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## Executive summary

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This document is one of two evidence-based cornerstones of the World Health Organization's (WHO) new initiative to develop and implement evidence-based guidelines for family planning. The first cornerstone, the *Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use (second edition)* published in 2000, provides guidance for *who* can use contraceptive methods safely. This document, the *Selected Practice Recommendations for Contraceptive Use*, provides guidance for *how* to use contraceptive methods safely and effectively once they are deemed to be medically appropriate. The recommendations contained in this document are the product of a process that culminated in a scientific Working Group meeting convened by WHO and held in London, 3–6 October 2001. The meeting brought together 33 participants from 16 countries to make selected practice recommendations for contraceptive use. The recommendations were the Working Group's response to 23 specific questions selected by WHO, based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from Working Group participants and family planning organizations/agencies.

The document provides selected practice recommendations based on the best available evidence and is intended to be used by policy-makers, programme managers, and the scientific community. It aims to provide guidance to national family planning/reproductive health programmes in the preparation of guidelines for service delivery of contraceptives. At appropriate intervals, WHO will update and add to the selected practice recommendations in this document.

These recommendations are available on the WHO web site ([www.who.int/reproductive-health](http://www.who.int/reproductive-health)). The web site will also provide additional information determined by WHO to be relevant to these practice recommendations, pending the next formal consensus Working Group meeting. WHO encourages research to address the key unresolved issues noted in this document.

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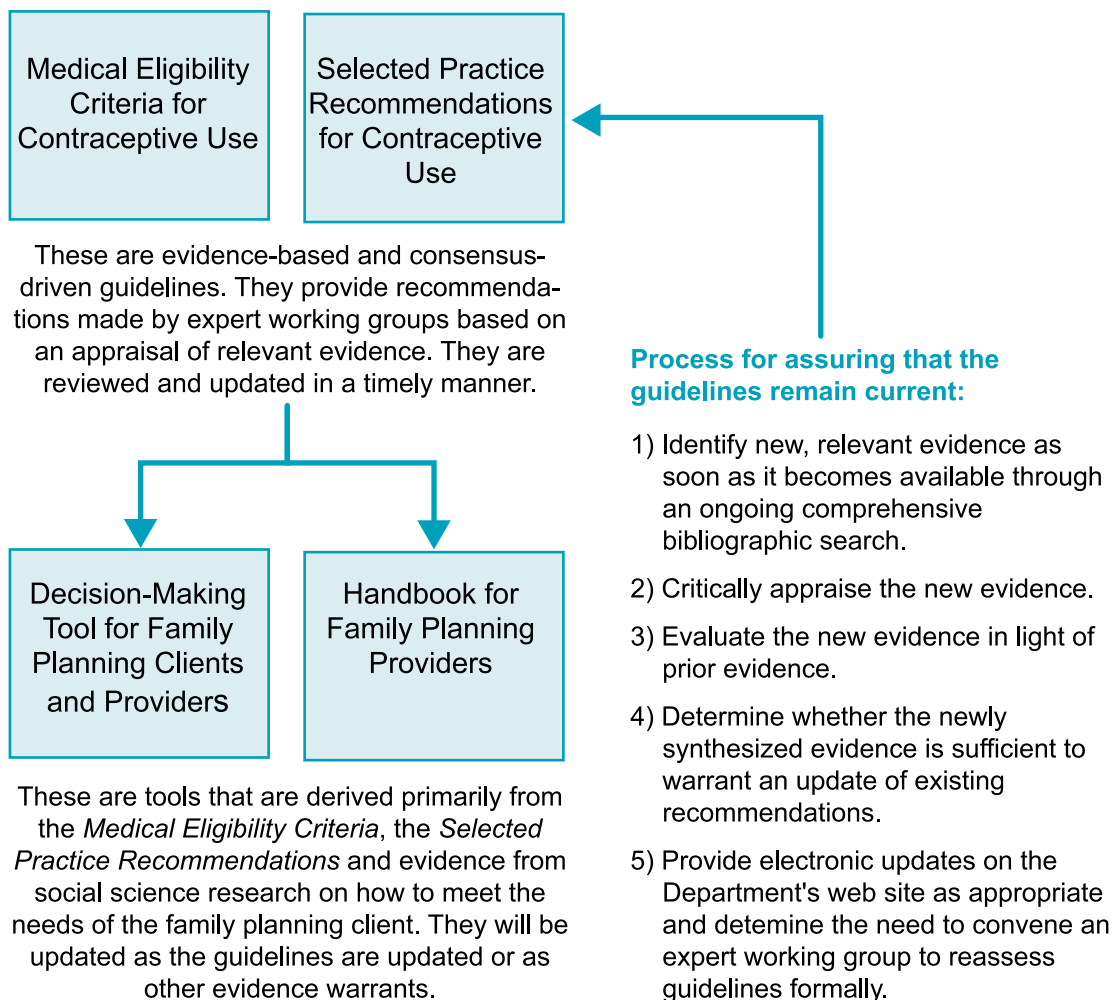
## Overview

