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Removing barriers to contraception through use of criteria to assess pregnancy risk☆

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Safe initiation of many contraceptive methods requires an accurate assessment of whether a woman may already be pregnant. Upon initial thought, routine administration of pregnancy tests would seem to be the easiest way to assess pregnancy status. However, pregnancy tests may not be available in every setting, are associated with some cost and have limitations in detection, particularly for very early or recent pregnancies. The US Centers for Disease Control and Prevention (CDC) developed contraceptive guidance, adapted from that of the World Health Organization, which is intended to provide evidence-based guidance on contraceptive provision and reduce barriers to access and use of contraception. According to the US Selected Practice Recommendations for Contraceptive Use (US SPR), health care providers can evaluate certain criteria related to pregnancy risk before initiating contraception [1]. These criteria are easy to assess, are likely already administered in routine practice and are highly accurate for excluding pregnancy [2]. The US SPR was first issued in 2013 and recently updated in 2016. While no changes were made to the criteria for excluding pregnancy, there may be challenges in interpretation and implementation. The intent of this commentary is to explain the rationale underpinning the current US SPR recommendations [1] and contribute to the dialog on removing barriers to immediate contraception initiation [3,4].

The US SPR states that a health care provider can be reasonably certain a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria [1]:

- is ≤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 ≤7 days after spontaneous or induced abortion;

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- is within 4 weeks postpartum;
- is fully or nearly fully breastfeeding [exclusively breastfeeding or the vast majority (≥85%) of feeds are breastfeeds], amenorrheic and <6 months postpartum.

The accuracy of the criteria is dependent on the assumption that a woman has not ovulated within a certain amount of time following delivery, miscarriage, abortion or last menses. The systematic review that provided the evidence base for the US SPR recommendation identified 4 articles from 3 studies comparing the accuracy of a pregnancy checklist adapted from the above criteria to urine pregnancy testing. These studies found a high negative predictive value of 99%–100% for the checklist, suggesting high accuracy in ruling out pregnancy [2]. While the sensitivity, specificity and positive predictive value of the checklist varied, the negative predictive value is most important to consider in this context, because the goal is to correctly identify women who are not pregnant and could safely begin contraception immediately. This body of evidence had several limitations including the small number of studies, lack of information about the reference pregnancy test and limited generalizability given that none of the studies were conducted in the United States and one study was limited to HIV-infected women. Two recently published studies have examined the performance of the checklist in the United States and found similarly high ability of the checklist to exclude pregnancy. One study found that the checklist had a negative predictive value of 96% among adolescents aged 14–19 years seeking care in a family planning clinic in Atlanta [5]. The other study found that the checklist had a negative predictive value of 99.8% for excluding luteal-phase pregnancy among women with a negative urine pregnancy test who participated in a prospective cohort study of contraceptive provision in St. Louis [6].

These criteria were initially developed for global use and pregnancy tests may not be available in many areas [4,7]. Pregnancy tests are widely accessible in the United States, and theoretically could be offered to every woman wishing to initiate contraception. However, the criteria may be more accurate than pregnancy tests, in the setting of early or recent pregnancy. The accuracy of pregnancy tests can vary widely based on sensitivity of the test and timing of testing relative to missed menses [8-11]. If a woman has had recent unprotected intercourse, a negative pregnancy test will not necessarily exclude pregnancy. Pregnancy tests also remain positive for several weeks after the end of pregnancy; a positive pregnancy test in this situation could lead to a missed opportunity to initiate contraception.

Despite wide availability of pregnancy tests in the United States, routine use for all women initiating contraception still incurs costs to women and providers and requires time and resources. The intent of the US SPR guidance was to reduce barriers to initiating contraception by not requiring routine pregnancy testing for all women. It has been suggested that contraception can be initiated by woman with a negative pregnancy test along with administration of emergency contraception (EC), if appropriate [3,12-14]. Emergency contraceptive pills are effective but do not prevent 100% of pregnancies, and may be less effective in obese women [15]. In addition, women who use ulipristal acetate should delay initiation of hormonal contraception for 5 days because of concerns about reduced effectiveness of both ulipristal acetate and hormonal contraception [1].

