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Development, updates, and future directions of the World Health Organization Selected Practice Recommendations for Contraceptive Use

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1. | INTRODUCTION

Correct and consistent use of contraception decreases the risk of unintended pregnancy; yet, outdated policies or practices can delay initiation or hinder continuation of contraceptive methods. To promote the quality of, and access to, family planning services, WHO created a series of evidence-based guidance documents for family planning, known as WHO's Four Cornerstones of Family Planning Guidance (Fig. 1). The *Medical eligibility criteria for contraceptive use* (MEC), first published in 1996,¹ provides guidance on the safety of various contraceptive methods in users with specific health conditions or characteristics (i.e. who can use a contraceptive method safely). The *Selected practice recommendations for contraceptive use* (SPR) is the second cornerstone,² outlining how to safely and effectively use contraceptive methods. These two documents can serve as a reference for policymakers and program managers as they develop their own national family planning policies in the context of local needs, values, and resources. The two other cornerstone documents—the *Decision making tool for family planning clients and providers*³ and *Family planning: a global handbook for providers*⁴—provide guidance to healthcare providers for applying these recommendations in practice.

Between 2013 and 2014, WHO convened a Guideline Development Group (GDG) to review and update the MEC and SPR in line with current evidence. As a result of these meetings, the fifth edition of the MEC was published in 2015,⁵ and the third edition of the SPR will be released on December 14, 2016. The purpose of the present report is to describe the methods

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CONFLICT OF INTEREST

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used to develop the SPR recommendations, research gaps identified during the guideline development process, and future directions for the dissemination and implementation of the SPR among policymakers and family planning program managers worldwide.

2. | BRIEF HISTORY OF THE WHO SPR

Inconsistencies in recommendations on how to use contraceptive methods could contribute to the disparity in contraceptive failure rates reported between “perfect” and “typical” use.^{2,6} In 2001, WHO convened the first scientific Working Group—with 33 participants from 16 countries—to address controversies or inconsistencies in recommendations to maximize the effective provision and management of contraception and to minimize and/or manage adverse effects that could contribute to discontinuation. The first edition of the SPR² included recommendations made in response to 23 specific questions on contraceptive use, including when to initiate a contraceptive method, how to be reasonably certain that a woman is not pregnant before initiation, the role of necessary examinations or tests before initiation, recommended follow-up, how to maintain correct and consistent use, and how to address abnormal bleeding from contraceptive use. The Working Group based their recommendations on the best available evidence generated from systematic reviews, with consideration of the level and applicability of the evidence (i.e. direct or indirect), and relied on expert consensus when evidence was lacking.

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To manage the continuously evolving body of medical evidence, WHO and its collaborators launched the Continuous Identification of Research Evidence system in 2002 as an ongoing mechanism to identify, evaluate, synthesize, and peer review new evidence pertinent to the four cornerstone documents.⁷ Using the Continuous Identification of Research Evidence system, WHO and its partners identified novel and relevant evidence resulting in the creation of the second edition of the SPR in 2004,⁸ an interim guidance in 2008,⁹ and the latest edition in 2016. In addition to maintaining up-to-date recommendations for the contraceptive methods in the guidance, WHO strives to include guidance for new contraceptive methods as they became available (Table 1).

3. | DEVELOPMENT OF THE THIRD EDITION OF THE SPR

In 2007, WHO’s Director General established the Guidelines Review Committee to ensure that WHO guidelines achieve a high methodological quality and are in accordance with the requirements described in the *WHO handbook for guideline development*.¹⁰ One of the first steps in the updated process was to create groups with different roles to undertake the revision. A Secretariat, comprising personnel within WHO headquarters, oversaw the guideline development process. The Secretariat provided administrative support, coordinated the process for guideline development, and selected participants for the GDG, Evidence Secretariat, and external review group. The GDG consisted of technical experts in the

contraceptive field, with geographical representation from all WHO regions. The GDG determined the scope and content of the guidelines; developed population, intervention, comparator and outcome (PICO) questions to guide systematic reviews; and formulated recommendations based on the available evidence. Experts in evidence synthesis formed the Evidence Secretariat and conducted the systematic reviews, following the pre-determined PICO question format. A guideline methodologist with expertise in assessing the quality of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was also part of the Evidence Secretariat. Finally, the external review group provided feedback on the draft guidelines from a real-world perspective.

The GRADE system offers a process for rating the quality of evidence from systematic reviews.¹¹ The GRADE approach considers the study design (i.e. randomized trial or observational study), risk of bias, inconsistency across studies, indirectness, data imprecision, and publication bias to categorize evidence as high, moderate, low, or very low quality. In addition to the GRADE rating, consideration of the values and preferences of contraceptive users, the balance of benefits and harms of contraceptive use, and the resource implications associated with providing contraceptive services also weighed into the determination of the strength of a particular guideline recommendation.

For the third edition of the SPR, the GDG reviewed 19 topics related to five new contraceptive methods (Table 2): the two-rod levonorgestrel implant (Sino-implant (II)), subcutaneously-administered depot medroxyprogesterone acetate, combined transdermal contraceptive patch, combined contraceptive vaginal ring, and ulipristal acetate for emergency contraception. Additionally, the GDG considered guidance regarding the initiation of regular contraception after emergency contraceptive use. The GDG evaluated direct evidence from 15 systematic reviews and extrapolated indirect evidence from pharmacologically similar contraceptive methods in the absence of direct evidence. In addition to the GRADE evidence profiles, the GDG explicitly considered the values and preferences of choice, ease of use, adverse effects, efficacy, and the importance of balancing the benefits of preventing unintended pregnancy with potential harms of contraceptive method use. The GDG designated a “strong” recommendation as one that could be adopted as policy in most situations, whereas a “conditional” recommendation would require substantial debate and involvement of various stakeholders before universal implementation in all or most settings.¹⁰

4. | RESEARCH GAPS

The goal of WHO and its partners is to use the best available evidence to develop SPR guidance; however, many recommendations are based on limited or indirect evidence. For example, limited information exists on optimal follow-up schedules after contraceptive method initiation, and further investigations on the impact of follow-up on contraceptive continuation can refine existing recommendations. Additionally, certain recommendations are based on indirect evidence from similar contraceptive methods in the absence of direct evidence. As an example, recommendations on when to start the combined contraceptive patch and contraceptive vaginal ring are derived from indirect data from the combined oral

contraceptive pill in view of the similarities in the type and dose of hormone used in combined hormonal contraceptive methods. Although these recommendations are likely to be scientifically valid, evidence review highlights the relative lack of available data for newer contraceptive methods.

Knowledge gaps for future research in contraceptive management are identified with every update of the SPR.^{2,8,9,12,13} Prior SPR editions highlight gaps or key unresolved issues for each of the contraceptive methods, such as “Does starting each pill pack on a specific day of the week increase consistent, correct and continued use of combined oral contraceptive pills?”, “How quickly is protection reliably established by injections of DMPA [depot medroxyprogesterone acetate] and NET-EN [norethisterone enantate]?”, and “What are the mechanisms underlying progestogen-only injectable-associated bleeding abnormalities and how can they best be treated?”.^{2,8} During the creation of the third edition of the SPR, the GDG identified the following research gaps related to the new methods: “How long after the start of the menstrual cycle can a woman initiate use of the combined hormonal vaginal ring without needing to use a backup method of contraception?”, “Does the timing of return to fertility after a DMPA subcutaneous injection differ compared with the timing following a DMPA intramuscular injection?”, and “Can Sino-implant (II) be used as an effective method of contraception for more than 4 years?”.¹² Another research gap is when to start regular hormonal contraception after using ulipristal acetate for emergency contraception. New evidence suggests that taking ulipristal acetate and progestin-containing contraception in close succession could impact effectiveness of both UPA and the regular contraceptive in terms of pregnancy prevention.¹² Recognition of such research gaps during the SPR revision process can serve as a framework to direct future high-quality studies that will further inform recommendations, better meet providers’ needs, and improve quality of family planning services.

5. | NEXT STEPS AND FUTURE DIRECTIONS

Translating policy into practice is a challenge across all disciplines. To bridge this gap, WHO follows the core principles of dissemination, adaptation, implementation, and monitoring and evaluation after the creation and publication of a guideline.¹⁰ Dissemination should be broad and in multiple languages, including online and print publications, peer-reviewed journals, social media, and regional or scientific meetings. Adaptation takes into account specific needs of the country or region. Robust implementation consists of both active strategies (e.g. interactive workshops, educational follow-ups, clinical audits, reminders, and multifaceted interventions) and passive modalities (e.g. dissemination of guidelines in print and electronic form).¹⁴ For successful utilization, future guidelines should incorporate these effective but underutilized active techniques into detailed, stepwise implementation plans. Finally, systems to monitor and evaluate SPR use can determine its impact and provide feedback for future implementation strategies.¹⁰

In April 2016, WHO convened a Working Group to advise WHO on the preparation of an implementation guide for the MEC/SPR, which could enable users of these guides to put these principles into action. Since the inception of the SPR, WHO has received few requests to translate the SPR into other languages, indicating that the dissemination and uptake of the

guidance has been limited, especially when compared with the MEC.¹⁵ The Working Group reviewed strategies for dissemination of the SPR guideline, which currently include distribution throughout WHO regional and country offices, coordination with UN partners, broadcasting via social media, and promotion of the recommendations at relevant conferences and regional meetings. Promoting the SPR and MEC together is important because of their inter-related nature; however, the Working Group advised WHO to highlight the distinct purpose of the SPR in addressing contraceptive management when disseminating both guidelines.

The Working Group proposed a multipronged approach according to three strategies—(1) improving guideline usability, (2) assisting countries in adapting the guidelines within their local contexts, and (3) turning policy into practice—to structure the implementation guide.

To improve the usability of the updated SPR, the document has been reformatted to be more intuitive and user-friendly. For example, the SPR is now organized by contraceptive methods rather than by clinical questions, as previous editions had been.

For adaptation, the Working Group strategized ways to help countries to take ownership of the SPR, stressing the importance of integrating the guidance into current service delivery standards and protocols. Currently, only the USA,¹⁶ UK,¹⁷ and China have adapted the SPR into their national family planning recommendations. Once a country completes adaptation of the SPR guidelines, WHO could provide technical support to assist countries to put policy into practice through monitoring and evaluation. Strategies to achieve this aim include programmatic audits, formation of specialized implementation groups, and creation of a repository of implementation prototypes.

Lastly, the Working Group recommended developing a research and documentation plan to inform future steps in the implementation process. For example, WHO can take a qualitative approach to formally assess a country's uptake, utilization, and adaptation of contraceptive guidelines and tools. Research is important not only in monitoring and evaluating the implementation of current guidelines, but also in generating evidence to inform future guideline recommendations. The persistent pursuit to close the research gaps identified through the SPR guideline update process is paramount to promoting quality in family planning care.

WHO has a long-standing history of developing and updating its evidence-based guidance on contraceptive method use for a global audience; however, this technical organization recognizes the importance of engaging with partners in the guideline development and subsequent dissemination, adaptation and implementation processes. Many global partners—including the Implementing Best Practices Consortium, the International Federation of Gynecology and Obstetrics, the International Confederation of Midwives, country-level medical societies, and non-governmental organizations—contribute to distributing, promoting uptake, and facilitating utilization of the WHO contraceptive guidelines in individual countries.