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In 1999, WHO reviewed its family planning guidance and determined that the creation of new evidence-based guidelines was warranted. Accordingly, the World Health Organization through its Department of Reproductive Health and Research initiated the creation of a new series of evidence-based family planning guidelines beginning with the second edition of *Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use*, published in 2000. The two evidence-based cornerstones of this series (Figure 1) are the *Medical Eligibility Criteria*, which provides guidance regarding *who* can use contraceptive methods safely, and this document, the *Selected Practice Recommendations for Contraceptive Use*, which provides guidance regarding *how* to use contraceptive methods safely and effectively. These two documents give evidence-based guidance for choosing (the *Medical Eligibility Criteria*) and for using (the *Selected Practice Recommendations*) contraceptive methods. The forthcoming third and fourth documents, the *Decision-Making Tool for Family Planning Clients and Providers*

and the *Handbook for Family Planning Providers*, are intended to improve the quality of the family planning encounter and will be derived from the *Medical Eligibility Criteria* and the *Selected Practice Recommendations*. These four documents comprise the four cornerstones of WHO's family planning guidance. This guidance is best interpreted and used in a broader context of reproductive and sexual health care.

## Evidence-based guidance for family planning



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## Reproductive and sexual health care

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“Reproductive rights embrace certain human rights that are already recognised in national laws, international human rights documents and other relevant consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number and spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health.” (para. 95, Beijing Platform for Action, 1995)

Reproductive and sexual health care including family planning services and information is recognized not only as a key intervention for improving the health of women, men and children but also as a human right. All individuals have the right to access, choice, and the benefits of scientific progress in the selection of family planning methods. A rights-based approach to the provision of contraceptives assumes a holistic view of clients, which includes taking into account clients' sexual and reproductive health care needs and considering all appropriate eligibility criteria and practice recommendations in helping clients choose and use a family planning method.

Over the past 30 years, there have been significant advances in the development of new contraceptive technologies, including transitions from high-dose to low-dose estrogen combined oral contraceptives (COCs) and from inert to copper and levonorgestrel-releasing intrauterine devices (IUDs). In addition, progestogen-only injectables (POIs), combined injectable contraceptives (CICs), and progestogen-only implants have been introduced. Advances in scientific knowledge and in research and development in recent decades have resulted not only in an increasingly wider choice of new contraceptive methods, but also in improvements in the safety and effectiveness of existing methods. However, the full range of modern family planning methods still remains unavailable to at least 350 million couples worldwide, many of whom wish to space or prevent another pregnancy. Even when family planning methods are accessible and individuals wish to space or limit births, family planning services are often under-used.

Many factors contribute to the gap between access to, and use of, services. In addition to many logistic, social and behavioural obstacles to meeting the contraceptive needs and wishes of individuals and couples, there may be obstacles that stem from the structure, organization or procedures of the health system that can be corrected. To meet people's needs and close the existing large gap in quality services, reproductive health care providers, programmes and contraceptive suppliers will need to improve services, and information will need to be disseminated about new contraceptive developments, appropriateness of methods and introduction strategies.

Thus, WHO is giving priority to improving access to high-quality care in family planning through a variety of strategies. These include: ensuring that women's and men's rights and perspectives are taken into account in the planning, management and evaluation of services; promoting the widest availability of different contraceptive methods so that people may select what is most appropriate to their needs and circumstances; ensuring that contraceptive counselling and service delivery will be based on eligibility criteria and practice recommendations that are supported by a scientific rationale; and conducting research to develop new family planning methods and improve existing ones.

Delivery of care in accordance with the client's human and reproductive rights is fundamental to quality of care. The development of international norms for eligibility criteria and practice recommendations for contraceptive use is only one aspect of improving the quality of reproductive health care. Many family planning programmes have included screening, treatment and follow-up procedures that reflect high standards of public health and clinical practice but should not be seen as eligibility or use requirements for specific contraceptive methods. These procedures include the screening and treatment of cervical cancer, anaemia and sexually transmitted infections (STIs), and the promotion of breastfeeding and cessation of smoking. Such procedures should be strongly encouraged if the human and material resources are available to carry them out, but they should not be seen as prerequisites for the acceptance and use of family planning methods when they are not necessary to establish eligibility for the use or continuation of a particular method.

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## The selected practice recommendations for contraceptive use

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This document addresses ongoing controversies and inconsistencies regarding how to maximize the effectiveness of contraceptive methods and how to manage their side-effects. For instance, current recommendations are inconsistent as to when in the menstrual cycle a method can be initiated, how consistent and correct use can be maintained, and how menstrual abnormalities that frequently lead to discontinuation can be addressed. The methods for which the existing guidelines have been most inconsistent include combined estrogen-progestogen and progestogen-only oral contraceptives, injectable and implantable hormonal contraceptives; IUDs; fertility awareness-based methods and emergency contraceptive pills. As Table 1 shows, the effectiveness of some of these methods varies substantially depending on whether they are used consistently and correctly. The gap between the effectiveness of perfect and typical use is at least partially explained by inconsistent or unclear guidance about how to use these methods properly. The willingness and ability of contraceptive users to use their methods effectively also depends on minimizing and managing side-effects.

Like the *Medical Eligibility Criteria*, these *Selected Practice Recommendations* are meant to provide guidance that is both evidence-based and consensus-based. They will be reviewed and updated in a timely manner and are meant to be used by policy-makers, family planning programme managers and the scientific community. They are to be used as a reference and resource for the development of practice guidelines in the light of national health policies, needs, priorities and resources. Country situations and programme environments vary too greatly to set international guidelines for contraceptive use that apply in all settings and circumstances. Adaptations are best made by those well-acquainted with the health, habits and culture of the region, addressing questions or misperceptions held by providers as well as the needs and perspectives of women and men seeking contraception.

**Table 1. Effectiveness of family planning methods†**

Effectiveness group	Family planning method	Pregnancies per 100 women in first 12 months of use	
		As commonly used	Used correctly & consistently
Always very effective.	Norplant implants	0.1	0.1
	Vasectomy	0.2	0.1
	Combined injectables‡	0.3	0.3
	DMPA and NET-EN injectables	0.3	0.3
	Female sterilization	0.5	0.5
	TCu-380A IUD	0.8	0.6
	Progestogen-only oral contraceptives (during breastfeeding)	1	0.5
Effective as commonly used. Very effective when used correctly and consistently.	Lactational amenorrhoea method	2	0.5
	Combined oral contraceptives	6–8	0.1
	Progestogen-only oral contraceptives (not during breastfeeding)	§	0.5§§
Only somewhat effective as commonly used. Effective when used correctly and consistently	Male condoms	14	3
	Coitus interruptus§§	19	4
	Diaphragm with spermicide	20	6
	Fertility awareness-based methods	20	1–9
	Female condoms	21	5
	Spermicides	26	6
	Cap		
	Nulliparous women	20	9
Parous women	40	26	
	No method	85	85

Key: 

0–1	Very effective	2–9	Effective	10–30	Somewhat effective
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Notes:

† Adapted from Hatcher RA, Rinehart W, Blackburn R, Geller JS and Shelton JD. *The essentials of contraceptive technology*. Baltimore, Johns Hopkins University Bloomberg School of Public Health, Population Information Program, 1997.

‡ UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. Facts about once-a-month injectable contraceptives: Memorandum from a meeting. *Bulletin of the World Health Organization* 1993; 70(6):677-689.

§ Outside the context of breastfeeding, progestogen-only contraceptives are somewhat less effective than combined oral contraceptives. See Hatcher RA, Trussell J, Stewart F, Cates Jr W, Stewart GK, Guest F, Kowal D. *Contraceptive technology (17th edition)*. New York, Ardent Media Inc., 1998.

§§ Hatcher RA, Trussell J, Stewart F, Cates Jr W, Stewart GK, Guest F, Kowal D. *Contraceptive technology (17th edition)*. New York, Ardent Media Inc., 1998.

