b>									
<b>Systemic lupus erythematosus</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.	Initiation	Continuation				Initiation	Continuation		
a. Positive (or unknown) antiphospholipid antibodies	1*	1*	3*	3*		3*	3*	3*	4*

See table footnotes on page 61.

**TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA		POP	CHCs
b. Severe thrombocytopenia	3*	2*	2*	2*	2*	3*	2*	2*	2*
c. Immunosuppressive therapy	2*	1*	2*	2*	2*	2*	2*	2*	2*
d. None of the above	1*	1*	2*	2*	2*	2*	2*	2*	2*
<b>Rheumatoid arthritis</b>	Initiation	Continuation	Initiation	Continuation					
a. Receiving immunosuppressive therapy	2	1	2	1	1	2/3*		1	2
b. Not receiving immunosuppressive therapy		1		1	1	2		1	2
<b>Neurologic Conditions</b>									
<b>Headaches</b>									
a. Nonmigraine (mild or severe)		1		1	1		1	1	1*
b. Migraine									
i. Without aura (This category of migraine includes menstrual migraine.)		1		1	1		1	1	2*
ii. With aura		1		1	1		1	1	4*
<b>Epilepsy</b>		1		1	1*		1*	1*	1*
This condition is associated with increased risk for adverse health events as a result of pregnancy.									
<b>Multiple sclerosis</b>									
a. With prolonged immobility		1		1	1		2	1	3
b. Without prolonged immobility		1		1	1		2	1	1
<b>Depressive Disorders</b>									
<b>Depressive disorders</b>		1*		1*	1*		1*	1*	1*
<b>Reproductive Tract Infections and Disorders</b>									
<b>Vaginal bleeding patterns</b>									
			Initiation	Continuation					
a. Irregular pattern without heavy bleeding		1	1	1	2		2	2	1
b. Heavy or prolonged bleeding (includes regular and irregular patterns)		2*	1*	2*	2*		2*	2*	1*
<b>Unexplained vaginal bleeding (suspicious for serious condition) before evaluation</b>	Initiation	Continuation	Initiation	Continuation					
	4*	2*	4*	2*	3*		3*	2*	2*
<b>Endometriosis</b>		2		1	1		1	1	1
<b>Benign ovarian tumors (including cysts)</b>		1		1	1		1	1	1
<b>Severe dysmenorrhea</b>		2		1	1		1	1	1
<b>Gestational trophoblastic disease</b>									
This condition is associated with increased risk for adverse health events as a result of pregnancy.									
<b>a. Suspected gestational trophoblastic disease (immediate postevacuation)</b>									
i. Uterine size first trimester		1*		1*	1*		1*	1*	1*
ii. Uterine size second trimester		2*		2*	1*		1*	1*	1*
<b>b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)</b>									
i. Undetectable/nonpregnant $\beta$ -hCG levels		1*		1*	1*		1*	1*	1*
ii. Decreasing $\beta$ -hCG levels		2*		2*	1*		1*	1*	1*
iii. Persistently elevated $\beta$ -hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease		2*		2*	1*		1*	1*	1*

See table footnotes on page 61.

TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
iv. Persistently elevated $\beta$ -hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*	1*	1*	1*
<b>Cervical ectropion</b>	1		1		1	1	1	1
<b>Cervical intraepithelial neoplasia</b>	1		2		2	2	1	2
<b>Cervical cancer</b> (awaiting treatment)	Initiation 4	Continuation 2	Initiation 4	Continuation 2	2	2	1	2
<b>Breast disease</b> Breast cancer is associated with increased risk of adverse health events as a result of pregnancy.								
a. Undiagnosed mass	1		2		2*	2*	2*	2*
b. Benign breast disease	1		1		1	1	1	1
c. Family history of cancer	1		1		1	1	1	1
d. Breast cancer								
i. Current	1		4		4	4	4	4
ii. Past and no evidence of current disease for 5 years	1		3		3	3	3	3
<b>Endometrial hyperplasia</b>	1		1		1	1	1	1
<b>Endometrial cancer</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.	Initiation 4	Continuation 2	Initiation 4	Continuation 2	1	1	1	1
<b>Ovarian cancer</b> This condition is associated with increased risk for adverse health events as a result of pregnancy.	1		1		1	1	1	1
<b>Uterine fibroids</b>	2		2		1	1	1	1
<b>Anatomical abnormalities</b>								
a. Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion)	4		4		—	—	—	—
b. Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion	2		2		—	—	—	—
<b>Pelvic inflammatory disease</b>								
a. Past PID (assuming no current risk factors for STDs)								
i. With subsequent pregnancy	1	1	1	1	1	1	1	1
ii. Without subsequent pregnancy	2	2	2	2	1	1	1	1
b. Current PID	4	2*	4	2*	1	1	1	1
<b>Sexually transmitted diseases</b>	Initiation	Continuation	Initiation	Continuation				
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1	1	1	1
b. Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis)	2	2	2	2	1	1	1	1
c. Other factors related to STDs	2*	2	2*	2	1	1	1	1
<b>HIV</b>								
<b>High risk for HIV</b>	Initiation	Continuation	Initiation	Continuation				
<b>HIV infection</b> For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy.	2	2	2	2	1	1*	1	1
a. Clinically well receiving ARV therapy	—	—	—	—	1*	1*	1*	1*

See table footnotes on page 61.

TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs		
b. Not clinically well or not receiving ARV therapy	2	1	2	1	—	—	—	—		
<b>Other Infections</b>										
<b>Schistosomiasis</b>										
Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy.										
a. Uncomplicated	1		1		1	1	1	1		
b. Fibrosis of the liver (if severe, see Cirrhosis)	1		1		1	1	1	1		
<b>Tuberculosis</b>										
	Initiation	Continuation	Initiation	Continuation						
This condition is associated with increased risk for adverse health events as a result of pregnancy.										
a. Nonpelvic	1	1	1	1	1*	1*	1*	1*		
b. Pelvic	4	3	4	3	1*	1*	1*	1*		
<b>Malaria</b>	1		1		1	1	1	1		
<b>Endocrine Conditions</b>										
<b>Diabetes</b>										
Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, neuropathy, or diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk of adverse health events as a result of pregnancy.										
a. History of gestational disease	1		1		1	1	1	1		
b. Nonvascular disease										
i. Non-insulin dependent	1		2		2	2	2	2		
ii. Insulin dependent	1		2		2	2	2	2		
c. Nephropathy, retinopathy, or neuropathy	1		2		2	3	2	3/4*		
d. Other vascular disease or diabetes of >20 years' duration	1		2		2	3	2	3/4*		
<b>Thyroid disorders</b>										
a. Simple goiter	1		1		1	1	1	1		
b. Hyperthyroid	1		1		1	1	1	1		
c. Hypothyroid	1		1		1	1	1	1		
<b>Gastrointestinal Conditions</b>										
<b>Inflammatory bowel disease</b> (ulcerative colitis or Crohn's disease)	1		1		1	2	2	2/3*		
<b>Gallbladder disease</b>										
a. Symptomatic										
i. Treated by cholecystectomy	1		2		2	2	2	2		
ii. Medically treated	1		2		2	2	2	3		
iii. Current	1		2		2	2	2	3		
b. Asymptomatic	1		2		2	2	2	2		
<b>History of cholestasis</b>										
a. Pregnancy related	1		1		1	1	1	2		
b. Past COC related	1		2		2	2	2	3		
<b>Viral hepatitis</b>										
a. Acute or flare	1		1		1	1	1	Initiation	Continuation	
b. Carrier	1		1		1	1	1	3/4*	2	
c. Chronic	1		1		1	1	1	1	1	
<b>Cirrhosis</b>										
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy.										
a. Mild (compensated)	1		1		1	1	1	1		
b. Severe (decompensated)	1		3		3	3	3	4		
<b>Liver tumors</b>										
Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy.										
a. Benign										

See table footnotes on page 61.

**TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
i. Focal nodular hyperplasia	1		2		2	2	2	2
ii. Hepatocellular adenoma	1		3		3	3	3	4
b. Malignant (hepatoma)	1		3		3	3	3	4
<b>Respiratory Conditions</b>								
<b>Cystic fibrosis</b>	1*		1*		1*	2*	1*	1*
This condition is associated with increased risk for adverse health events as a result of pregnancy.								
<b>Anemias</b>								
<b>Thalassemia</b>	2		1		1	1	1	1
<b>Sickle cell disease</b>	2		1		1	1	1	2
This condition is associated with increased risk for adverse health events as a result of pregnancy.								
<b>Iron-deficiency anemia</b>	2		1		1	1	1	1
<b>Solid Organ Transplantation</b>								
<b>Solid organ transplantation</b>	Initiation	Continuation	Initiation	Continuation				
This condition is associated with increased risk for adverse health events as a result of pregnancy.								
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	2	3	2	2	2	2	4
b. Uncomplicated	2		2		2	2	2	2*
<b>Drug Interactions</b>								
<b>Antiretroviral therapy</b>	Initiation	Continuation	Initiation	Continuation				
a. Nucleoside reverse transcriptase inhibitors (NRTIs)								
i. Abacavir (ABC)	1/2*	1*	1/2*	1*	1	1	1	1
ii. Tenofovir (TDF)	1/2*	1*	1/2*	1*	1	1	1	1
iii. Zidovudine (AZT)	1/2*	1*	1/2*	1*	1	1	1	1
iv. Lamivudine (3TC)	1/2*	1*	1/2*	1*	1	1	1	1
v. Didanosine (DDI)	1/2*	1*	1/2*	1*	1	1	1	1
vi. Emtricitabine (FTC)	1/2*	1*	1/2*	1*	1	1	1	1
vii. Stavudine (D4T)	1/2*	1*	1/2*	1*	1	1	1	1
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)								
i. Efavirenz (EFV)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
ii. Etravirine (ETR)	1/2*	1*	1/2*	1*	1	1	1	1
iii. Nevirapine (NVP)	1/2*	1*	1/2*	1*	1	1	1	1
iv. Rilpivirine (RPV)	1/2*	1*	1/2*	1*	1	1	1	1
c. Ritonavir-boosted protease inhibitors								
i. Ritonavir-boosted atazanavir (ATV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
ii. Ritonavir-boosted darunavir (DRV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
iii. Ritonavir-boosted foseprenavir (FPV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
iv. Ritonavir-boosted lopinavir (LPV/r)	1/2*	1*	1/2*	1*	1	1	1	1
v. Ritonavir-boosted saquinavir (SQV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
vi. Ritonavir-boosted tipranavir (TPV/r)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
d. Protease inhibitors without ritonavir								
i. Atazanavir (ATV)	1/2*	1*	1/2*	1*	1	1	1	2*
ii. Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*	2*	2*	3*
iii. Indinavir (IDV)	1/2*	1*	1/2*	1*	1	1	1	1
iv. Nelfinavir (NFV)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
e. CCR5 co-receptor antagonists								
i. Maraviroc (MVC)	1/2*	1*	1/2*	1*	1	1	1	1
f. HIV integrase strand transfer inhibitors								
i. Raltegravir (RAL)	1/2*	1*	1/2*	1*	1	1	1	1
ii. Dolutegravir (DTG)	1/2*	1*	1/2*	1*	1	1	1	1
iii. Elvitegravir (EVG)	1/2*	1*	1/2*	1*	1	1	1	1

See table footnotes on next page.

**TABLE A1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices**

Condition	Cu-IUD		LNG-IUD		Implants	DMPA	POP	CHCs
g. Fusion inhibitors								
i. Enfuvirtide	1/2*	1*	1/2*	1*	1	1	1	1
<b>Anticonvulsant therapy</b>								
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	1		1		2*	1*	3*	3*
b. Lamotrigine	1		1		1	1	1	3*
<b>Antimicrobial therapy</b>								
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. Rifampin or rifabutin therapy	1		1		2*	1*	3*	3*
<b>Psychotropic medications</b>								
a. SSRIs	1		1		1	1	1	1
<b>St. John's wort</b>	1		1		2	1	2	2

**Abbreviations:** BMI = body mass index; COC = combined oral contraceptive; Cu-IUD = copper-containing IUD; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IUD = intrauterine device; LDL = low-density lipoprotein; LNG-IUD = levonorgestrel-releasing IUD; NA = not applicable; PE = pulmonary embolism; PID = pelvic inflammatory disease; POP = progestin-only pill; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease.

