ELSEVIER

Contraception 87 (2013) 513–516

Contraception

Commentary

Adaptation of the World Health Organization's Selected Practice Recommendations for Contraceptive Use for the United States☆

Kathryn M. Curtis*, Naomi K. Tepper, Denise J. Jamieson, Polly A. Marchbanks

Division of Reproductive Health, Centers for Disease Control and Prevention, Atlanta, GA 30341, USA

Received 17 August 2012; accepted 21 August 2012

Abstract

Background: The Centers for Disease Control and Prevention (CDC) recently adapted global guidance on contraceptive use from the World Health Organization (WHO) to create the US Selected Practice Recommendations for Contraceptive Use (US SPR). The WHO guidance includes evidence-based recommendations on common, yet sometimes complex, contraceptive management questions.
Study Design: We determined the need and scope for the adaptation, conducted 30 systematic reviews of the scientific evidence and convened a meeting of health care professionals to discuss translation of the evidence into recommendations.
Results: The US SPR provides recommendations on contraceptive management issues such as how to initiate contraceptive methods, what regular follow-up is needed, and how to address problems, including missed pills and side effects such as unscheduled bleeding.
Conclusion: The US SPR is intended to serve as a source of clinical guidance for providers in assisting women and men to initiate and successfully use contraception to prevent unintended pregnancy.
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1. Introduction

Unintended pregnancy rates remain high in the United States; about 50% of all pregnancies are unintended, with higher proportions among adolescents and young women, women of racial and ethnic minorities, and women with less education and lower incomes [1]. Unintended pregnancies increase risk for poor maternal and infant outcomes [2] and cost the United States about $5 billion a year in direct medical costs [3]. About half of unintended pregnancies are among women who were not using contraception at the time they became pregnant; the other half are among women who became pregnant despite reported use of contraception [4]. Therefore, strategies to prevent unintended pregnancy for those who are sexually active include promoting (1) appropriate choice of contraceptive methods and (2) correct and consistent use of contraceptive methods to prevent pregnancy. However, many individuals encounter barriers that make it difficult to access contraceptive methods or to use them correctly and consistently. For example, unnecessary screening exams or multiple visits to initiate contraceptive methods may inhibit the initiation of a contraceptive method. Side effects such as irregular bleeding may lead to contraceptive method discontinuation, increasing the risk of unintended pregnancy. Missed pills and problems with adherence with other methods may also decrease contraceptive effectiveness.

In 2010, the Centers for Disease Control and Prevention (CDC) published the US Medical Eligibility Criteria for Contraceptive Use (US MEC), which provides recommendations for the safe use of contraceptive methods for patients with various medical conditions and characteristics, such as diabetes, parity and smoking status [5]. The US MEC is intended to provide clinical guidance for providers on *who* can safely use contraceptive methods and assist providers when counseling women, men and couples about contraceptive choices. CDC is currently developing a second evidence-based guidance document for contraceptive use,

☆ The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

* Corresponding author.
E-mail address: kmc6@cdc.gov (K.M. Curtis).

0010-7824/$ – see front matter. Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.contraception.2012.08.024

the US Selected Practice Recommendations for Contraceptive Use (US SPR; forthcoming), which provides recommendations on *how* to use contraceptive methods safely and effectively. The goal of the US SPR is to use scientific evidence to address common, yet sometimes complex, contraceptive management issues, including questions such as how and when to initiate a contraceptive method, what examinations and tests are needed prior to initiating a contraceptive method, what regular follow-up is needed, and how to address problems, including missed pills and side effects such as unscheduled bleeding. Evidence-based guidance on addressing these issues should assist providers in counseling clients about optimal use of contraceptive methods in order to maximize contraceptive effectiveness. The US SPR specifically focuses on practices as they are related to contraceptive use; for example, while cervical cancer screening and clinical breast examination may be recommended for well-woman care, they are not needed to determine safe use of contraceptive methods.

