Enhancing Coordination Among the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, and National Institutes of Health

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This paper focuses on the relationships among the U.S. Preventive Services Task Force (USPSTF); Agency for Healthcare Research and Quality (AHRQ); and NIH. After a brief description of the Task Force, AHRQ, NIH, and an example of how they interact, we describe the steps that have been taken recently by NIH to enhance their coordination. We also discuss several challenges that remain and consider potential remedies that NIH, AHRQ, and investigators can take to provide the USPSTF with the data it needs to make recommendations, particularly those pertaining to behavioral interventions. (Am J Prev Med 2015;49(3S2):S166–S173) Published by Elsevier Inc. on behalf of American Journal of Preventive Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Introduction

The papers in this Special Issue describe the U.S. Preventive Services Task Force (USPSTF) and its role in evaluating evidence relevant to preventive services. The USPSTF interfaces with the Agency for Healthcare Research and Quality (AHRQ) and NIH, and this article describes their relationships. This article also highlights some of the challenges of merging evidence-based traditions across disciplines. It includes specific suggestions for steps that NIH, AHRQ, and the research community can take to provide better evidence for use by the USPSTF.

The U.S. Preventive Services Task Force

The USPSTF is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine; it is composed of primary care providers such as internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists. The USPSTF commissions systematic evidence reviews that examine the existing body of research on preventive services to be provided by primary care clinicians or referred from primary care. The USPSTF uses these reviews as the basis for its recommendations, carefully assessing the evidence on the benefits and harms of screening tests, counseling about healthful behaviors, and preventive medications for children, adolescents, adults, older adults, and pregnant women. The USPSTF does not formally consider cost in its evaluations.

By examining both potential benefits and harms, the USPSTF makes recommendations that help clinicians and patients make informed, individualized choices based on the best available data.

The primary audience for the USPSTF’s work is the primary care clinician. USPSTF recommendations are now considered by many to provide definitive standards for preventive services. In addition, the work of the USPSTF is recognized by the Patient Protection and Affordable Care Act; preventive services with a grade of A or B (www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions) must be covered without cost sharing (e.g., copayment or deductible) under new health insurance plans or policies.1
USPSTF members are appointed by the Director of the AHRQ. AHRQ staff provide support for the USPSTF’s activities.

The Agency for Healthcare Research and Quality

The mission of AHRQ is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the USDHHS and with other partners to make sure that the evidence is understood and used. AHRQ supports the USPSTF through the work of its staff and Evidence-based Practice Centers that prepare the evidence reviews for the USPSTF. In turn, the work of the USPSTF addresses the mission of AHRQ by issuing recommendations to make health care safer; of higher quality; and more accessible, equitable, and affordable. The recommendations of the USPSTF, which are updated every 5 years, provide evidence that will improve healthcare affordability, efficiency, and cost transparency.

The NIH

The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. According to NIH Research, Condition, and Disease Categorization data (report.nih.gov/rcdc/), NIH support for prevention research in 2013 was estimated to be about 22% of the total NIH expenditures. Yet, even with this substantial investment, important gaps remain and are identified in the Evidence-based Practice Centers and by the USPSTF. These gaps prevent the USPSTF from making clear recommendations for all of the preventive services that it reviews. This is one of the primary reasons to enhance the coordination among the NIH, AHRQ, and USPSTF.

An Example

An example of how the USPSTF, working through AHRQ, uses NIH-funded research is found in its recommendation statement “Screening and Behavioral Counseling in Primary Care to Reduce Alcohol Misuse” (www.uspreventiveservicestaskforce.org/Page/Document/ evidence-summary9/alcohol-misuse-screening-and-behavioral-counseling-interventions-in-primary-care). When reviewing any topic, the USPSTF first develops a research plan with an Analytic Framework and Key Questions, as

![Diagram of the USPSTF analytic framework and key questions for screening and behavioral counseling in primary care to reduce alcohol misuse.](image-url)

**Figure 1.** U.S. Preventive Services Task Force analytic framework and key questions for screening and behavioral counseling in primary care to reduce alcohol misuse.


