U.S. Preventive Services Task Force

STANDARDS FOR GUIDELINE DEVELOPMENT

Standard for Developing Trustworthy Clinical Practice Guidelines*	U.S. Preventive Services Task Force Policy	U.S. Preventive Services Task Force Compliance With Standard
1. Establishing transparency		
1.1. The processes by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly and publicly accessible.	**1.1.** Independent of the federal government, U.S. Preventive Services Task Force (USPSTF) members are volunteer experts in evidence-based medicine and are not federal employees. The U.S. Congress mandates that the USPSTF receive administrative, scientific, and dissemination support from the Agency for Healthcare Research and Quality (AHRQ). **1.2.** All USPSTF systematic evidence reviews, recommendation statements, and other materials are developed according to methods explained in detail in a publicly available procedure manual. Draft research plans, draft evidence reviews, and draft recommendation statements are available for public comment.	**Meets All Standards**
2. Management of conflict of interest		
2.1. Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in conflict of interest (COI) with development group activity, by written disclosure to those convening the GDG. • Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), noncommercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.	**2.1.** Anyone being considered for appointment to the USPSTF must provide written disclosure of all interests and activities that may be a COI with USPSTF activities. These forms are updated prior to the start of each topic cycle. • Disclosure reflects all current and planned involvement in commercial (including services from which a clinician derives a substantial proportion of income), noncommercial, intellectual, institutional, and patient/public activities related to the potential scope of the recommendation.	**Meets All Standards**

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2. Management of conflict of interest (continued)		
2.2. Disclosure of COIs within the GDG • All COIs of each GDG member should be reported and discussed by the prospective development group prior to the onset of its work. • Each panel member should explain how his or her COI could influence the CPG development process or specific recommendations. **2.3.** Divestment • Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations. **2.4.** Exclusions • Whenever possible, GDG members should not have COI. • In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their income from services pertinent to the CPG. • Members with COIs should represent no more than a minority of the GDG. • The chair or co-chairs should not be a person(s) with COI. • Funders should have no role in CPG development.	**2.2.** Disclosure of COIs within the GDG • USPSTF members report and discuss all COIs prior to starting work on each topic and prior to each meeting. • Each member explains how his or her COI could influence specific recommendations. **2.3.** Divestment • The leadership of the USPSTF may ask members to divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by USPSTF recommendations. **2.4.** Exclusions • Whenever possible, USPSTF members do not have COI. • Members with a real or potential COI may be asked by the USPSTF leadership to either disclose the COI, not participate in a topic workgroup or as a lead member, or remove themselves from discussion of and voting on a topic. • Members with significant COIs do not participate in discussion of or voting on a topic. • The chair and vice chairs are subject to all COI policies. • The USPSTF makes its recommendations independent of the federal government.	**Meets All Standards**

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3. Guideline development group composition		
3.1. The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians and populations expected to be affected by the CPG. **3.2.** Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG. **3.3.** Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by the GDG.	**3.1.** The USPSTF makes recommendations for a broad range of prevention topics and populations seen in primary care setting. It comprises a multidisciplinary and balanced group of experts in primary care and clinical preventive services, including methodological experts and clinicians. The USPSTF seeks the input of disease specialists as expert consultants and reviewers and engages patient advocacy groups and consumer organizations for their opinions and input at various stages of the evidence review. **3.2.** The USPSTF solicits patient, consumer, and public involvement during the draft research plan, draft evidence review, and draft recommendation stages. **3.3.** The USPSTF engages patient and consumer representatives through regular conference calls and meetings with liaisons from its dissemination and implementation partners, including those representing patients and consumers. These calls and meetings often include discussions about the methodological issues related to evaluating evidence and making evidence-based recommendations.	**Substantially Meets Standards**
4. Clinical practice guideline and systematic review intersection		
4.1. CPG developers should use systematic reviews that meet the standards set by the Institute of Medicine's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research. **4.2.** When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.	**4.1.** The USPSTF uses systematic reviews that are independently performed by Evidence-based Practice Centers, which are funded by AHRQ. These systematic reviews meet the standards set by the Institute of Medicine's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research. **4.2.** The USPSTF and the systematic review team interact regularly regarding the scope, approach, and output of both processes.	**Meets All Standards**

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5. Establishing evidence foundations for and rating strength of recommendations		
5.1. For each recommendation, the following should be provided: • An explanation of the reasoning underlying the recommendation, including: o A clear description of potential benefits and harms. o A summary of relevant available evidence (and evidentiary gaps) and a description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence. o An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation. • A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation. • A rating of the strength of the recommendation in light of the preceding bullets. • A description and explanation of any differences of opinion regarding the recommendation.	**5.1.** Each USPSTF recommendation provides: • An explanation of the reasoning underlying the recommendation, including: o A clear description of potential benefits and harms. o A summary of relevant available evidence and evidence gaps and a description of the quality, applicability, quantity, and consistency of all available evidence. o An explanation of any values, opinion, theory, and clinical experience that the USPSTF may have used in deriving the recommendation. • A rating of the level of confidence in (certainty regarding) the evidence informing the recommendation. • A rating of the strength of the recommendation in light of the preceding bullets. • A statement that summarizes and explains the range of opinions regarding the recommendation.	**Meets All Standards**
6. Articulation of recommendation		
6.1. Recommendations should be articulated in a standardized form, detailing precisely what the recommended action is and under what circumstances it should be performed. **6.2.** Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.	**6.1.** The USPSTF writes recommendations in a standardized format, detailing what the recommended action is and under what circumstances clinicians should perform it. **6.2.** The USPSTF's "A" and "B" recommendations are worded so that compliance with the recommendation(s) can be evaluated.	**Meets All Standards**

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7. External review		
7.1. External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public. **7.2.** The authorship of external reviews submitted by individuals and/or organizations should be kept confidential, unless that protection has been waived by the reviewer(s). **7.3.** The GDG should consider all external review comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments. **7.4.** A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.	**7.1.** External reviewers of USPSTF documents include relevant stakeholders, such as scientific and clinical experts, health care and specialty organizations, and federal health agencies. Public input is solicited from patients and representatives of the public. **7.2.** Unless given permission, the identity of external reviewers is kept confidential. **7.3.** The USPSTF considers all external reviewer and public comments and keeps a written record of the rationale for modifying or not modifying a recommendation statement in response to reviewers' comments. **7.4.** A draft of the recommendation statement is made available to the general public for comment. Reasonable notice of impending upcoming publication is provided to interested public stakeholders.	**Meets All Standards**
8. Updating		
8.1. The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG. **8.2**. Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG. **8.3.** The CPG should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm, a new intervention is significantly superior to a previously recommendation intervention from an efficacy or harms perspective, or a recommendation can be applied to a new population(s).	**8.1.** The recommendation statement and systematic evidence review publication dates are documented. The USPSTF aims to keep all recommendations current and review each topic every 5 years for either an update or reaffirmation. **8.2.** Through a separate Scientific Resource Center funded by AHRQ, the literature is monitored regularly to identify the release of new, potentially relevant evidence and to evaluate the continued validity of the recommendation statement. **8.3.** The USPSTF updates its clinically important recommendations when new evidence shows the need for reevaluation and modification. This could mean that a recommended intervention causes previously unknown harm, a new intervention is significantly superior to a previously recommended intervention, or a recommendation can be applied to a new population(s).	**Meets All Standards**

* **Source:** https://iom.nationalacademies.org/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx