Understanding Research Gaps and Priorities for Improving Behavioral Counseling Interventions
Lessons Learned From the U.S. Preventive Services Task Force

Ann E. Kurth, PhD, CNM, MPH,1 Therese L. Miller, DrPH,2 Meghan Woo, ScD, ScM,3 Karina W. Davidson, PhD4

Behavioral counseling interventions can address significant causes of preventable morbidity and mortality. However, despite a growing evidence base for behavioral counseling interventions, there remain significant research gaps that limit translating the evidence into clinical practice. Using U.S. Preventive Services Task Force (USPSTF) examples, we address how researchers and funders can move the research portfolio forward to achieve better application of behavioral counseling interventions to address substantial health burdens in the U.S. This paper describes the types of gaps that the USPSTF encounters across its behavioral counseling intervention topics and provides suggestions for opportunities to address these gaps to enhance the evidence base for primary care-based behavioral counseling recommendations. To accomplish this, we draw from both the USPSTF experience and issues identified by researchers and clinicians during the USPSTF-sponsored Behavioral Counseling Intervention Forum. We also discuss the dilemma posed by having “insufficient” evidence with which to make a behavioral counseling intervention–related recommendation, and describe two case examples (screening for alcohol misuse in adolescence and screening for child maltreatment), detailing the research gaps that remain. Recommendations are outlined for researchers, funders, and practice implementers to improve behavioral counseling intervention research and application.

Introduction

The contribution of health behaviors to preventable morbidity and premature mortality in the U.S. is significant; therefore, scaling efficacious behavioral counseling interventions (BCIs) to enhance healthy behaviors for the U.S. population is critical. Recently, Curry and colleagues1 described challenges in applying the methodology of the U.S. Preventive Services Task Force (USPSTF) to BCIs with the goal of encouraging researchers, clinicians, and funders to support research that optimizes the ability to make evidence-based recommendations on BCIs for primary care, based on research that can usefully inform these decisions. They focused on challenges that had hindered previous research from being relevant, such as the choice of study populations, intervention protocols, and behavioral and health outcomes. Additional major research gaps in making evidence-based recommendations on BCIs were further defined during the USPSTF-sponsored Behavioral Counseling Forum (hereafter noted as the “Forum” and described in further detail by Curry and Whitlock2 in this supplement) held on November 6, 2013. The USPSTF evidence review process provides insights to key research gaps, which are described both in the evidence reviews as well as in summary form in the USPSTF recommendation statements. Despite this, the field often does not fill these gaps or systematically compare gaps that have been identified across topics. As a result, the same unaddressed themes of missing or under-described data or design elements are repeated over time. Therefore, the goal of
Establishing the Effectiveness of Behavioral Counseling Interventions

To address the USPSTF Analytic Framework,\(^1\) the USPSTF first examines the evidence to determine if there is direct evidence that changes in a patient’s health behavior lead to reduced morbidity or mortality (Key Questions, Figure 1). If direct evidence of effectiveness is not available, the USPSTF then examines the evidence to determine if there are sufficient links in indirect evidence to make a recommendation (Key Questions 1–5, Figure 1). For example, does a BCI lead to a patient’s sustained health behavior change, which in turn leads to improvements in intermediate and final health outcomes? The likely benefits and harms are assessed, and a net benefit is estimated, in evaluating the contribution of the clinical service (counseling intervention).

When the USPSTF is unable to find direct or indirect evidence to demonstrate the effectiveness of a clinical preventive service, it issues an “I” statement indicating that “the current evidence is insufficient to assess the balance of benefits and harms of the service.”\(^3\) Currently, there are four behavioral counseling topics for which the USPSTF has found the current evidence to be insufficient to make a recommendation. These include screening and BCIs in primary care to reduce alcohol misuse in adolescents, behavioral interventions to prevent or reduce illicit drug or nonmedical pharmaceutical use in children and adolescents, behavioral counseling to prevent sexually transmitted infections in non–sexually active adolescents and in adults not at increased risk for sexually transmitted infections, and counseling adults older than age 24 years about minimizing risks to prevent skin cancer.

Despite an established field of research with a number of rigorous studies that are funded and adequately reported in reputable journals, many USPSTF recommendations in these areas remain as an “Insufficient” or “I” recommendation. Here, we briefly present two such cases.