Both of these guidance documents, the US MEC and the US SPR, have been adapted from global guidance from the World Health Organization (WHO). WHO began developing evidence-based contraceptive guidance in the 1990s to address medical barriers to contraceptive use and improve the quality of care in family planning services [6,7]. The WHO MEC was first published in 1996 and is currently in its fourth edition [7], and the WHO SPR, first published in 2002, is currently in its second edition, with an update in 2008 [8,9]. The Division of Reproductive Health at CDC has contributed during the last 15 years to the creation and updating of WHO's global family planning guidance. CDC has supported WHO's effort by coordinating the identification, critical appraisal and synthesis of the scientific evidence on which the WHO guidance is based. Working with WHO, CDC uses the Continuous Identification of Research Evidence (CIRE) system to ensure that WHO guidance is based on the best available evidence and that there is a mechanism to update guidance as needed, when new evidence becomes available [10].

WHO has always intended for its global guidance to be used by local or regional policy makers, family planning program managers, and the scientific community as a reference when developing family planning guidance at the country or program level. The United Kingdom is one example of a country that has adapted the WHO guidance for its own use [11,12]. After publication of the US MEC in 2010, CDC began a formal adaptation process to create the US Selected Practice Recommendations for Contraceptive Use (US SPR). The objective of this article is to describe the process and the outcome of the adaptation of the WHO SPR for use by health care providers in the United States. In addition, this issue of *Contraception* includes many of the systematic reviews of the scientific evidence that were conducted and serve as the background for the US SPR recommendations.

2. Methods

2.1. Determining the scope of and process for the adaptation

In October 2010, CDC held a small planning meeting of 10 partners and US family planning experts to discuss the scope of and process for a US adaptation of the WHO SPR. During discussions at this meeting, CDC identified specific WHO recommendations for which a compelling reason existed to consider modification for the United States because of the availability of new scientific evidence or the context in which family planning services are provided in the United States. CDC also identified several WHO recommendations that needed clarity or further specificity for US providers, as well the need for adding recommendations not currently contained in the WHO SPR. We also determined that some recommendations could be removed, as they provided information about contraceptive methods that are not currently available in the United States. Meeting participants also provided feedback on the format of the WHO SPR, including ideas on how to improve the format for clarity and usability by US health care providers.

2.2. Critically appraising and synthesizing the scientific evidence

CDC conducted or updated systematic reviews of the scientific evidence for each of the WHO SPR recommendations considered for adaptation and for each of the new topics considered for addition to the guidance. The purpose of these systematic reviews was to identify evidence that addressed the biomedical and behavioral components of the common clinical challenges represented by the topics addressed in this guidance. We sought information about indirect evidence or theoretical considerations when direct evidence was not available. We followed standard guidelines for conducting and reporting results from systematic reviews [13,14], and we graded the strength and quality of the evidence using the system of the US Preventive Services Task Force [15]. Two to three experts peer-reviewed the systematic reviews before their use in the adaptation process.

2.3. Using the evidence to adapt the WHO SPR for the United States

In October 2011, CDC held a meeting of 36 experts who were invited to provide their individual perspective on the scientific evidence presented and the discussions on potential recommendations that followed. The group included obstetrician/gynecologists, pediatricians, family physicians, nurse-midwives, nurse practitioners, epidemiologists and others with expertise in contraceptive safety, effectiveness and management. For each topic discussed, the evidence from the systematic review was presented. Meeting participants discussed translation of this scientific evidence into recommendations that would meet the needs of US health care providers. CDC gathered individual input from the

experts during the meeting and finalized the recommendations. The participants also identified research gaps that need further investigation.

3. Results

From the 2010 planning meeting, we identified several key issues to consider for adaptation for the US SPR. Overall, the meeting participants provided feedback that most of the WHO SPR recommendations would need to be reviewed to ensure best implementation in the United States and make the recommendations more specific to US practice. For example, while the WHO SPR recommends that providers use a list of criteria to be reasonably certain that a woman is not pregnant prior to initiating a contraceptive method, meeting participants considered that the role of pregnancy tests might differ in the United States compared with the global context. The WHO SPR contains a subset of more programmatic recommendations, such as how many pill packs can be provided in a single visit and what follow-up schedules should be used, that were based on expert opinion from WHO Expert Working Group meetings. We decided to conduct systematic reviews of the evidence for these topics and revisit these recommendations based on the evidence that was identified. We also considered adding recommendations for several additional issues that would be of interest to US providers, including when a woman can rely on female sterilization for contraception, management of bleeding irregularities with extended or continuous use of combined hormonal contraceptives, how to start regular contraception after taking emergency contraceptive pills, and at what age a woman can discontinue contraception and not be at risk of unintended pregnancy. We eliminated WHO recommendations that addressed contraceptive methods not available in the United States (i.e., levonorgestrel implant, combined injectable which contains both estrogen and a progestin, and norethisterone enantate). Finally, the meeting participants recommended that the format of the document should be revised to be more useful to clinicians during a clinical encounter, including streamlining the recommendations, organizing the recommendations by contraceptive method, and developing provider tools such as summary tables and clinical algorithms.

