



## METHODOLOGY

In order to support the accuracy, integrity and clinical relevance of recommendations from the Women's Preventive Services Initiative, the recommendation development process is based on adaption of the eight criteria for evidence-based clinical practice guideline development as articulated in the 2011 IOM published report, *Clinical Practice Guidelines We Can Trust*. These IOM criteria for trustworthy guideline development provide the framework for development of the Women's Preventive Service Initiative recommendations as described in detail below.

[Transparency](#)

[Conflicts of Interest](#)

[Multidisciplinary Steering Committee Composition](#)

[Evidence Review](#)

[Establishing strength of recommendations](#)

[Recommendation Development and Consensus Process](#)

[Consensus Development](#)

[External Review](#)

[Updating Existing Recommendations](#)

**Transparency.** The Multidisciplinary Steering Committee (MSC) is comprised of health care professionals who provide and oversee delivery of women's preventive services across the lifespan. This broad representation from national organizations increases transparency to the public by ensuring the perspectives and approaches of many different types of providers are represented and minimizes the impact of individual biases and opinions so as not to adversely influence the outcome of discussion and consensus recommendation formulation.

The MSC also includes patient and public representative members to help ensure that patient and consumer perspectives are included in defining the scope, evidence review, recommendation development, and dissemination. These public members serve as a full MSC committee and subcommittee members and are involved in all aspects of recommendation development. As a member of the evidence review subcommittee, these patient representatives are expected to have some methodologic training in reviewing scientific evidence, but there will be no requirement of expertise. These public members serve an important role in ensuring that the recommendations are made with patients' perspectives and levels of understanding in mind. In future years, patient education materials are an important component of a larger dissemination effort, and the public member's role in development and distribution of the recommendations is essential.



To ensure transparency of the process and to provide an opportunity to ensure balance, comprehensiveness, and quality, the public is given opportunities for input. The MSC process will allow for broad public input through public comment periods as described below in more detail. To further ensure transparency, the dispensation of any public comment responses, including a change to the recommendation or no action, will be documented and retained by WPSI project staff.

In order to deliver consistent and actionable recommendations on the components of women's preventive care, and to promote interaction and transparency, WPSI will feature an interactive website as its cornerstone. A detailed explanation of the methodology employed in the recommendation development process will be publicly available on the WPSI website. The methodology section will detail the process including evidence identification and analysis, recommendation development, public comment process, updates and new topic selection, and dissemination.

[Back to top](#)

**Conflict of Interest.** As part of the process for conflict of interest (COI) disclosure, all WPSI participants and project staff follow the ACOG Conflict of Interest Disclosure Policy, and submit the standard organizational disclosure form prior to appointment to the initiative and annually thereafter. Any disclosures are shared with the MSC at each meeting, although strong consideration is given to including members with no conflicts. All disclosed COI will be listed in conjunction with a final report of the recommendations, and posted to the WPSI website. Members of the Advisory Panel (AP), WPSI Chair, Subcommittee Chairs, and project staff are not permitted to have any financial COI.

[Back to top](#)

**Multidisciplinary Steering Committee Composition.** Members of the MSC are multispecialty, multidisciplinary representatives from national health professional organizations with expertise in women's health care across the lifespan, including obstetricians and gynecologists, family physicians, internal medicine, nurse practitioners, nurse-midwives, women's health nurses, women's health researchers, and clinicians representing primary care, chronic disease management, mental health, and gerontology, in addition to public health professionals and patient representatives. These appointed members are divided into subcommittees based on clinical and methodologic expertise and tasked with developing recommendations on 1-2 topics per year.

[Back to top](#)

**Evidence Review.** The WPSI has contracted with physician scientists with extensive experience in systematic review methodology and clinical guideline development from the [Pacific Northwest Evidence-based Practice Center \(EPC\) at Oregon Health & Science University](#) to conduct reviews and updates of the evidence for each topic under consideration. Focused updates of evidence reviewed for the nine topics considered for revision include overviews of recent systematic reviews for the U.S. Preventive Services Task Force (USPSTF) published since the last recommendations were issued by the Institute of Medicine (IOM) Committee in 2011, as well as systematic reviews and key studies published since the most recent systematic reviews for the USPSTF (1).



A research librarian conducted searches in Ovid MEDLINE, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews through July 2016 for all topics. For topics on counseling for sexual transmitted infections (STIs), interpersonal and domestic violence, and well-woman visits, searches were also conducted in PyschINFO.

A best evidence approach was applied when reviewing abstracts and selecting studies to include for the updates that involves using the most relevant studies with the strongest methodologies (2-4). For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations, therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized controlled trials and large (>100) prospective cohort studies were included if they provided relevant information for each topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings applicable to the United States were targeted. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic were developed to address issues specific to the WPSI.

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under “real-world” conditions (4). It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered including differences in the interventions and comparators, populations, and settings.

No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings were summarized in a narrative, descriptive format to provide an overview of the new evidence for each topic.

MSC members interact with the EPC to identify topics and scope. Updates to previous recommendations were evaluated using established methodology.

