

# Keeping up with Evidence

## A New System for WHO's Evidence-Based Family Planning Guidance

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**Abstract:** The World Health Organization (WHO) is responsible for providing evidence-based family planning guidance for use worldwide. WHO currently has two such guidelines, *Medical Eligibility Criteria for Contraceptive Use* and *Selected Practice Recommendations for Contraceptive Use*, which are widely used globally and often incorporated into national family planning standards and guidelines. To ensure that these guidelines remain up-to-date, WHO, in collaboration with the Centers for Disease Control and Prevention and the Information and Knowledge for Optimal Health (INFO) Project at the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs, has developed the Continuous Identification of Research Evidence (CIRE) system to identify, synthesize, and evaluate new scientific evidence as it becomes available.

The CIRE system identifies new evidence that is relevant to current WHO family planning recommendations through ongoing review of the input to the POPulation information onLINE (POPLINE®) database. Using the *Meta-Analysis of Observational Studies in Epidemiology* guidelines and standardized abstract forms, systematic reviews are conducted, peer-reviewed, and sent to WHO for further action. Since the system began in October 2002, 90 relevant new articles have been identified, leading to 43 systematic reviews, which were used during the 2003–2004 revisions of WHO's family planning guidelines.

The partnership developed to create and manage the CIRE system has pooled existing resources; scaled up the methodology for evaluating and synthesizing evidence, including a peer-review process; and provided WHO with finger-on-the-pulse capability to ensure that its family planning guidelines remain up-to-date and based on the best available evidence. (Am J Prev Med 2005;28(5):483–490) © 2005 American Journal of Preventive Medicine

### Introduction

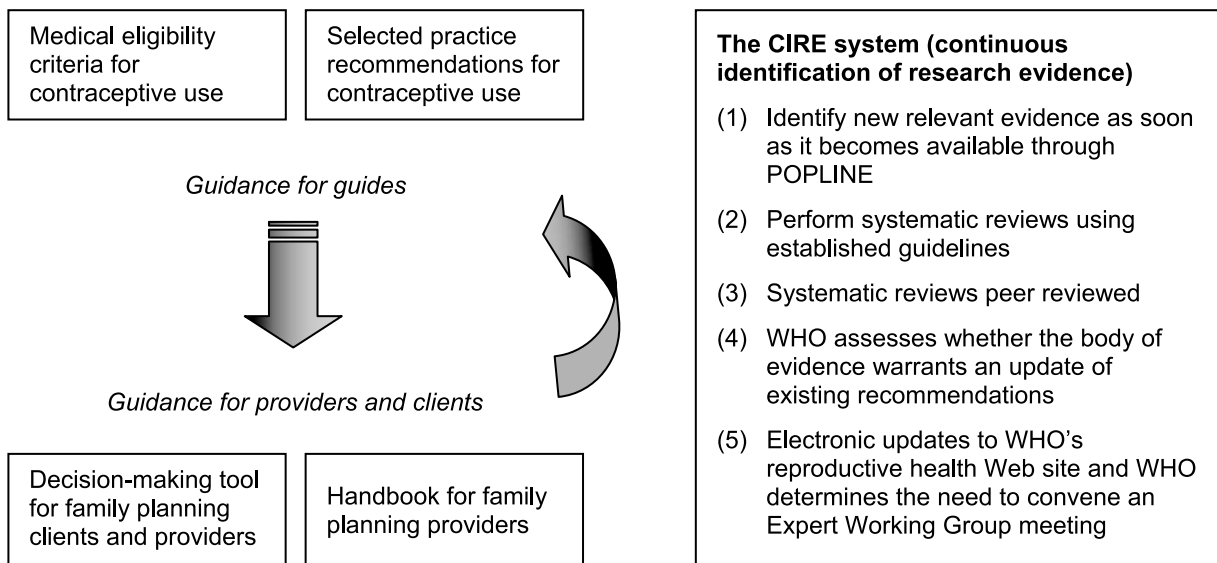
In the 1990s, the World Health Organization (WHO) re-invigorated its efforts to develop family planning guidelines that are based on the best available evidence. *Medical Eligibility Criteria for Contraceptive Use* (MEC),<sup>1</sup> which provides guidance on **who** can use contraceptives safely and effectively, and *Selected Practice Recommendations for Contraceptive Use* (SPR),<sup>2</sup> which provides guidance on **how** to safely and effectively use contraceptive methods, are the first two cornerstones of WHO's evidence-based family planning guidance. Both the MEC and the SPR are evidence-