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**Table 2. List of questions posed to the Working Group**

1. When can a woman start combined oral contraceptives?
2. What can a woman do if she misses combined oral contraceptives?
3. What can a woman do if she vomits and/or has severe diarrhoea while using combined oral contraceptives or progestogen-only pills?
4. When can a woman start combined injectable contraceptives?
5. When can a woman have repeat combined injectable contraceptive injections?
6. When can a woman start progestogen-only pills?
7. What can a woman do if she misses progestogen-only pills?
8. What can a woman do if she vomits after taking emergency contraceptive pills?
9. When can a woman start progestogen-only injectables – depot medroxyprogesterone acetate (DMPA) or norethisterone enantate (NET-EN)?
10. When can a woman have repeat progestogen-only injectables – DMPA or NET-EN?
11. What can be done if a woman has menstrual abnormalities when using a progestogen-only injectable – DMPA or NET-EN?
12. When can a woman start using an implant?
13. What can be done if a woman experiences menstrual abnormalities using implants?
14. When can a copper-bearing IUD be inserted?
15. What can be done if a woman experiences menstrual abnormalities when using a copper-bearing IUD?
16. What should be done if a woman using a copper-bearing IUD is diagnosed with pelvic inflammatory disease?
17. What should be done if a woman using a copper-bearing IUD is found to be pregnant?
18. Should prophylactic antibiotics be provided for copper-bearing IUD insertion?
19. What can a Standard Days Method user do if she has menstrual cycles outside the 26–32 day range?
20. What examinations or tests should be done routinely before providing a method of contraception?
21. How many pill packs (combined or progestogen-only pills) should be given at initial and return visits?
22. What follow-up is appropriate for combined oral contraceptive, progestogen-only pill, implant and IUD users?
23. How can a provider be reasonably sure that a woman is not pregnant?

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## Method of work

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This document is the product of a process that culminated in a scientific Working Group meeting convened by WHO and held in London, 3–6 October 2001, with the support of the International Planned Parenthood Federation (IPPF) to facilitate the participation of IPPF's International Medical Advisory Panel. The meeting brought together 33 participants from 16 countries to make selected practice recommendations for contraceptive use. (The list of participants is given as an annex to this document.) The recommendations were the Working Group's response to 23 specific questions selected by WHO, based on 1) important controversies or inconsistencies in existing guidance, 2) the likelihood that relevant evidence was available, and 3) proposals from Working Group participants and family planning organizations/agencies. The list of questions that were posed to the group is given in Table 2.

The Working Group was charged with reviewing evidence obtained primarily from a systematic review of the literature published from 1980 to 2000. The purpose of the review was to identify evidence to address the biomedical and behavioural components of the common clinical challenges represented by Questions 1–19. Questions 20–23 represented broader programmatic issues and were not addressed by the systematic review.

The systematic review began with a search of MEDLINE and POPLINE to identify studies that could potentially provide relevant evidence. Additional reports were identified from the reference lists in the articles obtained by the literature search. Each article was reviewed by WHO to determine its relevance to the questions posed, the quality of the evidence provided, and whether the evidence was directly or indirectly applicable to answering the questions (Table 3). This information, along with a detailed summary of the relevant evidence for each question, was provided to the Working Group as a background document prior to the meeting. In addition, individual members of the Working Group were asked to serve as resource persons for specific questions and were provided prior to the meeting with complete copies of all relevant reports reviewed in the background paper.

Four sub-groups met for the first two days of the meeting to draft preliminary recommendations for the 23 questions. The sub-groups were asked to make recommendations based on the evidence provided from the systematic review and on other relevant biomedical, behavioural, or programmatic evidence or considerations provided by sub-group members. Each sub-group was encouraged to base its recommendations on the best available evidence, to cite the level and applicability of the evidence, and to comment on the rationales for the recommendations made. In addition, the sub-groups were asked to determine major gaps in evidence and thereby identify key unresolved issues that would benefit from further research.

The sub-groups presented their recommendations and rationales to the plenary session convened on the final two days of the meeting. The entire Working Group then deliberated to reach consensus on final recommendations. After the meeting, the comments provided by the sub-group and plenary sessions deliberations were used by WHO to create the comments for each question in this document.