[Back to top](#)

**Establishing strength of recommendations.** In addition to current systematic reviews and randomized controlled trials, other supporting evidence is considered including organization guidelines and policies, epidemiologic data, and other relevant sources.

Physician investigators from the EPC attend in-person and teleconference MSC meetings to assist with interpretation of evidence, including addressing queries about individual studies included in the literature search. Investigators work closely with the MSC, and each of the subcommittees, to provide expert perspective on the quality and strength of the supporting evidence.



In addition, like the 2011 IOM Panel, the MSC panel considered multiple levels of evidence when developing the recommendations and permitted recommendations to be based on varying levels of evidence, expert consensus, or standard best practices.

[Back to top](#)

**Recommendation Development and Consensus Process.** WPSI recommendations are articulated in two sections: clinical recommendation and implementation considerations. An overarching summary recommendation, based on the best available evidence and clinical expertise, forms the clinical recommendation. The implementation recommendations address aspects of clinical and practical applications of the recommendation. Both parts are integral to the overall WPSI recommendations that address the important issues in women's preventive health services.

Preventive services recommended by the committee followed the criteria of the 2011 IOM Panel:

- The condition to be prevented affects a broad population
- The condition to be prevented has a large potential impact on health and well being
- The quality and strength of evidence is supportive.

Recommendations were developed with robust discussion and review among subgroups and the full committee. If evidence was lacking, recommendations were supplemented with the expert consensus of the over 20 multidisciplinary women's health experts of the MSC, taking into consideration standards of best practice, risk-benefit analysis, and expert opinion.

[Back to top](#)

**Consensus Development.** As part of the WPSI process, an evidence summary on a particular topic is presented to the whole MSC to be used as the basis for recommendation development. A subcommittee of the MSC is then asked to consider the evidence in depth and to formulate a recommendation. Once a draft recommendation is developed by the MSC subcommittee, agreement must be reached by the full MSC for the recommendation to be finalized. To build consensus, the foundation for the recommendation must be transparent and clearly articulated to provide an understanding of the volume and quality of the supporting evidence, and an accurate assessment of the benefits and harms for each topic.

Once the initial MSC discussion has concluded, the proposed draft recommendation is put forth for a vote by the full MSC. Votes are taken by hand, without secret ballots, and will be recorded as approve, not approve, or abstain. Abstention is permitted if the member has a disclosed conflict of interest for a recommendation. Each member of the MSC is given one vote. The MSC must reach at least 75% agreement for the recommendation to be adopted. If 75% agreement is not reached after one round of voting, further discussion will be permitted, and an email vote outside of the meeting is permitted if additional time is needed. If, after discussion and a second round of voting 75% agreement is not



reached, the recommendation can be returned to the subcommittee for reconsideration, at the discretion of the MSC chair. The subcommittee can then determine if the recommendation should be reconsidered after a reevaluation of the supporting evidence and information, or if the topic should be held for consideration in a subsequent cycle and be added to a pending list of topics for future evaluation.

A methodologist from the EPC attends in-person and teleconference MSC meetings to assist with interpretation of level and strength of evidence, including any queries about individual studies included in the literature search. The methodologist works closely with the MSC, and each of the subcommittees, to provide expert perspective on the quality and strength of the supporting evidence.

[Back to top](#)

**External Review.** A draft of each final recommendation is released for on-line public comment. Public comment is solicited for one month. All comments are reviewed and summarized by project staff, then provided to the corresponding subcommittee for consideration. Comments are reviewed and addressed by the subcommittee or full MSC as needed. Input is solicited from all interested organizations and individuals, who represent a broad array of perspectives and expertise on women's preventive health care.

The Advisory Panel member organizations and those participating in the MSC will promote public comment and request review and input by outreach to their membership of clinicians, patients, policy experts, public health advocates, and others with an interest in women's health care, through newsletters, email blast notices, list serves, and other means of communication, to request their review and input. In particular, outreach will be targeted to organizations representing special populations, including underserved communities. This outreach will direct the public to a location on the WPSI website that will allow electronic submission of comments. For future recommendations, a process for in-person public comment addressed directly to the MSC will be considered as time permits.

[Back to top](#)

**Updating existing recommendations.** Recommendations will be reviewed for currency and accuracy at least every 24 months after submission to and adoption by HRSA. For each recommendation, the literature search dates, along with the proposed date for review, will be reported. The EPC and ACOG project staff will seek identify emerging evidence on an ongoing basis to assess current validity of each recommendation and to identify or clarify associated benefits and harms. Recommendation identified for update will be included on the list of next topics to be addressed by the MSC.

## References

1. IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.
2. Institute of Medicine Committee on Standards for Systematic Reviews of Comparative Effectiveness R. In: Eden J, Levit L, Berg A, Morton S, eds. Finding What Works in Health Care: Standards for Systematic Reviews. Washington (DC): National Academies Press (US) Copyright 2011 by the National Academy of Sciences. All rights reserved.; 2011.



3. Nelson HD. Systematic Reviews to Answer Health Care Questions: Lippincott Williams & Wilkins; 2014.
4. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication Number 10(14)-EHC062-EF. Rockville, MD: Agency for Healthcare Research and Quality January 2014.