based and consensus-driven guidelines; a WHO Expert Working Group (EWG) determines the recommendations on the basis of systematic reviews of scientific evidence. Both documents are intended to assist national family planning and reproductive health programs in preparing guidelines for contraceptive service delivery, and are meant to be adapted locally by taking into account the social, cultural, and economic environment in which contraceptives are provided. As of 2004, the MEC and the SPR had been incorporated into many national family planning standards, were used in  $\geq 50$  developing and developed countries, and will be included in the next two cornerstones of WHO's family planning guidance, the *Decision-making Tool for Family Planning Clients and Providers*, and a handbook for family planning providers (Figure 1). Organizations such as the International Planned Parenthood Federation, American College of Obstetricians and Gynecologists, the Planned Parenthood Federation of America, and U.S. Agency for International Development (USAID) have considered the MEC and SPR recommendations in developing their own guidance recommendations.

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**Figure 1.** The four cornerstones of family planning guidance and the Continuous Identification of Research Evidence system. POPLINE, POPulation information onLINE; WHO, World Health Organization.

Although the MEC and SPR have received widespread praise, reviewers suggested strengthening the approach for obtaining and evaluating the evidence on which these recommendations are based.<sup>3,4</sup> Therefore, in 2002, WHO and partners launched the Continuous Identification of Research Evidence (CIRE) system to continuously and systematically identify, evaluate, synthesize, and peer-review new evidence as it becomes available. The system is a collaborative effort among WHO, the Centers for Disease Control and Prevention (CDC), and the Information and Knowledge for Optimal Health (INFO) Project at the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs, with funding from USAID and the National Institute of Child Health and Human Development. The CIRE system provides the mechanism to update the four cornerstones and present consistent guidance that is based on up-to-date evidence. Evidence identified by the CIRE system since 2002 has led to 43 systematic reviews, which contributed to revisions of the MEC and SPR, reflected in the subsequent publication of the third edition of the MEC<sup>1</sup> and the second edition of the SPR<sup>2</sup> in 2004.

This article describes the methodology of the CIRE system and the process of developing WHO's evidence-based guidelines with a real-life example of how an article identified by the CIRE system was used in creating new guidance.