Note: KQ 1–6 refer to key questions addressed by this framework.
exemplified in Figure 1. For each Key Question, AHRQ’s Evidence-based Practice Center searches PubMed, Cochrane, and other databases for RCTs, observational studies, and review articles, with prespecified inclusion/exclusion criteria for each question. The USPSTF determines whether the available evidence for each key question is “inadequate,” “adequate,” or “convincing.” In this example, the USPSTF determined that the evidence for the benefits (Key Question 1) and harms (Key Question 3) of screening were inadequate (Table 1). Even so, the USPSTF still gave a “B” recommendation reflecting the USPSTF assessment that there is moderate certainty of moderate net benefit. This determination was based on adequate evidence on the detection of the condition (Key Question 2) and benefits of interventions (Key Questions 4 and 6). In this example, the evidence for the benefits of counseling and intervention came from NIH-funded research.

NIH Steps to Enhance Coordination With the U.S. Preventive Services Task Force

The NIH established the Office of Disease Prevention (ODP) in 1986 to provide leadership for the development, coordination, and implementation of prevention research in collaboration with NIH Institutes and Centers (ICs) and other Federal partners. The ODP serves as the NIH liaison to the USPSTF, attending USPSTF meetings and providing updates to the NIH Director as needed. With the arrival of a new Director (DMM) in September 2012, the ODP reviewed its work as the NIH USPSTF liaison to consider opportunities to enhance the coordination between the NIH and the USPSTF and identified seven areas for enhanced coordination:

1. nomination of new USPSTF members;
2. nomination of new topics or topics to revisit;
3. comments on proposed topics and topic prioritization;
4. comments on proposed research plans;
5. comments on draft evidence reports and clinical recommendations;
6. comments on final evidence reports, clinical recommendations, and messaging; and
7. communicating insufficient evidence statements to the NIH research community.

ODP then developed steps it could take to address these areas and presented that plan to the NIH Director and the IC Directors in August 2013.

After the NIH leadership had endorsed the plan, the ODP asked each IC Director to identify a liaison for USPSTF activities who was familiar with activities relevant to the USPSTF and had authority to make assignments to other staff. IC Directors often named their Deputy Director or a Division Director as the liaison. Those liaisons were asked to identify primary and secondary content experts for each current and previous USPSTF topic that was of interest to their IC. They were also asked to identify primary and secondary communications staff who would be able to review and comment on USPSTF announcements.

In November 2013, the ODP convened a meeting of the USPSTF liaisons from the ICs to review the plan to improve coordination. The USPSTF Scientific Director (QNM) gave an overview of the USPSTF activities, and ODP staff described the plan, presented below.

In January of each year, the ODP will ask the IC liaisons to nominate new members for the USPSTF, to provide suggestions for new topics and existing topics to be revisited. ODP will share this input with the AHRQ.

Table 1. Evidence in Screening and Counseling Alcohol Misuse

<table>
<thead>
<tr>
<th>Key questions</th>
<th>Assessment of evidence</th>
<th>Magnitude of effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Direct evidence of screening benefit</td>
<td>Inadequate</td>
<td></td>
</tr>
<tr>
<td>2. Detection</td>
<td>Adequate</td>
<td>Acceptable sensitivity/specificity</td>
</tr>
<tr>
<td>4/6. Benefits of brief behavioral counseling</td>
<td>Adequate</td>
<td>Moderate</td>
</tr>
<tr>
<td>Intermediate outcomes:</td>
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<td></td>
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<tr>
<td>• Reduced consumption (drinks/week)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No binge drinking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Attainment of recommended drinking levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare utilization (no. of hospital days)</td>
<td>Adequate</td>
<td>Moderate</td>
</tr>
<tr>
<td>Morbidity (alcohol-related accidents or liver problems)</td>
<td>Inadequate</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>Inadequate</td>
<td></td>
</tr>
<tr>
<td>3/5. Harms of screening and treatment</td>
<td>Inadequate</td>
<td>Can bound as no greater than small</td>
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experts for comment on proposed topics and topic prioritization. The IC content experts also will be asked to comment on which proposed topics might benefit from a delay. Those experts might know, for example, that a major study with important implications for a topic would be completed in another year, so that it would make more sense to delay the review.

Once AHRQ releases the draft research plan for each topic, the ODP will ask the IC content experts for comments. As AHRQ implements the research plan, the ODP will work with IC content experts to identify new research developments that may be relevant and share them with AHRQ.

The ODP will alert IC liaisons and content experts once a schedule is set for the release of a preliminary evidence report. This version is not released to the public but is shared with the USPSTF’s federal partners to allow them to provide feedback while the report is being developed. The ODP staff will share the NIH feedback with AHRQ. NIH content expert reviews help to ensure that all the relevant literature has been included and interpreted correctly.

