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Introduction to the Supplement Development of Federal Recommendations for Family Planning Services

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Introduction

In 2014, the U.S. CDC and the Office of Population Affairs (OPA) released clinical recommendations for providing family planning services, entitled “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.”¹ Family planning services help women and their male partners achieve the number and spacing of children they desire, and increase the likelihood that those children are born healthy. As such, family planning includes contraceptive services to prevent pregnancy, services to help clients achieve pregnancy, and preconception services to improve the health of infants and their parents.

The purpose of this journal supplement is to describe the process by which the CDC–OPA recommendations were developed. This effort is consistent with recent calls for more rigorous processes for guideline development and more thorough and transparent articulation of that process. For example, WHO has defined a rigorous process for developing clinical guidelines,^{2,3} and IOM recently published standards for how to develop “trust-worthy” clinical practice guidelines.⁴ Yet, many guidelines are still developed without following the WHO and IOM procedures and—perhaps even more important—without clearly articulating the process by which they were developed.⁵

The Public Health Challenge

Over the course of a lifetime, most individuals will make decisions related to childbearing, that is, how to prevent or achieve pregnancy so that they can achieve their desired number and spacing of children. Of the 310 million people in the U.S., 62 million (20%) are women of reproductive age, 15–44 years.⁶

More than half of the women of reproductive age (nearly 36 million) are in need of contraceptive services because they are at risk for unintended pregnancy—that is, they are sexually active, are able to get pregnant, and want to avoid or space pregnancy.⁷

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Contraception is highly effective at preventing unintended pregnancy, and the most effective methods of long-acting reversible contraception, intrauterine devices and implants, have a failure rate that is less than 1%.^{8,9} Further, numerous studies^{10–14} have documented the cost effectiveness of contraception, with \$6–\$8 saved for every \$1 invested. Yet, 15% of women at risk of unintended pregnancy are not using any method of contraception; 14% are using less effective methods of contraception (such as condoms,¹ periodic abstinence, rhythm, and withdrawal), and among those who use contraception, many do so inconsistently, which lowers its effectiveness.^{8,15} Given these patterns of contraceptive use, the rate of unintended pregnancy is high in the U.S. About half (51%) of the 6.7 million pregnancies each year (3.2 million) are unintended.¹⁶ Approximately 700,000 of these pregnancies are to women aged less than 20 years¹⁷; as a result, many teen mothers will achieve less education and lower incomes, and their children may experience higher rates of negative outcomes such as poorer health, lower academic achievement, and higher rates of teen pregnancy for female children and incarceration for male children.¹⁸ Taxpayers also pay a high price for the nation's high rate of teen and unintended pregnancy. For example, the cost of teen pregnancy has been estimated at \$9.4 billion per year.¹⁹ Two thirds of births resulting from unintended pregnancies among women of all ages—more than 1 million births—are publicly funded; the direct medical cost of those births is estimated at \$11.1 billion annually.²⁰ Recognizing the public health importance of unintended pregnancy, the prevention of teen and unintended pregnancy has been included in the U.S.'s National Prevention Strategy²¹ and Healthy People 2020 objectives.²²

Family planning services also help couples achieve pregnancy. In 2006–2010, 6.7 million women aged 15–44 years had impaired fecundity (i.e., impaired ability to get pregnant or carry a baby to term), and 1.5 million married women aged 15–44 years were infertile (i.e., were unable to get pregnant after at least 12 consecutive months of unprotected sex with their husband/partner).²³ Although the focus has traditionally been on women, men also experience infertility. For example, 7.5% of all sexually experienced men reported making a visit for help with having a child.²⁴ Family planning service providers advise couples on how to achieve pregnancy (e.g., how lifestyle factors such as diet and exercise can affect fecundity) and offer basic infertility services focused on preliminary diagnosis and referral for specialty care as needed.

Further, family planning services can increase the chances that an infant will be born healthy. Approximately one of every eight pregnancies in the U.S. result in preterm birth, and infant mortality rates remain high relative to other developed countries.^{25–27} By using contraceptive services to space births, and by offering preconception health services as part of family planning, the health of the infant (as well as the woman and man) can be improved.²⁸

¹Condoms are very effective at preventing pregnancy and sexually transmitted diseases when used correctly and consistently. For example, only 2% of women will experience an unintended pregnancy in a year if male condoms are used correctly every time she has sex.

Overview of the Guideline Development Process

In response to these challenges to Americans' reproductive health, CDC and OPA collaborated to develop clinical recommendations for how to provide quality family planning services. No existing clinical practice guidelines addressed the full range of family planning services in a cohesive manner. The collaboration drew on the strengths of both agencies; CDC has a long-standing history of developing evidence-based recommendations for clinical care, and OPA's Title X Family Planning Program has served as a national leader in direct family planning service delivery since the Title X Program was established in 1970.

A central premise underpinning the recommendations is that improving the quality of family planning services will lead to improved reproductive health outcomes.^{29–31} IOM defines healthcare quality as “the degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”^{29,32} According to IOM, quality health care has the following attributes: being safe, effective, client-centered, timely, efficient, accessible, equitable, and of value.

