METHODOLOGY

The Women's Preventive Services Initiative (WPSI) recommendations are intended to guide clinical practice and coverage of services for the Health Resources and Services Administration (HRSA) and other stakeholders. The target audience for recommendations includes all clinicians providing preventive health care for women across the lifespan, particularly in primary care settings, and are intended to be inclusive (https://www.womenspreventivehealth.org/wpsi-statements/). The recommendation development process of the WPSI is based on the eight criteria for evidence-based clinical practice guideline development as articulated in the 2011 report, *Clinical Practice Guidelines We Can Trust* from the National Academy of Medicine (formerly the Institute of Medicine [IOM]). These criteria provide the framework and support the accuracy, integrity, and clinical relevance of WPSI recommendations as described in detail below.

WPSI Structure

Advisory Panel. The WPSI is overseen by an Advisory Panel (AP) comprised of representatives from the American College of Obstetricians and Gynecologists (ACOG) and three other major professional organizations representing the majority of women's health care providers, including the American Academy of Family Physicians (AAFP), American College of Physicians (ACP), and National Association of Nurse Practitioners in Women's Health (NPWH). In addition, members of the AP include four former members of the Institute of Medicine's 2011 Committee on Preventive Services for Women, the WPSI Chairperson, and the chairs of the WPSI committees. The AP guides the work of the WPSI and ensures that the initiative stays within the scope outlined in the funding agreement with HRSA.

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Multidisciplinary Steering Committee. Members of the Multidisciplinary Steering Committee (MSC) are multispecialty, multidisciplinary representatives from national health professional organizations with expertise in women's health care across the lifespan. Members include obstetricians and gynecologists, family physicians, internal medicine physicians, nurse practitioners, nurse-midwives, women's health nurses, and women's health researchers representing primary care, chronic disease management, mental health, adolescent health, and gerontology, in addition to public health professionals and patient

advocate representatives. Nominations to the MSC are made by the executive leadership of a professional organization. The WPSI Advisory Panel reviews all nominations and selects members based on qualifications and balance of disciplines across the committee. Qualified nominees demonstrate experience and skills in the following areas:

- The critical evaluation of research published in peer-reviewed literature and in the methods of evidence review.
- Clinical preventive health care, health promotion, and primary health care.
- Implementation of evidence-based recommendations in clinical practice, including at the clinician-patient level, practice level, and health system level.

Other qualifications include expertise in methodological issues, such as meta-analysis, analytic modeling, or clinical epidemiology. Appointed MSC members often work in subcommittees based on clinical and methodologic expertise and are tasked with developing recommendations on 1-2 topics per year.

The MSC also includes patient advocate representative members to help ensure that patient and public perspectives are included in defining the scope, evidence review, recommendation development, and dissemination. These representatives are expected to have some methodologic training in reviewing scientific evidence, but there will be no requirement of expertise. They serve an important role in ensuring that the recommendations are made with patients and consumer perspectives and levels of understanding in mind. Patient education materials are an important component of a larger dissemination effort, and the consumer representative role in development and dissemination of the recommendations is essential.

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Dissemination and Implementation Steering Committee. The Dissemination and Implementation Steering Committee (DISC) supports the efforts of the MSC through the implementation and dissemination of new or revised clinical recommendations put forth by the WPSI. The charge of the DISC is twofold: to develop strategies for the implementation and dissemination of new or revised WPSI clinical recommendations; and to increase health care provider and consumer knowledge of preventive services through existing, adapted, and new tools and resources. Activities of the DISC that support this charge include dissemination of the WPSI products, presentations at professional organization meetings, and development of tools and resources such as the Billing and Coding Guide. DISC members come from a broad coalition of groups with a demonstrated commitment to implementing health care services for women across the lifespan, including national health professional organizations, advocacy organizations, and payers.

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- Women's preventive health care
- Implementation science and familiarity with implementing clinical recommendations into practice
- Public and community health
- Assuring healthcare for all women
- Communication of scientific findings to multiple audiences, including health care professionals, policymakers, and the general public

The Advisory Panel also considers the composition of the committee as a whole to ensure gender, geographic, and disciplinary diversity.

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Transparency. The WPSI increases transparency to the public by requiring multidisciplinary representation. This ensures that multiple perspectives and approaches of many different types of clinicians and stakeholders are represented and minimizes the impact of individual biases and opinions that could adversely influence the outcome of discussion and recommendation formulation.

A website (https://www.womenspreventivehealth.org/) provides timely information about the WPSI, its membership, methods, recommendations and evidence reports, and dissemination materials. In addition, the public is given opportunities for input as described below. The dispensation of public comment responses, including a change to the recommendation or no action, are documented and retained by WPSI project staff.