The ODP will alert IC liaisons and content experts once a schedule is set for the release of a draft evidence report and recommendation, together with any press release prepared by the USPSTF. These materials are released for public comment. The ODP typically receives the material 1 week before public release and will share it with the appropriate ICs so that they may identify a staff member to respond to press inquiries. As appropriate, the ODP will also alert senior NIH leadership. The ODP will send suggestions on the press release to AHRQ. When the draft evidence report and recommendation are released to the public, the ODP will post links to the documents on its website.

The ODP will follow the same procedures for the final evidence reports and recommendations, together with any press releases prepared by the USPSTF.

The ODP will review final evidence reports and insufficient evidence statements to identify research gaps and share those with the relevant ICs. The ODP will also ask IC liaisons to report annually on their activities planned or in place that address those research gaps. The goal will be to identify areas in which NIH is not doing enough to address the insufficient evidence statements and then work with the ICs to try to do more. This could happen, for example, by collaborating with multiple ICs to develop cooperative Funding Opportunity Announcements (FOAs) to address those areas, whether in the form of new grants or as supplements to existing grants.

The ODP has created a tracking system to monitor the progress of active topics and to monitor the research portfolios of the ICs that are relevant to insufficient evidence statements.

**NIH Steps to Enhance the Evidence Base for Behavioral Counseling Interventions**

Behavioral counseling interventions often lack the evidence to allow the USPSTF to fully evaluate the intervention and make a clear recommendation. This results in an “insufficient,” or I, statement for those interventions. In an effort to determine whether ICs are developing the needed evidence, the ODP queried several ICs that support behavioral counseling interventions in August 2014 on their activities in six specific areas identified by the USPSTF as challenges in these intervention studies. This section summarizes their responses.

**Risk Stratification**

The USPSTF needs evidence on the effects of the intervention according to the symptoms or risk status of the participants. However, there is often no consensus among investigators for reporting outcomes stratified in this way. None of the responding ICs had initiated activities to develop a consensus in this area, so this is an area where ODP may be able to work with the ICs to address this issue. In addition, it may be helpful for others, such as professional societies, to lead the effort to develop that consensus.

**Feasibility of Referral From Primary Care**

The USPSTF needs evidence on the feasibility of referral from primary care to a behavioral counseling intervention that is delivered in some other clinical or community setting. A number of the ICs are supporting projects in this area. For example, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has funded research based on the Diabetes Prevention Program to screen for prediabetes in primary care and refer to a lifestyle intervention delivered in community settings such as the YMCA or by community health workers. The National Institute on Drug Abuse (NIDA) is supporting two studies that are examining screening for substance use risk and referral through primary care either to a community-based or online intervention. NIDA is also supporting a study to test an intervention to improve primary care provider compliance with chronic opioid therapy guidelines to reduce opioid misuse among patients; a component of the intervention is assessment and referral to substance abuse treatment. The National Institute for Mental Health (NIMH) is supporting a study that screens adolescents for depression risk in primary care and refers those at risk to an Internet-based depression prevention intervention.

**Dose and Component Effects**

The USPSTF needs evidence on the dose of the intervention used in behavioral counseling studies as well as
information on the relative contribution of specific components in multicomponent interventions. However, there is often no consensus for how to measure the dose of the intervention or how to assess the relative contribution of specific components. None of the responding ICs had initiated activities to develop a consensus in this area, so this is another area where ODP may be able to work with ICs to address this issue. In addition, professional societies may be able to help here, by leading discussions appropriate to their areas of interest.

Adverse Events
The USPSTF needs evidence for adverse events that may result from behavioral counseling studies so that it can fully evaluate potential harm. NIH does require administrative reporting of adverse events in all of its clinical trials, including those evaluating behavioral counseling interventions. One limitation appears to be the lack of consensus on reporting this information in published reports of study outcomes. NIH cannot require such reporting, but professional societies may be able to help by leading discussions appropriate to their areas of interest. Transparent reporting standards, such as CONSORT,7,8 can help by requiring reports of adverse events.