6. | CONCLUSIONS

As one of the four cornerstones of family planning guidance, the SPR plays a vital part in advancing the quality of, and access to, family planning on a global scale. The present report has reviewed the history of the SPR and its evolution as both new evidence and novel contraceptive methods became available. Additionally, the revision process uncovered evidence gaps, highlighting the significant role that research has in informing this guideline's recommendations and continual updates. In view of the relative underuse of the SPR as compared with the MEC, the recent update of the SPR has underscored the need and importance of applying effective and efficient approaches to promote its dissemination and implementation. Findings from high-quality research studies will further strengthen the recommendations to ultimately promote the provision of quality family planning care worldwide.

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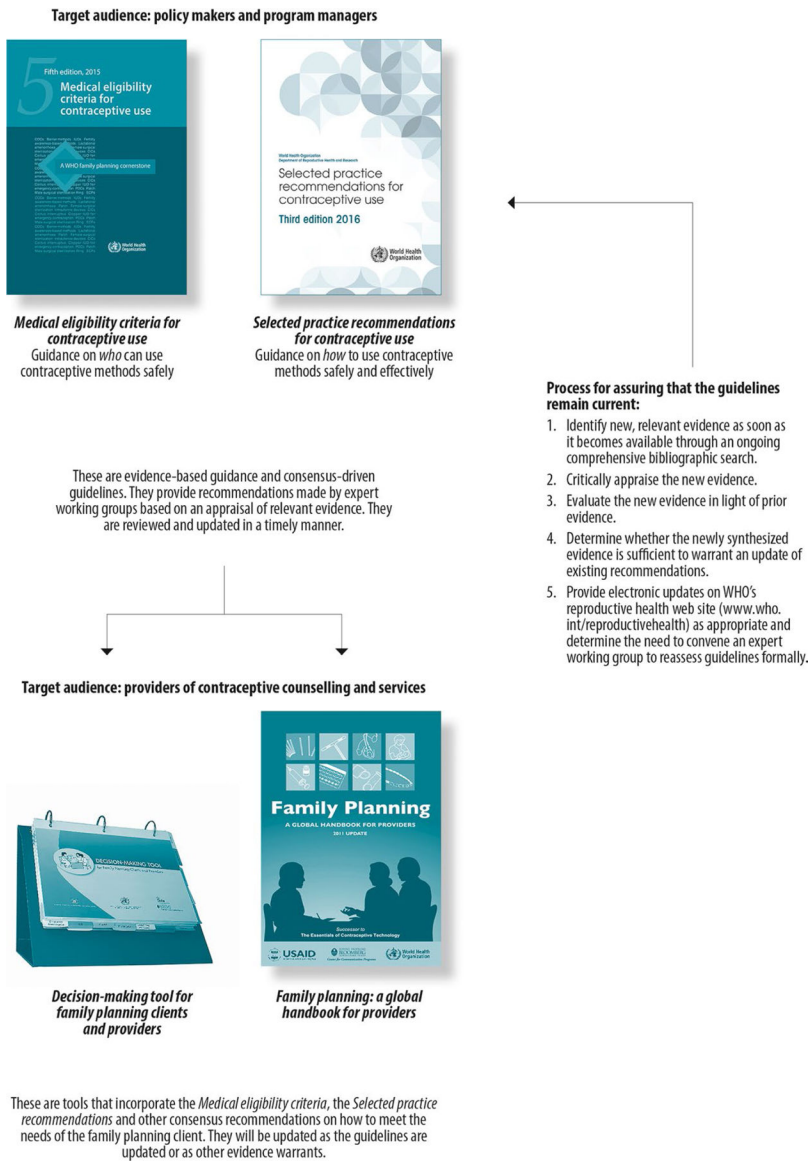


FIGURE 1. The four cornerstones of family planning guidance. Abbreviations: MEC, medical eligibility criteria for contraceptive use; SPR, selected practice recommendations for contraceptive use. Adapted from SPR, 3rd edition, with the permission of WHO.

Questions addressed in each edition of the WHO selected practice recommendations for contraceptive use.