During the 2011 expert meeting, we presented the results from 30 systematic reviews on 29 clinical questions for which we considered adaptation or addition to the guidance. While few recommendations were changed substantively, we made small adaptations to most of the WHO recommendations to make the language and details of the recommendations more specific to US practice. Much of the discussion focused on how the recommendations could be adapted to be relevant to US practice and context. For example, CDC modified the recommended physical examinations and laboratory tests needed before initiating a method of contraception, based on prevalence of the conditions being screened for in the US versus globally. As another example, CDC also adapted recommended treatment strategies for unscheduled bleeding with certain contraceptive methods, based on availability of certain drugs used for treatment in the United States.

The US SPR contains evidence-based recommendations that generally fall into three categories: (1) initiation of contraception methods, including how to be reasonably certain that a woman is not pregnant at the time of initiation, timing of initiation, need for alternative or back-up contraception and examinations and laboratory tests needed before initiating a method, (2) routine follow-up after starting a method of contraception and (3) management of problems during use of a contraceptive method, such as missed pills or other dosing errors, vomiting with certain methods, and bleeding irregularities or amenorrhea. In addition, there is guidance on specific aspects of emergency contraceptive use (the copper intrauterine device and emergency contraceptive pills), the standard days method, male and female sterilization and contraceptive use among women over 44 years of age.

4. Discussion

The US SPR contains recommendations to assist providers in helping women, men, and couples to be successful contraceptive users in order to reduce the risk for unintended pregnancy. The US SPR can be used in conjunction with the US MEC as providers are counseling contraceptive users on contraceptive method choice, method initiation, and management of problems with contraceptive use. We anticipate that the US SPR will be published in early 2013 and will be available on our website: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm.

As with the US MEC, working with our partners at the federal, national, and local levels to disseminate, implement, and evaluate the US SPR will be critical in reaching health care providers with this new guidance. Strategies for dissemination and implementation include collaborating with other federal agencies and professional and service organizations to widely disseminate this guidance through presentations, electronic distribution, newsletters and other publications; development of provider tools and job aids to assist providers in implementing this new guidance; and training activities for students, as well as for continuing education. CDC will be conducting a survey of family planning providers before and after release of the US SPR in order to assess attitudes and practices related to contraceptive use. Results from this survey will assist CDC in evaluating the impact of the US SPR on contraceptive provision in the United States.

As with any evidence-based guidance document, a key challenge is keeping the recommendations up to date as new scientific evidence becomes available. CDC will continue to work with WHO to identify and assess all new relevant

evidence and to determine whether changes in the recommendations are warranted [10]. In most cases, updates to the US SPR will follow any updates to the WHO guidance, which typically occur every 3–4 years (or sooner if warranted by new data). In addition, CDC will review any interim WHO updates for their application in the United States. CDC will also identify and assess any new literature for the recommendations and medical conditions that are not included in the WHO guidance. CDC will completely review the US SPR every 3–4 years as well. Updates to the guidance can be found on the CDC website at: http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm.

Finally, as with most evidence-based guidance, there are often limitations in the scientific evidence available to make some recommendations stronger or more specific. As part of the US SPR process, we identified some of the gaps which exist in the evidence for effective contraceptive use. The research gaps are published in another article in this issue of *Contraception*, and we hope that this list will be useful to researchers and funders, who can address these gaps and provide evidence to refine this guidance in the future.

5. Conclusions

Women, men and couples have an increasing array of safe and effective contraceptive methods from which to choose to prevent unintended pregnancy. However, with these expanded options comes the need for evidence-based guidance to help contraceptive users choose the most appropriate contraceptive method for their individual circumstances and to use that method correctly, consistently and continuously to maximize contraceptive effectiveness. It is anticipated that the US SPR will be able to provide guidance to health care providers in order to remove unnecessary barriers to patients in accessing and successfully using contraceptive methods.

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