Clinicians and patients need a trusted source for high-quality recommendations about preventive services. Preventive services are for people who are not suffering from a condition and may be healthy and well. They are intended for those without signs or symptoms of a disease to improve the quality and/or length of life. Although many recommended services are highly beneficial, prevention also has a potential for harm—a chance for making a healthy and well individual sick or anxious through false positives, overdiagnosis, and overtreatment. Making recommendations based on the most up-to-date evidence must consider this important balance. If a recommendation is made too soon, before evidence truly demonstrates effectiveness, people could be harmed; and if a recommendation is not made quickly in response to new evidence, the delivery of lifesaving preventive care may be delayed. Accordingly, it is critical for preventive service recommendations to assess the balance of benefits and harms rigorously and accurately based on the evidence and to do so in a timely and efficient manner.

The mission of the U.S. Preventive Services Task Force (USPSTF) is to provide evidence-based recommendations on preventive services to primary care clinicians who deliver preventive care. Recommendations are based on a systematic review of all evidence, assessment of both benefits and harms, determination of the certainty and magnitude of net benefit, and assignment of a letter grade. This process is rigorous, objective, and transparent; and it is well documented and continually updated. Foundational methods principles of the USPSTF include that recommendations are based solely on existing evidence and expert opinion is not used as a substitute for evidence; interpretation of the literature uses the tenets of evidence-based medicine, Bradford Hill criteria for causation, and concepts described in the National Academy of Medicine’s report—Clinical Practice Guidelines We Can Trust, and the potential conflicts of interest are minimized.

Although grounded in foundational principles of evidence-based medicine, the USPSTF’s methods are not static. The USPSTF routinely faces methods challenges and has a process for methods review and advancement. Much of this work occurs as the USPSTF weighs the evidence for specific topics, but recurring issues arise that span topics. These issues are addressed by the USPSTF’s Methods Workgroup, which includes all members of the USPSTF, evidence-based practice centers, scientific research centers, and Agency for Healthcare Research and Quality medical officers. This workgroup has a diverse and robust set of prevention and methods skills. Tasks that the workgroup may undertake include assessing the consistency of the USPSTF’s methods, reviewing how other guideline-making bodies and methods leaders handle issues, and deciding whether to update the USPSTF’s methods. Several methods domains that the USPSTF is currently advancing include determining the applicability of evidence to primary care; making subpopulation- and risk-stratified recommendations; incorporating new forms of evidence (e.g., modeling, big data); weighing benefits and harms; using indirect evidence; and linking intermediate outcomes to health outcomes.

The purpose of this journal supplement issue is to present and discuss some of these key methodologic concepts and questions that the USPSTF is currently addressing.

**METHODS UPDATES AND CLARIFICATIONS**

Although RCTs with morbidity or mortality outcomes are the gold standard for determining the net benefit of a preventive service, these are often unavailable or outdated. The USPSTF recognizes the need for rigorous approaches to evaluating indirect evidence,
observational data, and studies with intermediate endpoints as outcomes. Two articles in this special supplement present finalized USPSTF methods updates to address these issues. In their article, Wolff et al. describe how the USPSTF refined its approach toward using evidence on intermediate outcomes when making recommendations. Krist and colleagues expand on the use of indirect evidence in their manuscript, which describes how the USPSTF applies the concepts of coherence, applicability, extrapolation, and conceptual bounding to assess a preventive service’s magnitude of net benefit.

Two additional articles discuss ongoing processes to evaluate potential USPSTF methods advancements. The first addresses the identification of appropriate evidence in less labor-intensive ways. In lieu of traditional systematic reviews, Patnode et al. suggest that the USPSTF consider the use of rapid review methods in ways that continue to meet the rigorous standards of the USPSTF. Once the evidence has been assessed, understanding when to stratify preventive services guidelines according to the underlying risk of a population is critical. Lin and colleagues provide a conceptual framework, developed by the USPSTF and the evidence-based practice centers, to understand when and how to incorporate evidence about specific subpopulations into recommendations.

CONCEPTUAL AND ANALYTIC METHODOLOGIC CHALLENGES

The USPSTF is committed to making recommendations relevant and applicable for a variety of populations. Evaluating evidence across diverse topics and populations comes with significant conceptual and analytic methodologic challenges. Three articles included in this supplement critically examine these challenges and demonstrate the USPSTF’s actions to assess methodologic consistency and identify novel cutting-edge approaches. This work may lead to future updates in USPSTF policy. Through a review of recommendation statements by the USPSTF and other recommendation-making groups, Jonas et al. identify how evidence linking intermediate outcomes and health outcomes is gathered and propose criteria for determining evidence adequacy. They suggest that recommendation-making groups use a standard and transparent approach to assessing the link between intermediate and health outcomes. This informed the USPSTF’s update to intermediate outcomes.

Petitti and colleagues describe how the USPSTF has used commissioned collaborative models in making its recommendations. They highlight the challenges and opportunities in using collaborative modeling and provide a checklist to evaluate collaborative modeling reports for cancer screening topics. Drawing on perspectives of experts in the fields of child health research, evidence-based guideline development, and research methodology provided during a March 2016 expert panel meeting, Kemper et al. review the challenges inherent in issuing recommendations on child health topics and highlight strategies to improve current processes.

IMPLEMENTATION AND DISSEMINATION OF RECOMMENDATIONS

To have the desired impact of improving the health of all Americans, USPSTF recommendations must be viewed as trustworthy. They must also be disseminated effectively to the patients and clinicians who will utilize this guidance and to the scientific community and policy makers who are responsible for helping to fill gaps in the available evidence. Ngo-Metzger and colleagues describe the comprehensive, multistep conflict of interest process recently undertaken by the USPSTF to update its policy in accordance with current best practices and review the updated policy. Kurth et al. describe the USPSTF’s approaches to disseminate their recommendations to a broad audience with diverse needs.

To explore how health organizations translate guidelines into practice, Doherty and colleagues conducted semi-structured interviews with representatives from nine large hospital-based systems and physician organizations. The authors describe commonalities among organizations’ processes and describe several challenges to guideline adherence. Finally, the USPSTF aims to find the most current and scientifically valid studies available when examining evidence; however, evidence gaps still exist. Mabry-Hernandez et al. describe the types of gaps encountered and how the USPSTF is trying to advance the science to close these gaps.

INVITED COMMENTARIES

In the monthly issue accompanying this journal supplement, two leaders in guideline development and preventive care, not directly involved with the USPSTF, were invited to provide their perspectives on the USPSTF. Sheldon Greenfield was asked to comment on the issues of conflict of interest, which the USPSTF has rigorous measures to minimize so as to ensure the trustworthiness of its recommendations to primary care. Dr. Greenfield addresses some of the unique conflict of interest issues for prevention and then explores the difficult concept of intellectual conflict of interest. Otis Brawley was asked to provide his perspective on the general methods and approach of the USPSTF. In his commentary, Dr. Brawley describes the value of the USPSTF’s methods and how this approach is needed to make good preventive service recommendations that will improve the length and quality of life for Americans.
CONCLUSION
The USPSTF is committed to helping clinicians and patients understand the evidence supporting recommendations for preventive care. The methods used by the USPSTF ensure that its recommendations are useful and trustworthy. Although many evidence-based medicine principles are well defined, there will always be a need to review and refine how these principles are applied to making recommendations and the USPSTF will continue its rigorous approach to advancing its methods.

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