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Disclosure and Management of Conflicts of Interest. All WPSI participants and project staff follow the ACOG Conflict of Interest Disclosure Policy and submit the standard organizational disclosure form prior to appointment and annually thereafter. Any disclosures are reviewed by the Advisory Panel and any potential conflicts are addressed and mitigated prior to approval for new or continuing committee membership. The relevant disclosures are shared with convening committees at each meeting.

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New Topic Selection. The WPSI selects topics that fill gaps in existing screening and prevention guidelines for women and meet eligibility criteria. Gaps include existing recommendations with narrow scopes, areas with new research, and topics not addressed by other guideline groups. The WPSI does not select new topics that replicate recommendations already in place from the United States Preventive Services Task Force (USPSTF), the American Academy of Pediatrics Bright Futures, and the Centers for Disease Control and Prevention's Advisory Panel for Immunization Practices (ACIP) recommendations.

Eligibility criteria include conditions that affect a broad population of women; that are specific, more common, more serious, or differ in women; and for which prevention would have a large potential impact on women's health and well-being. Additional criteria require that the health service be a primary or secondary preventive service feasible for practice in the United States including screening,

counseling, immunization, and prevention medication or therapy; and that the quality and strength of evidence directly or indirectly support its effectiveness.

Any individual or organization may nominate new topics for consideration for recommendation development. Nomination forms are available on the WPSI website. Nominations are reviewed by the Advisory Panel. The Advisory Panel prioritizes a list of 1-3 new topics that meet the criteria to move forward for consideration by the MSC. Preliminary key questions and an evidence horizon scan for the proposed topics are developed by Evidence Review Team (ERT) investigators at the Oregon Health & Science University and Kaiser Permanente School of Medicine, refined by the Advisory Panel, and then presented to the MSC. The MSC reviews and, if necessary, revises the preliminary key questions, then votes to move the topic forward to the next stage, if appropriate. If a new topic is approved by the MSC, it is posted on the WPSI website for 4-6 weeks for public comment. All comments are reviewed as described in sections below.

After a new topic is approved, the ERT moves forward with the evidence review, as described below.

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Evidence Review. The WPSI contracts with physician scientists with extensive experience in systematic review methodology and clinical guideline development from the Oregon Health & Science University and Kaiser Permanente School of Medicine (collectively known as the Evidence Review Team, or ERT) to conduct reviews and updates of the evidence for each topic under consideration. The ERT methods of evidence review are adapted from the USPSTF and the previous IOM panel on Preventive Services for Women. (2, 3) Focused updates of evidence for existing WPSI recommendations include systematic reviews and key studies published since the most recent evidence review and may address new or expanded key questions as required by the topic. Focused updates may adapt the general methods outlined below as needed depending on the scope of the update.

The WPSI Advisory Panel determines the scope and key questions for evidence reviews on topics approved by the MSC. ERT Investigators develop the research protocol according to established methods including an analytic framework outlining the key questions and patient populations, interventions, and outcomes. (4) To identify studies, selection criteria specific to each topic are developed addressing key questions, and are defined by populations, interventions, comparators, outcomes, timing, and setting.

For all evidence reviews, a research librarian conducts electronic database searches in Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and other relevant sources. Investigators also manually review reference lists of systematic reviews and articles. Using a two-step process, two investigators independently evaluate abstracts and then full-text articles to identify studies meeting prespecified eligibility criteria. Disagreements are resolved by consensus with a third reviewer. Results are tracked in an EndNote database (Clarivate Analytics).

In general, eligible studies include randomized controlled trials (RCTs), large (>100) prospective cohort studies, diagnostic accuracy studies, and systematic reviews that enroll women and provide relevant data. Included studies use preventive services applicable to primary care clinical settings in the United States. Findings related to specific populations are included when available.

To evaluate effectiveness of a preventive service, studies are generally included that compare the service with usual care and report health outcomes, such as clinical response, symptoms, function, or quality of life (e.g., days of disability, limitations in activity, absences, or other). To evaluate diagnostic accuracy of screening instruments, studies are included that report measures of test performance, such as areas under the receiver-operating characteristic curve (AUROC) (also known as the c-statistic), sensitivity and specificity, or likelihood ratios as reported by the studies. Potential harms of screening included false-positive or false-negative results, anxiety, distress, and other adverse events affecting quality of life.

A single investigator extracts data from included studies into evidence tables including characteristics of study populations, interventions, comparators, outcomes, study designs, settings, and methods. A second investigator verifies the completeness and accuracy of extracted data.

The risk of bias (quality or internal validity) of individual controlled trials, observational studies, and diagnostic accuracy studies are determined using predefined criteria developed by the USPSTF. (2) Systematic reviews are assessed using USPSTF criteria or the AMSTAR quality-rating instrument. (5) These criteria and methods are used in conjunction with the approach recommended in the AHRQ Methods Guide. (6) Studies are rated as good, fair, or poor, or as specified by the quality assessment criteria. Each study evaluated is independently dual-reviewed for quality by two team members. Disagreements are resolved by discussion and consensus with a third reviewer.