## Continuous Identification of Research Evidence System

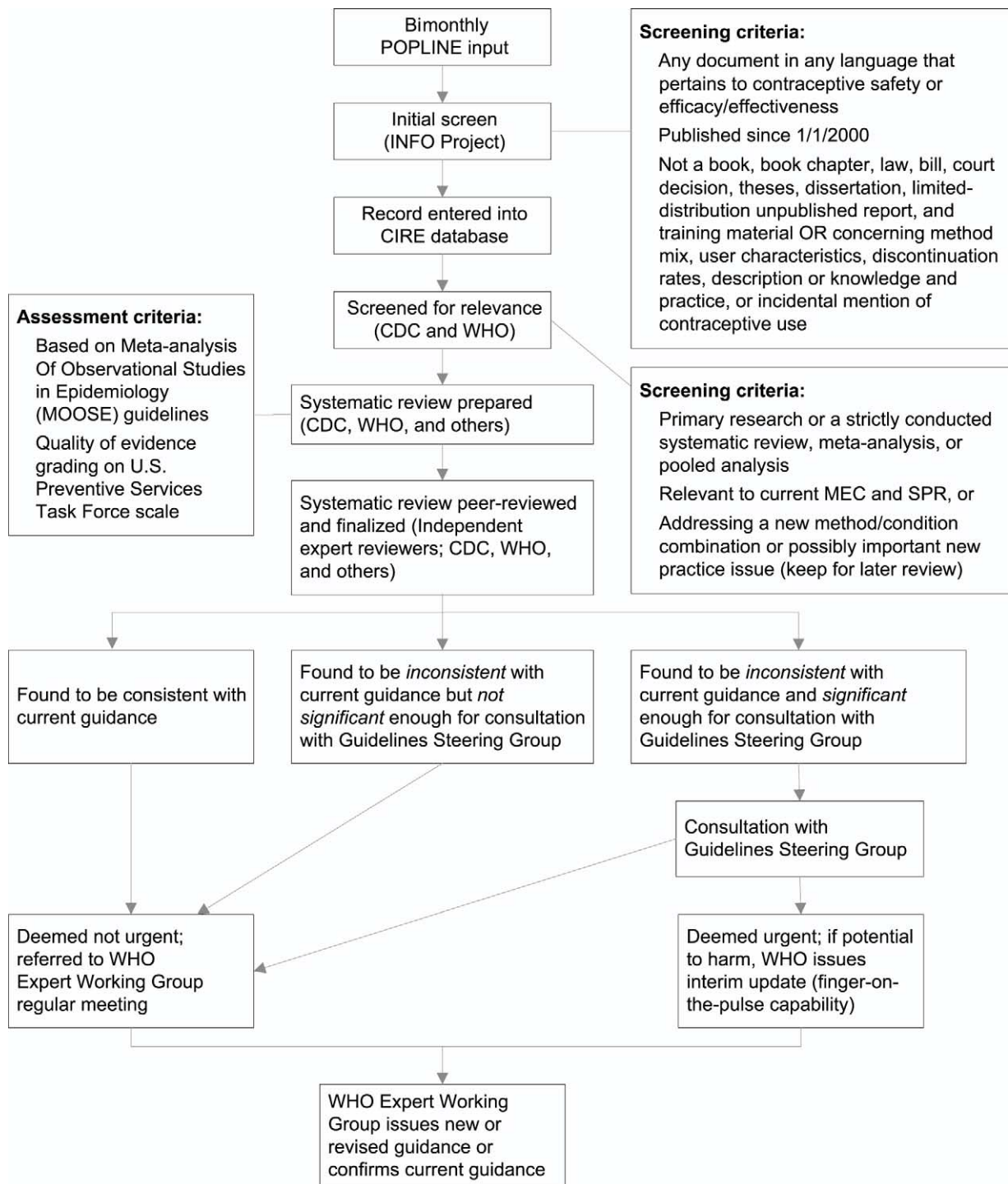
### Conceptual Approach

The MEC consists of >1700 recommendations on the use of specific contraceptive methods, depending on a

woman's characteristics (such as age or history of pregnancy) or presence of medical conditions (such as hypertension or AIDS). The SPR provides recommendations on how to use contraceptives and includes guidance regarding questions such as when to start and re-administer contraceptives, and how to manage frequently encountered problems such as missing a pill or having menstrual abnormalities. The current edition of the SPR contains 33 recommendations.<sup>2</sup> New topics are added in response to requests from the field, pressing health issues, release of new contraceptive methods, and important controversies or inconsistencies in existing family planning guidance. For example, for the 2004 MEC, WHO requested a systematic review of interactions between hormonal contraceptive methods and antiretroviral drugs because of the pressing need for guidance in the international community regarding the care of women with HIV/AIDS.

Given the >1700 recommendations contained in both documents, WHO needed a system that could identify new evidence as it became available and assess whether that new evidence would lead to a change in current recommendations, facilitate the conduct of systematic reviews as preparation for periodic WHO consultations to review and update the guidelines, and be responsive to WHO's need to provide expert guidance for family planning in a timely fashion.<sup>5</sup> Based on these needs, the CIRE system was created and includes five steps: identification of new evidence, systematic review and synthesis of the evidence, quality assessment, peer review, and submission of the final systematic review to WHO.