TABLE 1

	First edition, 2002	Second edition, 2004	Interim update, 2008
	When can a woman start COCs? What can a woman do if she misses COCs? What can a woman do if she vomits and/or has severe diarrhea while using COCs or POPS? When can a woman start CICs? When can a woman have repeat CIC injections? When can a woman start POPS? When can a woman do if she misses POPS? What can a woman do if she vomits after taking ECPs? When can a woman start POIs (DMPA or NET-EN)? When can a woman have repeat POIs (DMPA or NET-EN)? What can be done if a woman has menstrual abnormalities when using a POI (DMPA or NET-EN)? When can a woman start using an implant? What can be done if a woman experiences menstrual abnormalities when using implants? When can a copper-bearing IUD be inserted? What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD? What should be done if a woman using a copper-bearing IUD is found to be pregnant? Should prophylactic antibiotics be provided for copper-bearing IUD insertion? What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 d range? What examinations or tests should be done routinely before providing a method of contraception? How many pill packs (combined or POPS) should be given at initial and return visits? What follow-up is appropriate for COC, POP, implant, and IUD users? How can a provider be reasonably sure that a woman is not pregnant?	Initiation/continuation: When can a woman start COCs? When can a woman start CICs? When can a woman have repeat CIC injections? When can a woman start POPS? When can a woman start POIs (DMPA or NET-EN)? When can a woman have repeat POIs (DMPA or NET-EN)? When can a woman start using an implant? How long can levonorgestrel implants be left in place? When can a woman have a copper-bearing IUD inserted? Should prophylactic antibiotics be provided for copper-bearing IUD insertion? When can a woman have a LNG IUD inserted? Should prophylactic antibiotics be provided for LNG IUD insertion? How can a woman take ECPs? Can a woman receive an advance supply of ECPs? When can a man rely on his vasectomy for contraception? What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 d range? Incorrect use: What can a woman do if she misses COCs? What can a woman do if she misses POPS? Problems during use: Vomiting and/or diarrhea What can a woman do if she vomits and/or has severe diarrhea while using COCs POPS? What can a woman do to prevent nausea and vomiting when taking ECPs? What can a woman do if she vomits after taking ECPs? Menstrual abnormalities What can be done if a woman has menstrual abnormalities when using a POI (DMPA or NET-EN)? What can be done if a woman experiences menstrual abnormalities when using implants? What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD? Pelvic inflammatory disease What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease? What should be done if a woman using a LNG IUD is diagnosed with pelvic inflammatory disease? Pregnancy What should be done if a woman using a copper-bearing IUD is found to be pregnant? What should be done if a woman using a LNG IUD is found to be pregnant? Programmatic issues What examinations or tests should be done routinely before providing a method of contraception?	When can a woman have repeat POIs (DMPA or NET-EN)? When can a woman have a copper-bearing IUD inserted? When can a woman have a LNG IUD inserted? What can a woman do if she misses COCs? What can a woman do if she misses POPS? What can be done if a woman has menstrual abnormalities when using POIs (DMPA or NET-EN)?

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First edition, 2002

Second edition, 2004

Interim update, 2008

How many pill packs (combined or POFs) should be given at initial and return visits?
 What follow-up is appropriate for COC, POP, implant, and IUD users?
 How can a provider be reasonably sure that a woman is not pregnant?

Abbreviations: COC, combined oral contraceptive; POP, progesterone-only pill; CIC, combined injectable contraceptive; ECP, emergency contraceptive pill; POI, progestogen-only injectable; DMPA, depot medroxyprogesterone acetate; NET-EN, norethisterone enantate; IUD, intrauterine device; LNG IUD, levonorgestrel-releasing intrauterine device.

TABLE 2

Updated recommendations for the third edition of the *Selected practice recommendations for contraceptive use*.