Data synthesis uses a hierarchy-of-evidence approach, where the best evidence is considered most highly for each key question. Qualitative data are summarized descriptively, while statistical meta-analysis is conducted to quantitatively summarize study results and obtain more precise estimates for outcomes when appropriate. The feasibility of a quantitative synthesis depends on the number and completeness of reported outcomes and lack of heterogeneity among the reported results. Meta-regression may be conducted to explore statistical heterogeneity.

Studies are also rated for applicability, 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. (2) 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 are considered including differences in the interventions and comparators, populations, and settings.

The strength of evidence for each key question is initially assessed by one investigator for each outcome by using the approach described in the AHRQ Methods Guide. (2) To ensure consistency and validity of the evaluation, the grades are reviewed by the entire team of investigators for study limitations (low, medium, or high level of study limitations); consistency (consistent, inconsistent, or unknown/not applicable); directness (direct or indirect); precision (precise or imprecise); and reporting bias (suspected or undetected). The strength of evidence is assigned an overall grade of high, moderate, low, or insufficient according to a four-level scale by evaluating and weighing the combined results of the above domains.

Investigators provide a report and presentation summarizing the evidence review to the Advisory Panel and MSC members prior to the development of recommendations. The report is continuously updated during development of the recommendation.

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Recommendation Development Process. WPSI recommendations are based on an assessment of evidence on the balance of benefits and harms of an intervention or service. Cost is not considered in the assessment of a service because it is outside the scope of the WPSI.

As part of the WPSI process, once the evidence review of an approved topic is presented to the MSC, the MSC is then asked to consider the evidence in depth and to formulate a recommendation. Subcommittees are formed if necessitated by the topic. An investigator from the ERT attends 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.

Members discuss the strengths and limitations of the evidence including weighing of benefits and harms. This includes consideration of the quality and applicability of direct evidence of benefits and harms of the preventive service on health outcomes, such as improved symptoms, function, and quality of life. In addition, the MSC considers indirect evidence that links the preventive service and health outcomes in the chain of evidence that could support the service in the absence of direct evidence, such as the validity of screening instruments and effectiveness and adverse effects of treatments. The MSC also considers the impact of screening on progression of symptoms and avoidance of advanced treatments, as well as implementation considerations.

Once a draft recommendation is developed, it is put forth for a vote by the full MSC. Each member of the MSC is given one vote. The MSC must reach at least 75% agreement for the recommendation to be approved. If 75% agreement is not reached after one round of voting, further discussion is 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 a subcommittee for reconsideration, at the discretion of the MSC chair. The subcommittee can then determine whether 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.

WPSI recommendations are articulated in three sections: clinical recommendation, implementation considerations, and research recommendations. An overarching summary recommendation, based on the best available evidence and clinical expertise, forms the clinical recommendation. The implementation considerations address aspects of clinical and practical applications of the recommendation. The research recommendations serve as a call to research and highlights areas where more evidence is needed to inform the development of clinical recommendations. All three sections are integral to the overall WPSI recommendations that address the important issues in women's preventive health services.

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Establishing Strength of Recommendations. The WPSI clinical recommendations are based on reaching a threshold of supportive evidence informed by the evidence review. In addition, the WPSI recognizes that many of the most important clinical questions regarding effective use of prevention services are not addressed by research studies. In the absence of direct evidence, the WPSI considers compelling indirect evidence to determine benefits and harms including prevalence and impact of the condition on women's health.

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External Review and Public Comment. Proposed new topics and drafts of each recommendation are released for public comment on the WPSI website. Public comment is announced on the Federal Register Notice and solicited for 4-6 weeks. All comments are reviewed and summarized by project staff, then provided to the MSC chair and corresponding subcommittee for consideration. Modifications to the draft recommendation may be made as needed. Input is solicited from all interested organizations and individuals representing a broad array of perspectives and expertise on women's preventive health care.

The Advisory Panel member organizations and those participating in the MSC 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. Broad promotion of public comment is achieved through newsletters, email blast notices, list serves, and other means of communication. In particular, outreach is targeted to organizations representing specific populations, including underserved communities.

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Submitting Recommendations to HRSA. Approved recommendations are submitted to the Health Resources and Services Administration (HRSA) for approval. If approved by the HRSA Administrator, the WPSI Clinical Recommendation is added to the HRSA-supported Women's Preventive Services Guidelines and covered by no cost-sharing by most non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage.

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Updating existing recommendations. Recommendations are reviewed and updated at least every 5 years after adoption by HRSA. The ERT investigators and project staff identify emerging evidence on an ongoing basis to assess current validity of each recommendation and to identify or clarify associated benefits and harms.

References

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