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### Table 3. Levels of evidence\*

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The levels and categories of evidence on which the recommendations were based were as follows:

**Level 1:** Evidence obtained from at least one properly designed randomized controlled trial.

**Level II-1:** Evidence obtained from well-designed controlled trials without randomization.

**Level II-2:** Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

**Level II-3:** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

**Level III:** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

\* U.S. Preventive Services Task Force. *Guide to clinical preventive services*, 2nd ed. Alexandria, Virginia: International Medical Publishing, 1996:862.

### Types of evidence

**Direct:** The evidence was based on data directly addressing the question.

**Indirect:** The evidence was extrapolated from other relevant data.

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### How to use this document

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This document is intended for adaptation at country and programme levels to reflect the diversity of situations and settings in which contraceptives are provided.

The document is organized by questions. For each question, the Working Group's recommendations are provided for key specific situations, along with the comments and key unresolved issues. Further, for questions addressed by the systematic review (Questions 1–19), the following information is also provided: 1) the phrasing of the question from which the literature search terms were derived, 2) the level of evidence and whether that evidence was directly or indirectly related to the question, and 3) the references identified by the systematic review and provided to the Working Group.

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## Issues of service quality and access that affect method use

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While this document chiefly addresses selected practice recommendations for contraceptive use, there are many other considerations in the appropriate provision of contraceptive methods. WHO will be examining, in depth, these programmatic and service delivery concerns, in various programme settings, during the next phase of this initiative. However, it is critical, even at this stage, to bear in mind the following service delivery criteria, which are universally relevant to the initiation and follow-up of all contraceptive method use.

- a) Clients should be given adequate information in order to make an informed, voluntary choice of a contraceptive method. Information given to clients to help them make this choice should at least include: understanding of the relative effectiveness of the method; correct use of the method; how it works; common side-effects; health risks and benefits of the method; signs and symptoms that would necessitate a return to the clinic; information on return to fertility after discontinuing method use; and information on STI protection.
- b) For those methods that require surgical approaches, insertion, fitting and/or removal by a trained health care provider (sterilization, implants, IUDs, diaphragms, cervical caps), appropriately trained personnel in adequately equipped facilities must be available in order for those methods to be offered, and appropriate infection prevention procedures must be followed.
- c) Adequate and appropriate equipment and supplies need to be maintained and held in stock (for example, contraceptive commodities, equipment and supplies for infection prevention procedures).
- d) Service providers should be provided with guidelines (or client cards or other screening tools) to enable them to appropriately screen clients for conditions in which use of certain contraceptive methods would carry unacceptable health risks.
- e) Service providers must be trained in providing family planning counselling to help clients make informed and voluntary decisions about their fertility. Counselling is a key element in quality of care and is also an important part of both initiation and follow-up visits and should respond to clients' needs, not only in contraception but also in relation to sexuality and the prevention of STIs, including infection with the human immunodeficiency virus (HIV).

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## Special considerations

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### Return to fertility

The use of contraceptive methods, with the exception of male and female sterilization, does not result in an irreversible change in fertility. Return to fertility is immediate with all methods, with the exception of DMPA and NET-EN; the median delay in return to fertility with these methods is 10 and 6 months, respectively, from the date of the last injection, regardless of the duration of their use. Male and female sterilization should be regarded as permanent methods.

## STIs and contraception: dual protection

While the development of international norms for contraceptive provision is essential for quality of care in services, the social and cultural context of each client must also be considered. In this regard, the problems of exposure to STIs, including HIV, deserve special consideration because of the importance of both preventing pregnancy and preventing transmission of infection. When a risk of STI/HIV transmission exists, it is important that health care providers strongly recommend dual protection, either through the simultaneous use of condoms with other methods or through the consistent and correct use of condoms alone for both pregnancy prevention and disease prevention. Women and men seeking contraceptive advice must always be reminded of the importance of condom use for preventing the transmission of STI/HIV. Male latex condoms are proven to protect against STI/HIV when used consistently and correctly.