Given that the intent of the US SPR guidance is to reduce barriers to contraception, what should be done if a woman does not fulfill any of the criteria and therefore may be pregnant? Even if the woman does not meet any of the listed criteria and therefore the healthcare provider may be uncertain whether she may be pregnant, the US SPR provides permissive guidance on initiation of contraception. For all methods except intrauterine devices (IUDs), the US SPR states that the benefits of starting the method likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2–4 weeks. This is intended to reduce barriers by encouraging same-day initiation of implants, injectables, pills, patch and ring.

Initiation of IUDs in women who are pregnant poses certain health risks, as pregnancies in women with in situ IUDs may be at increased risk for adverse outcomes including spontaneous abortion, preterm delivery and chorioamnionitis [16]. The US SPR therefore states that IUD insertion should be delayed until the provider is reasonably certain the woman is not pregnant. However, if the woman is within 5 days of unprotected intercourse, the copper IUD can be used as EC and continued as contraception. Recent studies provide limited evidence as to whether the copper IUD can be safely inserted beyond 5 days of unprotected intercourse or whether women can safely use EC plus an LNG-IUD; while results indicate low risk of pregnancy, further studies are needed before recommending these practices given potential serious adverse outcomes [17,18].

Use of the criteria relies on some clinical judgment and presents some challenges in interpretation of women's history. The criteria may be difficult to implement among women who are uncertain about timing of menses or women who have irregular menses. This is pertinent for adolescents who may have irregular menses. Although the study of adolescents found a high negative predictive value of the criteria, the most common reason for the criteria incorrectly ruling out pregnancy (i.e., a positive pregnancy test but criteria indicated that pregnancy was unlikely) was that respondents reported last menses within the last 7 days [5]. Additional study is needed to assess the accuracy of the criteria among adolescents or women who may be uncertain about their last menses or who have irregular menses (Table 1). Another challenge may be in interpretation of "correct and consistent" use of a "reliable" method of contraception. This criterion is intentionally not further delineated in the US SPR and left to the clinical judgment of the provider based on the reported patient history. Many women use shorter acting hormonal methods (i.e., pills, patch or ring), barrier methods or fertility awareness-based methods that reliably prevent pregnancy with perfect use; however, unintended pregnancies often occur as a result of incorrect or inconsistent use [19]. Additional study on performance of these criteria among women who report using specific methods of contraception is needed. In addition, further study should be conducted to determine the performance of the criteria in settings where there may be less opportunity to apply clinical judgment, for example, over-the-counter provision of EC or pharmacist-prescribed hormonal methods.

Women who desire to initiate contraception should have access to a full range of contraceptive methods and should not face unnecessary barriers to initiation, such as requiring additional visits, requiring routine testing or waiting until next menses. The intent of CDC's contraceptive guidance is to reduce barriers to initiation and use of contraception.

By applying the criteria to assess pregnancy risk, health care providers can reasonably assess whether a woman may be pregnant without performing routine pregnancy tests, which incur costs, time and resources and cannot reliably exclude early pregnancy. Even if a provider is not reasonably certain that the woman is not pregnant, most contraceptive methods can still be initiated on the day requested, with follow-up pregnancy tests to rule out any missed early pregnancies. For IUDs, initiation should be delayed until pregnancy can be ruled out, due to potential risks of IUD insertion in the setting of ongoing pregnancy. However, for women who are in the window to receive EC and who desire an IUD for contraception, copper IUDs may be a good option. Use of the criteria should allow providers to quickly, easily and accurately exclude pregnancy.

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Table 1

Selected research gaps related to the use of criteria to assess pregnancy risk

Characteristics of women	Performance of criteria among adolescents
	Accuracy of criteria among women with irregular menses or who are unsure about timing of last menstrual period
Contraceptive methods	Accuracy of criteria among women who report correct and consistent use of different methods
Settings	Accuracy of criteria when contraception obtained without healthcare provider assessment