Standardization of Measures
One of the barriers to pooling evidence across studies is the lack of standardization of behavioral measures often used as outcomes. NIH supports a number of activities to help develop standardized measures. The National Cancer Institute (NCI) supports the Grid-Enabled Measures Program, an interactive web-based portal that enables consensus on the standardization of behavioral measures and theories used in behavioral counseling intervention studies. It includes constructs in distress measurement, care planning, and shared decision making in the clinical setting. In addition, many of the ICs support the PhenX toolkit project.9 Begun by the National Human Genome Research Institute, the toolkit project is developing standard measures in a variety of areas, including anthropometrics (National Institute of Child Health and Human Development [NICHD]; National Institute of Aging [NIA]); alcohol, tobacco, and other substance abuse (NIDA, NCI, National Institute of Alcohol Abuse and Alcoholism [NIAAA]); cancer (NCI); cardiovascular disease (National Heart Lung and Blood Institute [NHLBI]); diabetes (NIDDK); environmental exposures (National Institute of Environmental Health Sciences); infectious disease (National Institute of Allergy and Infectious Diseases [NIAID]); nutrition (Office of Dietary Supplements); oral health (National Institute of Dental and Craniofacial Research); physical activity and fitness (NCI, NIDDK); psychiatric (NIMH), psychosocial (NCI), and reproductive health (NICHD); respiratory ailments (NHLBI, NIAID); skin, bone, and muscle diseases (National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIA); social environments (NIDA, NIAAA); and speech and hearing impairment (National Institute on Deafness and Other Communication Disorders).

In addition, the Office of Behavioral and Social Sciences Research in collaboration with CDC, the Centers for Medicare and Medicaid Services, the Robert Wood Johnson Foundation, and the Pritzker Traubert Family Foundation funded an IOM Report that recommended harmonized psychosocial and behavioral measures for inclusion in the electronic health record.10 The IOM committee evaluated the association between the domains and health outcomes and considered the value of information in each domain for clinical decision making, population monitoring, and health policy for clinical and public health research, reliability and validity, response burden, and the sensitivity of the requested information. Based on these criteria, the committee recommended a dozen measures for routine capture in the electronic health record:

1. tobacco use;
2. alcohol use;
3. race/ethnicity;
4. place of residence;
5. education level;
6. financial resource strain;
7. stress;
8. depression;
9. physical activity;
10. social isolation;
11. intimate partner violence; and
12. neighborhood median household income obtained from residence.

The NIH has also developed a set of harmonized measures for the assessment of neurologic function and behavior. Their publically available NIH Toolbox for Assessment of Neurological and Behavioral Function is an integrated set of tools for measuring cognitive, emotional, motor, and sensory function. These tools have been validated for use in diverse cultures, ethnic and geographic groups, and ages (3–85 years). Measures in the toolbox are low-cost and royalty-free, use computer-adaptive testing, and are available in English and Spanish.
Effects on Health Outcomes
The USPSTF needs evidence linking behavioral outcomes from behavioral counseling interventions to health outcomes or intermediate biometric risk factors. This is a particular challenge because of the time lags that often exist between behavior change and change in biometric risk factors or health outcomes. In addition, studies powered to detect differences in health behaviors are rarely powered to detect differences in health outcomes or biometric risk factors. Even so, several of the ICs support projects that link behavioral outcomes from behavioral counseling interventions to health outcomes or intermediate biometric risk factors. For example, NIDDK requires inclusion of biometric risk factors (e.g., glycosylated hemoglobin, weight change expressed as BMI, percentage weight or body fat decrease, diabetes risk factor control) in a number of its funding opportunity announcements.

Discussion
There are many compelling reasons to coordinate the activities of the USPSTF, AHRQ, and NIH with respect to preventive services including behavioral counseling interventions. The USPSTF needs access to all available evidence as it develops its recommendations, and that evidence often comes from research supported by the NIH. The NIH needs to identify gaps in the evidence and the USPSTF’s evidence reviews, and recommendation statements regularly do that. AHRQ has a strong interest in supporting coordination in order to comply with its mandate to support the USPSTF and AHRQ’s mission to develop evidence to make health care safer; of higher quality; and more accessible, equitable, and affordable and to make sure that the evidence is understood and used.

Even so, barriers remain that often make it difficult for the USPSTF to issue clear recommendations. Some of these are a function of the differences between the foci of the USPSTF, AHRQ, and NIH, whereas others stem from a lack of consensus among investigators.

Primary Care Versus Other Settings
The USPSTF focuses on preventive services that can be linked to primary care, which can eliminate some preventive services from consideration. For example, a primary care provider cannot refer a child to a school-based intervention that is not offered in that child’s school. Similarly, a primary care provider cannot refer an adult patient to a church, worksite, or other community intervention if that organization and intervention are not available for that patient.