An effort was also made to implement IOM's standards for “trust-worthy” clinical practice guidelines. In particular, emphasis was placed on ensuring that the recommendations were as evidence-based as possible, and that decisions were made in a fully transparent manner. The papers in this journal supplement provide more detail about the evidence on which recommendations were based, and the steps taken to use that evidence to develop recommendations. Figure 1 shows the main steps in the development process.

Consistent with the IOM recommendation⁴ to form a guideline development group, CDC and OPA convened an Expert Work Group (EWG) when the guidelines were being planned in 2010 (Figure 1, Box A). The EWG was composed of family planning clinical providers, program administrators, representatives from relevant Federal agencies, and representatives from professional medical organizations. The overall purpose of the EWG was to advise OPA and CDC on the structure and content of the revised recommendations, and to ensure that the recommendations were feasible and relevant to the needs of the field (the Appendix lists the members of the EWG). CDC and OPA used feedback provided by individual committee members to develop the recommendations rather than obtaining consensus from all EWG members.

Early in the process, the EWG encouraged two primary focus areas for the effort. First, the EWG suggested that the guidelines should develop a comprehensive framework for family planning services addressing the needs of both female and male clients, which would help providers determine how and when to apply other guidelines for more specific aspects of related care (e.g., which sexually transmitted disease [STD] screening recommendations should be followed, and how they should be applied in the context of providing family planning services). Four areas addressing key components of the family planning service delivery system were recommended for prioritization for systematic review: counseling and education, serving adolescents, quality improvement, and community engagement. It was also decided that the audience for the recommendations was all providers or potential providers of family planning services. This included Title X service sites that are dedicated

to family planning service delivery, as well as private and public providers of more comprehensive primary care such as primary care physicians, pediatricians, obstetricians and gynecologists, nurse practitioners, nurse midwives, and physician assistants.

An extensive effort was made to gather existing information and evidence. This included compiling existing federal and professional medical associations' clinical guidelines for women and men on relevant topics (Figure 1, Box B). The synthesis of clinical recommendations was presented to two technical panels of subject matter experts, with one panel focused on women's services and a second focused on men's services (Figure 1, Box C). In a parallel process, systematic reviews of the literature were conducted on the priority areas identified by the EWG group: counseling and education, serving adolescents, quality improvement, and community engagement (Figure 1, Box D). Once the reviews were completed, four technical panels of subject matter experts considered the quality of the evidence identified in each of the systematic reviews, and made suggestions for what recommendations might be justified given the evidence (Figure 1, Box E).

Input from the technical panels about existing clinical guidelines and evidence was used by CDC and OPA to draft recommendations (Figure 1, Box F). These recommendations were subsequently presented to the EWG for consideration, with revisions considered over the course of two formal meetings (Figure 1, Boxes G–I). EWG members familiar with the family planning service delivery context could comment on the feasibility and appropriateness of the recommendations. CDC and OPA asked the EWG to provide input in a manner that was adapted from the Grading of Recommendations Assessment, Development, and Evaluation process.^{33,34} The following criteria were considered:

1. the quality of the evidence;
2. the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost savings, and implementation challenges; and
3. the relative importance of those consequences (Figure 1, Box J).

The final recommendations and their rationales are articulated in the guidelines document.¹

Scientific review of the recommendations was conducted via review by objective experts from throughout CDC who were not involved in the development of the recommendations. These included experts in STD/HIV, injury, cancer, immunizations, and violence/injury prevention. In addition, the recommendations were reviewed by the following DHHS agencies: Centers for Medicare and Medicaid Services, Health Resources and Services Administration, NIH, the Office of the Assistant Secretary for Health (OASH), and within OASH, the Office of Adolescent Health, the Office of Minority Health, and the Office on Women's Health. Finally, an external peer review was conducted in accordance with CDC's policy on Influential Scientific Information (ISI), and included experts in reproductive health policy, pediatrics, family medicine, men's health, and women's preventive services.

CDC and OPA intend to update the recommendations in the following manner:

1. continuously revise the recommendations to reflect new or updated guidelines issued by CDC or the U.S. Preventive Services Task Force;

2. if a major professional medical association issues an important update or new guideline, or an important new research finding is released, an ad hoc committee of experts will be convened by OPA and CDC to provide feedback about whether the recommendations should be updated to reflect this information; and
3. every 3–4 years, conduct a systematic review of new literature published since the last update, consider conducting reviews of additional topic areas, and publish an updated version of the recommendations.

Organization of This Supplement

The papers in this journal supplement describe several key steps in the process of developing the recommendations. This includes the synthesis of existing clinical guidelines for women and men on related health topics and systematic reviews of the literature.