## Adolescents

In general, adolescents are eligible to use any method of contraception and must have access to a variety of contraceptive choices. Age alone does not constitute a medical reason for denying any method to adolescents, although sterilization is rarely appropriate for this age group. While some concerns have been expressed regarding the use of certain contraceptive methods in adolescents (e.g., the use of progestogen-only injectables by those below 18 years), these concerns must be balanced against the advantages of avoiding pregnancy. It is clear that many of the same issues regarding appropriate contraceptive use that apply to older clients apply to young people. Social and behavioural issues are important considerations in the choice and use of contraceptive methods by adolescents. For example, in some settings, adolescents are also at increased risk for STIs, including HIV. While adolescents may choose to use any one of the contraceptive methods available in their communities, in some cases, using methods that do not require a daily regimen may be more appropriate. Adolescents, married or unmarried, have also been shown to be less tolerant of side-effects and therefore have high discontinuation rates. Method choice and use may also be influenced by factors such as sporadic patterns of intercourse and the need to conceal sexual activity and contraceptive use. For instance, sexually active adolescents who are unmarried have very different needs from those who are married and want to postpone, space or limit pregnancy. Expanding the number of method choices offered can lead to improved satisfaction, increased acceptance and increased prevalence of contraceptive use. Proper education and counselling both before and at the time of method selection can help adolescents address their specific problems and make informed and voluntary decisions.

## Clients with special needs

Contraceptive provision to people with special needs requires additional consideration. Individuals with a physical disability represent such a group. Decisions on appropriate contraception must take into account the nature of the disability, the expressed desires of the individual and the nature of the method. Decisions must be based on informed choice. Similar considerations should be given to individuals with mental disability or with serious psychiatric disease. Where the nature of the condition does not allow for informed choice, contraceptives should be provided only after full discussion with all parties including guardians or care-givers. The reproductive rights of the individual must be considered in any such decisions. Selected practice recommendations may need to be modified for clients with special needs; for example, clients with mental disabilities may have difficulty

remembering to take pills daily. Clients with physical disabilities may have difficulty obtaining supplies or otherwise accessing the family planning services.

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## Programmatic implications

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The goal of this document is to provide policy- and decision-makers and the scientific community with a set of recommendations that can be used for developing or revising national guidelines on selective practice recommendations for contraceptive use.

The document does not provide rigid guidelines but rather gives recommendations that provide a basis for the appropriate use of various contraceptives in view of the most up-to-date information available.

Because country situations and programme environments vary so greatly, it is inappropriate to set firm international guidelines on criteria for contraceptive use. However, it is expected that national programmes will use these recommendations as a reference tool, adapting them to develop their own contraceptive guidelines in the light of their national health policies, needs, priorities and resources. The intent is to help improve access to, and quality of, family planning services. These improvements must be made within the context of users' informed choice and medical safety. Adaptation is not always an easy task and is best done by those well-acquainted with the prevailing health situation, habits and culture.

### Programmatic issues that need to be addressed include:

- ◆ informed choice,
- ◆ elements of quality of care,
- ◆ essential screening procedures for administering the methods,
- ◆ provider training and skills,
- ◆ referral and follow-up for contraceptive use as appropriate.

In the application of the selected practice recommendations to programmes, service delivery practices that are essential for the appropriate use of the contraceptive should be distinguished from practices that may be appropriate for good health care but are not related to use of the method. The promotion of good health care practices unrelated to safe and appropriate contraceptive use should be considered neither as a prerequisite nor as an obstacle to the provision of a contraceptive method, but rather as complementary to it.

As a next step, the selected practice recommendations in this document need to be adapted so as to be applicable to providers at all levels of the service delivery system. Countries will need to determine how far and by what means it may be possible to extend their services to the more peripheral levels. This may involve upgrading both staff and facilities where feasible and affordable, or may require the extension of the skills of certain categories of health personnel or a modest addition of equipment and supplies, and redeployment of space. It will also be necessary to address questions of misperceptions sometimes held by providers and users on the risks and side-effects of the methods and

to look closely at the needs and perspectives of women and men in the context of informed choice.

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## Summary and conclusions

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The development and use of evidence-based and consensus-driven recommendations for contraceptive use will contribute to improvements in the quality of family planning services. Such recommendations increase the competence and confidence of service providers as they assist their clients in choosing and using contraceptive methods. This in turn should contribute to increased satisfaction and confidence among those clients. The guidance provided in this document will be most useful if it is adapted to meet specific needs at country and programme levels.

It is recognized that some of the selected practice recommendations in this report will need to be reviewed in the light of new research as it becomes available. At appropriate intervals, WHO will update and add to the selected practice recommendations in this document. These recommendations are available on WHO's reproductive health web site ([www.who.int/reproductive-health](http://www.who.int/reproductive-health)). The web site will also provide additional information determined by WHO to be relevant to these practice recommendations, pending the next formal consensus Working Group meeting. WHO encourages research to address the key unresolved issues noted in this document.

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