**Step 1: Identification of new evidence.** Identifying new reports of research evidence for the CIRE system begins



**Figure 2.** The Continuous Identification of Research Evidence (CIRE) process. CDC, Centers for Disease Control and Prevention; INFO, Information and Knowledge for Optimal Health Project; MEC, *Medical Eligibility Criteria for Contraceptive Use*; POPLINE, POPulation information onLINE; SPR, *Selected Practice Recommendation for Contraceptive Use*; WHO, World Health Organization.

with the POPulation information onLINE (POPLINE<sup>®</sup>) database, the world's largest database on reproductive health, population, and family planning, available at [www.popline.org](http://www.popline.org) (Figure 2). POPLINE contains over 300,000 citations and abstracts of scientific articles, books, papers, and unpublished reports on family

planning, related reproductive health, and other primary health topics. Staff at the INFO Project, where POPLINE is based, update the database every 2 weeks in batches ranging from several dozen to >1000 articles. A staff member reviews each new entry and selects those that meet the criteria for the CIRE system: any

document in any language that pertains to contraceptive safety or efficacy/effectiveness, publication date of January 1, 2000 or later (because the MEC and the SPR had been updated in 2000 and 2001, respectively, when CIRE was initiated), and publication in a peer-reviewed scientific journal.

On average, 6.5% (range 0.7% to 17.8%) of the entries from a batch of new POPLINE entries meet the selection criteria. The POPLINE entries identified by an INFO Project researcher are uploaded to the CIRE database on the Internet. Each article is then retrieved and reviewed by CDC and WHO staff to determine whether the article meets the criterion that triggers a systematic review or an update of an existing review, that is, the article must be a primary research report or a rigorously conducted systematic review, meta-analysis, or pooled analysis that is relevant to current MEC or SPR recommendations. Articles that are secondary reports of a research finding are kept until the primary report of the findings is identified. Since CIRE was launched in October 2002, a total of 90 articles have met these criteria and have been included in the system.

**Step 2: Systematic review and synthesis of the evidence.** The *Meta-Analysis of Observational Studies in Epidemiology* (MOOSE)<sup>6</sup> guidelines serve as the template for the synthesis and presentation of the evidence for the systematic reviews. Systematic reviews are conducted at CDC, WHO, and other institutions, including Family Health International. The databases used in the literature search may differ, depending on the topic. All reviews include searches of MEDLINE and PRE-MEDLINE, EMBASE, and the Cochrane Collaboration Database, and they may include other methods, such as manual searches, inclusion of articles in press, and contacts with experts in the field.

The approach to systematic reviews for the MEC is straightforward. Given a particular contraceptive method and health condition combination, the approach is to assess whether a person with this condition (e.g., hypertension) experiences increased risk of adverse health outcomes (e.g., cardiovascular disease) as a result of using the contraceptive method (e.g., combined oral contraceptives). Therefore, the systematic review question is quite specific with regard to the population (women with hypertension); intervention (combined oral contraceptive use); comparison group (women not using combined oral contraceptives); and outcome (cardiovascular disease, specifically myocardial infarction, stroke, and venous thromboembolism). Ideally, the evidence for MEC recommendations comes from clinical and epidemiologic studies that directly assess the health risks and benefits of use of a specific contraceptive method by women with the health condition or characteristic of interest. Such direct evidence is usually limited, however, and is sometimes absent

entirely. In such cases, extrapolations from studies that primarily involve healthy women, theoretical considerations, and expert opinion play roles in developing the recommendations.

The approach to the systematic reviews for the SPR is more complicated. The SPR questions are generally formulated as contraceptive management questions, "What can be done if. . .?" (e.g., what can be done if a woman experiences menstrual abnormalities while using contraceptive implants?). For these questions, one or more systematic review questions are developed to guide the literature search and evidence synthesis process (e.g., what is the evidence regarding effective treatment regimens for bleeding abnormalities during implant use?). For this question, the review would include studies of a population of implant users who were experiencing bleeding abnormalities and who received treatment, with assessment of treatment effect on menstrual bleeding. For most of the SPR questions, there is evidence that directly pertains to the issue. When no direct evidence is available, the recommendation may be based on indirect evidence. For example, questions regarding contraceptive effectiveness may use studies that report on surrogate measures for risk of pregnancy, such as hormonal levels or ultrasound measurements suggestive of ovulation.