Two papers—one focused on women’s services and another focused on men’s—describe the process of compiling existing federal and professional medical associations’ guidelines for clinical care. They also articulate how that information was used to develop the clinical recommendations about what services should be included under the umbrella term of “family planning services,” what screening components should be included in each of those services, and how those services should be provided (e.g., periodicity, risk groups).^{35,36}

One paper³⁷ describes the methods used to conduct the systematic reviews of the literature. Nine papers describe the results from the systematic reviews on the following topics: counseling and education (three papers)^{38–40}; serving adolescents (three papers)^{41–43}; community outreach (two papers)^{44,45}; and quality improvement (one paper).⁴⁶ A key finding is that the quality and strength of the evidence is highly variable across topics, with some areas (e.g., counseling, education, and parent–child communication) reasonably well established and other areas (e.g., community engagement) less established. Across all areas, research priorities to update and bolster the evidence base are identified.

Conclusions

This journal supplement provides an unprecedented compilation of the existing evidence for family planning service delivery. It also lays out, in a transparent manner, the process by which that evidence was used to develop recommendations. By doing so, the foundation has been established for future updates of the recommendations, and increased the chance that those updates will be done on a more timely and transparent basis.⁴

In sum, there is a robust body of evidence and expert opinion underpinning the recommendations for providing quality family planning services. There is also a need to continue building the evidence, filling gaps in our knowledge and updating clinical recommendations in accordance with that evidence. We hope that all primary care providers will use these recommendations when providing family planning services. We believe that if they do, more couples will achieve their desired number and spacing of children, more children will be born healthy, and the health and wellness of all women and men will be improved, regardless of whether they bear children.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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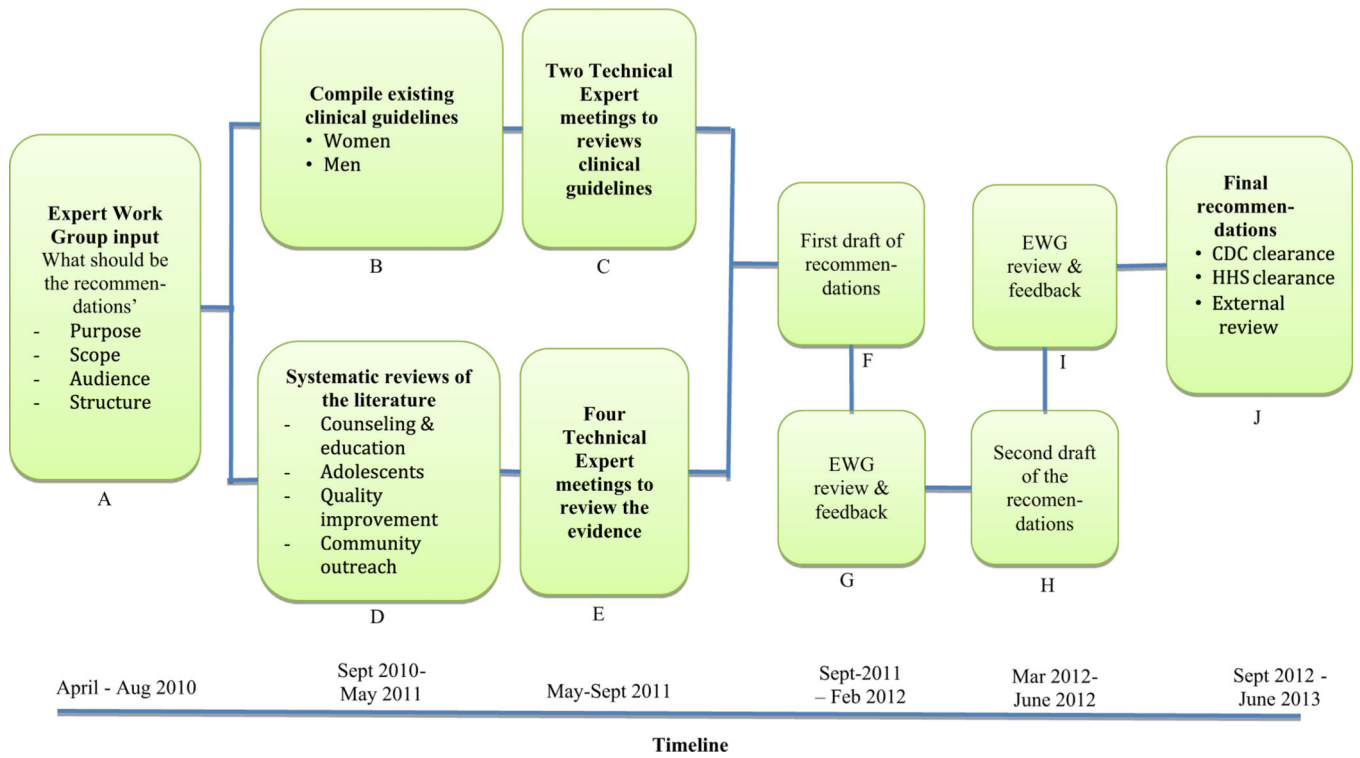


Figure 1. Key steps in developing recommendations for providing quality family planning services. EWG, expert working group.