Asymptomatic Versus Symptomatic Populations
The USPSTF focuses on the benefits of interventions for people who are asymptomatic, though it also considers evidence from studies conducted in symptomatic, diagnosed patients. Although the latter is included, for example, in the reviews of treatment benefits and harms, the USPSTF puts more weight on studies of treatment delivered to patients whose condition is detected through screening.

Rigor of Study Design
The USPSTF exercises very high standards for what is included in the systematic reviews conducted by AHRQ’s Evidence-based Practice Centers. The USPSTF considers a wide range of evidence and discussions take study design into consideration. RCTs are given the greatest weight because they maximize internal validity and are clearly the best tool for supporting causation. At the same time, RCTs testing efficacy often have poor external validity,2,11 NIH and AHRQ are exploring alternatives to RCTs, including pragmatic or practical clinical trials and a variety of methods that use “big data.” We are also seeing increased interest in the multiphase optimization strategy,12 in sequential multiple assignment randomized trial13 designs, and in other innovative approaches to evaluating preventive interventions (e.g., www.nihorbit.org/ORBIT%20Content/Workshops%20and%20Conferences.aspx?PageView=Shared). As these methods are validated, we expect greater acceptance by the academic communities. With peer acceptance, alternative methods may have a greater role in USPSTF evaluations.

Another concern has been standards for reporting research results. Some observers suggest that behavioral trials have not always employed the same level of transparent reporting seen in drug or surgical trials.14 For example, behavioral trials have been slower to adopt conventions such as intention-to-treat analyses and use of CONSORT diagrams has been less common in behavioral trials.

Outcome Measures
There is a growing recognition that clinical indicator measures cannot always be substituted for health outcomes. For example, we encourage exercise among people with type 2 diabetes because it may result in reductions in glycosylated hemoglobin; however, glycosylated hemoglobin is not a health outcome. The Action to Control Cardiovascular Risk in Diabetes trial demonstrated that aggressive management of blood glucose did not result in the expected reduction in cardiovascular deaths15,16; in fact, there was an increase in all-cause mortality among patients experiencing...
aggressive blood glucose control. The message that we cannot substitute clinical indicators for health outcomes is well accepted in the clinical trials community, yet this strategy has not made its way to the behavioral research community, and more behavioral trials could include health outcomes such as type 2 diabetes, coronary artery disease, or obesity. Investigators typically assume that a trial is successful if it has an effect on an intermediate outcome such as a targeted health behavior, although ultimately the impact of an efficacious intervention trial should lead to changes in health outcomes in order to support USPSTF recommendations. This also has implications for NIH, as the ICs will have to fund the research to evaluate behavioral interventions that address health outcomes, not just behavioral outcomes. NIH will also have to fund studies with long enough follow-up for health outcomes to satisfy the USPSTF that the behavioral interventions can have a durable effect that warrants an A or B recommendation.

Conclusions
In spite of the differences in their missions and foci, the USPSTF, AHRQ, and NIH complement and support each other to improve the health of the nation. The steps taken recently by the ODP, if fully implemented, will improve their coordination. For example, ODP will work actively with the NIH ICs to ensure that the USPSTF has access to the most up-to-date information about recent and ongoing studies supported by those ICs. ODP also will work actively with the ICs to explore opportunities to support new research to address insufficient evidence statements. Finally, NIH will continue to support efforts to standardize measures to make it easier for the USPSTF to compare findings across studies.

Even with these steps by NIH, additional steps will be required of others in order for the USPSTF to have all of the evidence it needs to make clear recommendations. Researchers need to provide evidence on the effects of their intervention according to the symptoms or risk status of the participants, on the feasibility of referral from primary care for their behavioral intervention, on the dose of the intervention and the relative contribution of specific components, on adverse events, and on the effects of their behavioral interventions on health outcomes in order to provide the kind of evidence that the USPSTF needs. Professional societies may be in a good position to play a helpful role with respect to encouraging reporting of outcomes stratified by symptoms or risk status, reporting of dose and the effects of individual components of multicomponent interventions, and reporting adverse events in publications they sponsor and not just in administrative reports.

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The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of the AHRQ or the USPSTF. No statement in this report should be construed as an official position of AHRQ or the U.S. Department of Health and Human Services.

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