Standardized abstract forms are used by CDC and WHO reviewers to aid in the synthesis and evaluation of evidence for the systematic reviews (see Appendixes A and B at AJPM-Online, available at: [www.elsevier.com/locate/ajpmonline](http://www.elsevier.com/locate/ajpmonline)). The abstract forms and guidance for systematic reviews draw heavily on an evaluation conducted by the Agency for Healthcare Research and Quality (AHRQ). In its 2002 report, *Systems to Rate the Strength of Scientific Evidence*,<sup>7</sup> AHRQ identified 19 systems that addressed key quality domains. AHRQ chose certain domains or topic areas (e.g., study quality and validity) that should be included in systems that evaluate evidence. Based on these domains and other sources,<sup>6,8-14</sup> elements pertinent to the critical appraisal of articles related to the MEC and the SPR were incorporated into two abstract forms—one for individual studies and one for published systematic reviews and meta-analyses. Each of the abstract forms includes a section for assessing strengths and limitations of each piece of evidence and a detailed section on potential for biases.

**Step 3: Quality assessment.** The CIRE system recognizes the importance of assessing both the quality of individual studies and the body of evidence. The U.S. Preventive Services Task Force (USPSTF) scale is used in assessing the quality of the study and the body of evidence.<sup>10</sup> Each individual study is given a rating of I, II-1, II-2, II-3, and III, based on the study design, and a rating of poor, fair, or good, based on the criteria for grading internal validity. A good study meets all criteria

for that study design, a fair study does not meet all criteria but is judged to have no fatal flaw, and a poor study contains a fatal flaw. Numeric scores are not used to rate the quality of evidence because these types of scores have generally been found to be arbitrary, highly variable, and unassociated with treatment effect.<sup>15,16</sup> Instead, each author of the systematic review assesses the quality of the study by using the section on the abstract forms to assess the strength and limitations of the individual study and gives the individual study a rating based on the USPSTF scale.

For the third edition of the MEC, a new grading scheme, the Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, was tested.<sup>17</sup> An element from GRADE, consistency of results across studies, has been added to the CIRE system for grading the evidence: If the results are inconsistent, the quality grading of the body of the evidence is lowered by one level.

**Step 4: Peer-review process.** An integral part of the CIRE system is the peer review process. Peer reviewers are international family planning experts, and include clinicians, researchers, program managers, and policy-makers. Peer reviewers are asked to review the original article that triggered the systematic review, assess the systematic review, and complete a brief form evaluating the systematic review. Peer reviewers are also asked whether the current WHO recommendation: (1) remains consistent with the overall body of evidence and no action is needed; (2) is now inconsistent with the overall body of evidence, but the inconsistency is not sufficient to warrant consultation at this time; or (3) is now strongly inconsistent with the overall body of evidence, and the inconsistency is sufficient to warrant consultation at this time. Two reviewers assess each systematic review; a third reviewer is involved if the first two differ in their assessment. Peer reviewers' suggestions and interpretations are incorporated into the final systematic review.

**Step 5: Submission of review to WHO.** The final systematic review, along with peer-reviewers' assessment regarding the consistency of the evidence with the WHO recommendation, is sent to WHO for further action. WHO will then use this review, along with the others, as the body of evidence for the next consultation to revise the guidelines. However, if the current recommendation is strongly inconsistent with the body of evidence, WHO may issue interim guidance before the next consultation (see Finger-on-the-Pulse Capability section).

### **Continuous Identification of Research Evidence Website**

An internal, password-protected website developed and hosted at the INFO Project houses all aspects of the

CIRE system, including all elements (citation, abstract, searchable key words, and the relevant MEC and SPR question) of identified articles that meet criteria for initiation of a systematic review or that need to be kept for other purposes; all systematic reviews of new evidence; an electronic system for requesting, sending, and tracking peer reviews, including peer reviewer contact information; and an electronic system for sending updates of new evidence among the participating organizations.

### **Translating Evidence into Guidance Expert Working and Guidelines Steering Groups**

The translation of evidence into recommendations is the responsibility of WHO and its EWG, which consists of 30 to 35 international family planning experts who meet to discuss the systematic reviews, consider the implications of the evidence, and, through consensus, determine the recommendations. EWG meetings usually take place every 3 to 4 years. Previous meetings for the MEC took place in 1994/1995, 1999, and 2003, and for the SPR, in 2001 and 2004.