\* Consult the respective appendix for each contraceptive method in the 2016 *U.S. Medical Eligibility Criteria for Contraceptive Use (1)* for clarifications to the numeric categories.

**References**

1. Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep* 2016;65(No. RR-3).
2. The Criteria Committee of the New York Heart Association. *Nomenclature and criteria for diagnosis of diseases of the heart and great vessels*. 9th ed. Boston, MA: Little, Brown & Co; 1994.

## 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*.

\* 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 1). 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 a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's *STD Treatment Guidelines* (<http://www.cdc.gov/std/treatment>), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).



## 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 (Table C1). 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 2016 *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) might be useful in such circumstances (1). 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. Any additional screening needed for preventive health care can be performed at the time of contraception initiation and initiation should not be delayed for test results.

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.

#### References

1. Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep* 2016;65(No. RR-3).

TABLE C1. 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 <sup>§</sup>	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 test)	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; 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*.

\* In instances in which blood pressure cannot be measured by a provider, blood pressure measured in other settings can be reported by the woman to her 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 1). 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 a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's *STD Treatment Guidelines* (<http://www.cdc.gov/std/treatment>), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

## 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 (Table D1). The recommendations refer to general situations and might

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

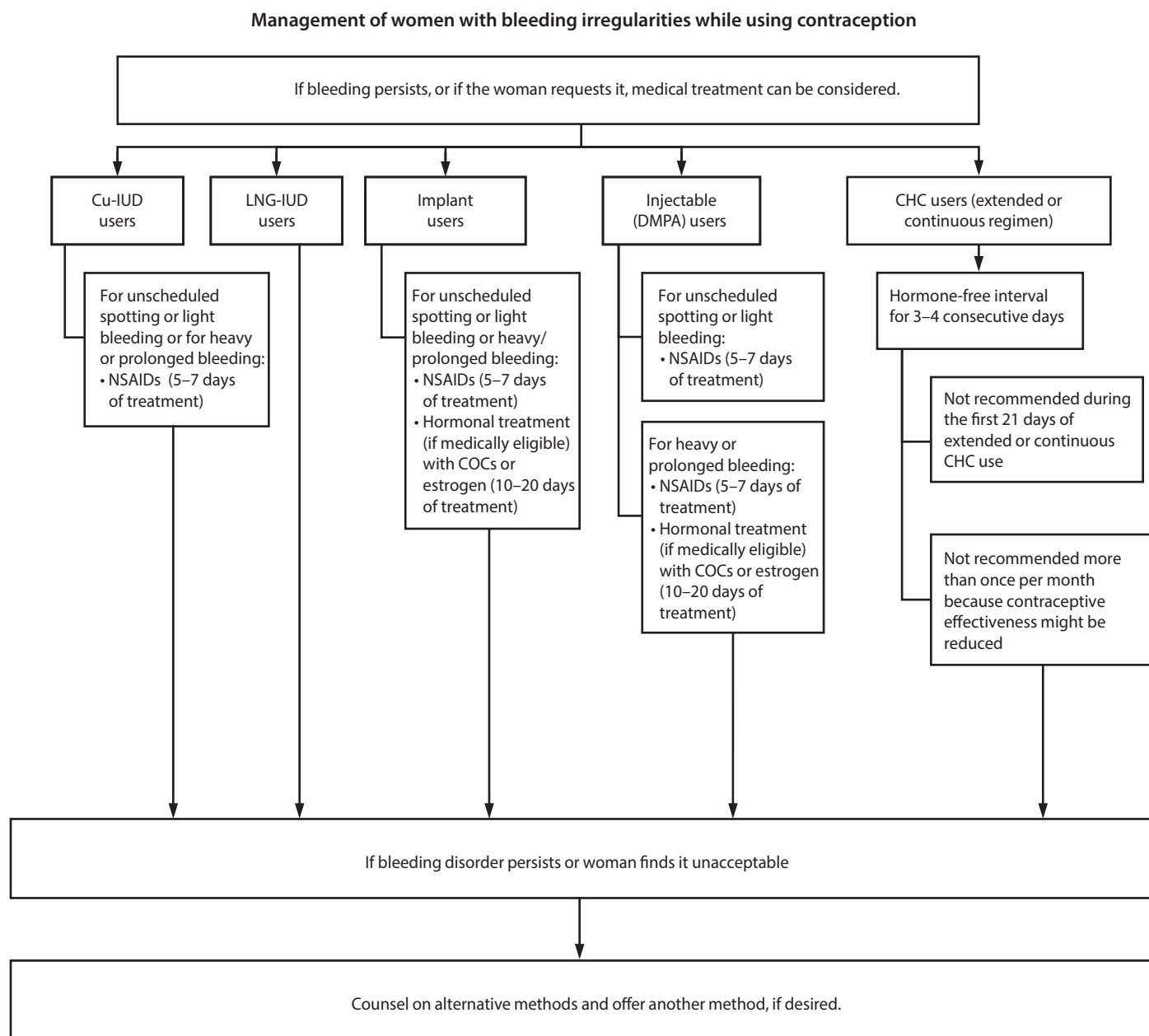
**TABLE D1. Routine follow-up after contraceptive initiation**