Clinical recommendation	GRADE assessment of quality of evidence	Strength of recommendation ^a
LNG implant: SI		
A woman can start SI(II) within 7 d after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are amenorrheic, post partum, post abortion, or switching from another method	No direct evidence	Strong
It is desirable to have blood pressure measurements taken before initiation of SI(II). Women should not be denied use of SI(II) simply because their blood pressure cannot be measured	No direct evidence	Strong
Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, hemoglobin test, STI risk assessment (medical history and physical examination), and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of SI(II)	No direct evidence	Strong
Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, hemoglobin test, STI risk assessment (medical history and physical examination), and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of SI(II)	No direct evidence	Strong
No routine follow-up is required after initiating SI(II)	No direct evidence	Strong
The product labelling for SI(II) states that the implant can be left in place for up to 4 y	Low	Strong
Progestogen-only injectable contraceptive: DMPA-SC		
A woman can start DMPA-SC within 7 d after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are amenorrheic, post partum, post abortion, or switching from another method	No direct evidence	Strong
It is desirable to have blood pressure measurements taken before initiation of DMPA-SC. Women should not be denied use of DMPA-SC simply because their blood pressure cannot be measured	No direct evidence	Strong
Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, hemoglobin test, STI risk assessment (medical history and physical examination), and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of DMPA-SC	No direct evidence	Strong
Provide repeat DMPA-SC injections every 3 mo. Recommendations are also available for early and late injections	Very low	Strong
CHCs: patch and CVR		
A woman can start the patch or CVR within 5 d after the start of her menstrual bleeding; she can also start at any other time if it is reasonably certain that she is not pregnant. Recommendations are also available for when additional protection is needed and for women who are amenorrheic, post partum, post abortion, or switching from another method	Patch: moderate to low; CVR: no direct evidence	Strong
It is desirable to have blood pressure measurements taken before initiation of the patch or CVR. Women should not be denied use of the patch or CVR simply because their blood pressure cannot be measured	No direct evidence	Strong
Breast examination by provider, pelvic/genital examination, cervical cancer screening, routine laboratory tests, hemoglobin test, STI risk assessment (medical history and physical examination), and STI/HIV screening (laboratory tests) do not contribute substantially to the safe and effective use of the patch and CVR	No direct evidence	Strong
A woman may need to take action if she has a dosing error with the patch or CVR. Recommendations are provided for management of the extension of the patch-free interval, unscheduled detachment of the patch, extended use of the patch, extension of the CVR-free interval, unscheduled removal of the CVR, and extended use of the CVR	Patch: No direct evidence; CVR: Very low	Strong

Clinical recommendation	GRADE assessment of quality of evidence	Strength of recommendation ^a
An annual follow-up visit is recommended after initiating the patch or CVR ECPs: UPA, LNG-only, or combined	No direct evidence	Strong
A woman should take UPA as early as possible after intercourse within 120 h	Low	Strong
LNG-only or UPA ECPs are preferable to combined estrogen-progestogen ECPs because they cause less nausea and vomiting. Routine use of antiemetics before taking ECPs is not recommended. Pretreatment with certain antiemetics can be considered depending on availability and clinical judgment	Range: Moderate to low	Strong
If the woman vomits within 3 h after taking UPA, she should take another UPA dose as soon as possible	No direct evidence	Strong
Resumption or initiation of regular contraception after using ECPs		
Following administration of LNG-only or combined estrogen-progestogen ECPs, a woman may resume her contraceptive method, or start any contraceptive method immediately	No direct evidence	Strong
Following administration of UPA ECPs, she may resume or start any progestogen-containing method (either CHC or progestogen-only contraceptives) 6 d after taking UPA. She can have the copper-bearing intrauterine device inserted immediately	No direct evidence	Strong

Abbreviations: LNG, levonorgestrel; SI(II), Sino-implant (II); STI, sexually transmitted infection; DMPA-SC, depot medroxyprogesterone acetate administered subcutaneously; CHC, combined hormonal contraceptive; CVR, combined contraceptive vaginal ring; ECP, emergency contraceptive pill; UPA, ulipristal acetate.

^aStrong recommendation: one that can be adopted as policy in most situations. Conditional recommendation: policy-making will require substantial debate and involvement of various stakeholders.