The WHO's recommendations for guidelines<sup>5</sup> mandate the creation of a Guidelines Steering Group. The role of the Guidelines Steering Group is to advise the guideline development process and assist WHO in determining when and how guidance should be revised and updated. The Guidelines Steering Group meets formally before the EWG meetings, and, in addition, can be convened ad hoc by WHO when peer reviewers recommend that a new systematic review presents strong evidence that is inconsistent with current guidance. In such cases, WHO may request that the Guidelines Steering Group provides assistance in preparing interim guidance pending the next EWG meeting.

### **Medical Eligibility Criteria Guidance**

During EWG meetings, the evidence from the systematic review is presented and the EWG discusses whether a modification of the recommendation is needed, based on the evidence. The EWG also considers effectiveness, benefits and harms, applicability, costs, and institutional barriers (including levels of training needed by providers) at the global scale, since both the MEC and SPR must be adapted locally to take into account these issues and the sociocultural context. The EWG members do not use any formal checklists or a set of criteria to determine the recommendations; however, their overall goal is to classify eligibility for the use of a contraceptive method into one of four categories. At times, the numeric category may not fully encompass the guidance the members want to convey, in which case a clarification by the group may accompany the classification. During the meetings, classification and clarification are captured electronically in "real time,"

and are approved in final form by the EWG at the end of the meeting. The body of evidence included in the systematic reviews is cited in the published document. Recommendations for which no evidence is cited are based on expert opinion and/or evidence obtained from sources other than a systematic review of the published literature.

### Selected Practice Recommendations Guidance

For the SPR, the Expert Working Group meetings follow a similar agenda, and in the final document, the EWG's recommendations are followed by comments that express the rationale of the group and may include explanation of the guidance; in addition, key unresolved issues are identified. For example, for the new question, "Can a woman receive an advance supply of emergency contraceptive pills?," the rationale included information about the type of evidence the EWG reviewed, and a clarification of the guidance stating that where advance supply is not possible, an advance prescription may be given. For this question, the unresolved issue addressed whether advance provision of emergency contraceptive pills results in differences in pregnancy rates and sexually transmitted infection (STI) rates.

As with the MEC, the recommendations are captured in "real time," and members approve the recommendations in final form at the end of the meeting. The recommendations are in the form of answers to questions about how to use contraceptive methods or how a woman can be advised to manage a specific situation. Where appropriate, pertinent guidance is included from the MEC about who can use a particular method.

### Finger-on-the-Pulse Capability

When new evidence warrants, WHO may decide to issue an interim update to the guidance on behalf of the EWG. This occurs when WHO, with the advice of the Guidelines Steering Group, concludes that a current WHO recommendation is both inconsistent with the body of evidence and may result in harm. These updates appear on the WHO's Reproductive Health and Research website ([www.who.int/reproductive-health/family\\_planning/index.html](http://www.who.int/reproductive-health/family_planning/index.html)). Then, at its next meeting, the EWG will review the entire body of relevant evidence and finalize or amend the interim guidance. Thus, the CIRE system allows WHO to systematically search current scientific literature for studies offering evidence that may warrant interim guidance. This feature of CIRE gives WHO finger-on-the-pulse capability to act quickly on new evidence as necessary.

### Dissemination and Implementation

Once WHO approves the MEC and the SPR, they are placed on WHO's Reproductive Health and Research website, and printed copies are sent to policymakers around the world. A public CIRE website is also maintained ([www.infoforhealth.org/cire/cire\\_pub.pl](http://www.infoforhealth.org/cire/cire_pub.pl)) to inform the international community of new research that pertains to WHO family planning guidance. Individuals can sign up at the public CIRE website for e-mail bulletins that provide notification when CIRE has identified new evidence, and when WHO has interim guidance. Abstracts of evidence identified by CIRE are available through this public website. In addition, the INFO Project's weekly electronic magazine, *The Pop Reporter*, highlights any new evidence or interim guidance.

The SPR and MEC recommendations are in the process of being incorporated into the other two cornerstones of WHO family planning guidance, which will be completed in 2005. Furthermore, WHO and the United Nations Population Fund (UNFPA) Strategic Partnership Programme includes a commitment to implementing the MEC and the SPR through WHO regional and country offices and UNFPA country support teams.