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 1).	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 contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

## Appendix E

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



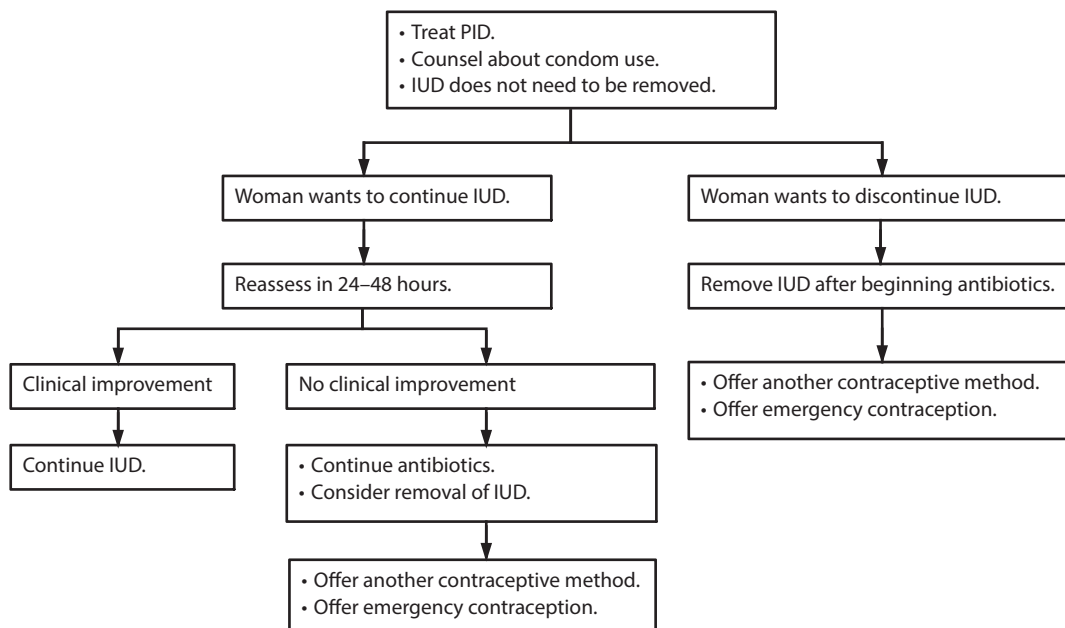
**Abbreviations:** CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

\* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care. Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon among LNG-IUD users and implant users.

## Appendix F

### Management of Intrauterine Devices When Users are Found To Have Pelvic Inflammatory Disease\*

Management of intrauterine devices when users of copper-containing intrauterine devices or levonorgestrel-releasing intrauterine devices are found to have pelvic inflammatory disease



**Abbreviations:** IUD = intrauterine device; PID = pelvic inflammatory disease.

\*Treat according to the CDC *Sexually Transmitted Diseases Treatment Guidelines* (<http://www.cdc.gov/std/treatment>).







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ISSN: 1057-5987 (Print)