### Case Study

In 2003, the CIRE system identified an article by Morrison et al.,<sup>18</sup> "Is the intrauterine device appropriate contraception for HIV-1 infected women?," which was relevant to the MEC recommendation for HIV-infected women and use of intrauterine devices (IUDs). This article triggered an update of the existing systematic review, conducted for the previous MEC meeting held in 2000. The main question guiding the review was: Are IUD users who are HIV infected at increased risk of pelvic inflammatory disease or other infection-related complications, HIV disease progression, and transmitting HIV to partners, possibly through increased viral shedding of HIV DNA, when compared with HIV-infected women who do not use IUDs? The Morrison et al.<sup>18</sup> study examined a slightly different question—whether the risk of complications is higher among HIV-infected IUD users compared with noninfected IUD users—but the article still provided information useful in determining whether HIV-infected women are appropriate candidates for IUD use. The reviewers updated the review by searching the MEDLINE, PRE-MEDLINE, EMBASE, and Cochrane databases for all studies that pertained to the above question. Five studies were identified, four of which had been included in the previous review and the fifth was the Morrison et al.<sup>18</sup> study. Since the completion of the systematic review occurred near the EWG meeting, the systematic review was not sent to peer reviewers.

The systematic review for HIV-infected women and IUD use was presented to the EWG in October 2003 in Geneva. After reviewing the total body of scientific evidence (including the Morrison et al.<sup>18</sup> article), the EWG members considered several issues, including (but not limited to) background prevalence of STIs and HIV/AIDS; STI risk among women with HIV/AIDS, and theoretical harms to women with HIV/AIDS if they use an IUD. Based on the total body of evidence, the EWG determined that HIV-infected women generally can use an IUD. For women with AIDS, initiation of the IUD is generally not recommended, with the exception that women with AIDS who are clinically well on antiretroviral therapy generally can initiate IUD use. Women who develop AIDS who already have an IUD generally can continue use. The EWG also added a clarification to these recommendations that IUD users with AIDS should be closely monitored for pelvic infection.

As an example of how these recommendations may be adapted to the local level, the United Kingdom Faculty of Family Planning and Reproductive Health Care endorses most of the guidelines from the MEC; however, at times their guidelines differ.<sup>19</sup> For example, in their guidance for the IUD, women who are HIV infected may be offered an IUD after testing for bacterial STIs.

## Discussion

The CIRE system is a novel approach by WHO to have continuous surveillance for new evidence and real-time updating of guidelines. A number of challenges have arisen in the first 2 years of operation. For example, during the early days of the CIRE system, each new piece of evidence was critically appraised and the critical appraisal was sent to the peer reviewers. With experience, it became apparent that sending the completed systematic reviews to the peer reviewers would be more efficient. Another challenge is that while the methodology for the systematic reviews is rigorous, formal meta-analyses have not yet been conducted due to the limited size of the body of evidence and the heterogeneity among observational studies. While in most cases meta-analyses will not be appropriate, more quantitative synthesis of the evidence will be conducted when possible.

Currently, when CIRE identifies a systematic review, CDC or WHO includes the published review in the CIRE systematic review. While it has not occurred yet, it is possible that the CIRE systematic review will differ in its assessment of the evidence and different conclusions could be drawn. If the published systematic review is of high quality and no additional individual articles are identified, then WHO uses the published systematic review as the basis for the recommendations.

Although there is a strong commitment to evaluating the quality of the evidence, it is still unclear which is the most appropriate grading scale (e.g., USPSTF, GRADE) for addressing the needs of the system and how to best summarize results across a body of evidence. For example in the systematic review for HIV/AIDS and IUD use, the evidence for different outcomes varied in quality; however, only the quality of evidence from one of the outcomes was used in the assessment of the overall body of evidence.

Through partnerships with the INFO Project and CDC, WHO has created a system for updating family planning guidelines that relies on the existing strengths and infrastructures of various institutions, specifically POPLINE and the *Pop Reporter* at the Johns Hopkins Bloomberg School of Public Health, and the technical assistance of the systematic reviewers at CDC, WHO, and other institutions. The CIRE system has ensured that WHO family planning guidance is based on the most current and best available evidence, allowing WHO to have finger-on-the-pulse capability in issuing guidance.

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