Example of “I” or Insufficient Behavioral Counseling/Behavioral Screening Recommendations

Screening for Alcohol Misuse in Adolescence

All would agree that early and accurate identification of those asymptomatic for, but already engaging in, alcohol misuse early in the life span is a critical preventive service. The lifetime burden of alcohol misuse, alcohol abuse, or both is estimated at $223.5 billion in 2006 or about $1.90 per drink.\(^4\) However, the USPSTF recommendations issued in 2004 and again in 2013 remained at an “I,” despite the prevalence and seriousness of this problem, the fact that validated screening tools for alcohol misuse and abuse for adolescents exist,\(^5\) and that multiple studies use these tools.\(^6\) How can this be?

---

**Figure 1.** Analytic framework for behavioral counseling interventions.

Note: Key questions: (1) Do changes in patients’ health behavior improve health or reduce risk factors? (2) What is the relationship between duration of health behavior change and health improvement (i.e., minimum duration, minimum level of change, change/response relationship)? (3) What are the adverse effects of health behavior change? (4) Does health behavior change produce other positive outcomes (e.g., patient satisfaction, changes in other healthcare behaviors, improved function, and decreased use of healthcare resources)? (5) Is risk factor reduction or measured health improvement associated with reduced morbidity and/or mortality? (6) Is sustained health behavior change related directly to reduced morbidity and/or mortality? (7) Are behavioral counseling interventions in clinical care related directly to improved health or risk factor reduction? (8) Are behavioral counseling interventions in clinical care related directly to reduced morbidity and/or mortality?

Optimal studies for BCI recommendation evidence would include randomization to a screening tool versus no screening tool and extensive enough follow-up on a sufficiently large asymptomatic population of interest to determine benefits and harms associated with that screening practice. This type of design and method is considered the firmest evidence on which to establish a recommendation for, or against, recommending that the nation be screened by a certain practice. However, this type of trial is rarely conducted in the behavioral screening/counseling field (Curry and Whitlock, in this supplement). At times, this type of screening trial is not conducted because the field does not have equipoise about the topic. On the face of it, it seems self-evident to many that screening for alcohol misuse in younger people must be a beneficial screening practice. Unfortunately, outside of behavioral screening, there also have been screening practices that seemed beneficial until they were actually empirically tested and found not to be so, including the annual physical exam. The repeated examination of the evidence by the USPSTF on screening for alcohol misuse in adolescents has now led the National Institute of Drug Abuse (NIDA) at the NIH to consider what must be done. A number of recent screening trials for both alcohol and pharmacologic misuse have been sponsored by NIDA, though these trials are focused on adults. As a result of this scientific investment by NIDA, the USPSTF soon will have evidence to judge with more certainty the recommendations for screening, at least in adults. Some of the logistics of conducting this type of trial hopefully will then be able to inform the design for conducting such a screening trial in adolescents, thereby allowing the field to move forward. The lack of direct evidence about the harms and benefits of screening for alcohol misuse in adolescents also should be highlighted in the USPSTF’s recommendations about research priorities that are presented to Congress each year.

Childhood Abuse

A second example of a USPSTF “I” recommendation exists for the screening for child maltreatment (i.e., abuse or neglect), a screening area that is profoundly important to society and its most vulnerable members. Child maltreatment identification guides exist and studies have documented the prevalence of the problem and its negative sequelae. However, direct evidence on the benefits and harms of screening in those not known to suffer abuse, or sufficient indirect evidence to establish a recommendation, was found to be lacking by the USPSTF in 2004 as well as in 2013.

In this case, a different approach was taken to start to tackle this issue. Instead of highlighting the gap in knowledge in a congressional report, the USPSTF considered altering the way the problem of childhood abuse was conceptualized. Because behavioral counseling is a main means of treating or ameliorating this particular issue, re-conceptualizing this topic as falling under counseling, rather than screening, allowed the USPSTF to consider the existing treatment evidence as it considered the next recommendation. This approach resulted in the prioritization of the re-conceptualized counseling for childhood abuse and neglect topic for review in 2015 by the USPSTF. An updated review and recommendation is expected to be forthcoming.

Summary of Core Research Gaps

Although a lack of sufficient evidence to make a USPSTF recommendation is an overarching issue in the BCI field, a number of additional research gaps have consistently emerged across USPSTF BCI topics. These research gaps were identified through two methods. The first was through a case-based approach involving a comprehensive review of all BCI evidence reviews and recommendations. The second was to hold the Forum in September 2013 to coalesce over major challenges in the field. As will be seen, gaps occur in the conduct of research for BCIs; although gaps also exist in the implementation and dissemination of evidence-based BCIs, we focus on the latter.

Issues in Defining and Describing the Intervention

A fundamental issue discussed during the Forum was the lack of a standard definition for BCIs. This has broad implications for both research and practice. Unfortunately, there is not a single standardized definition of what behavioral counseling means, though several exist, from the Office of Behavioral and Social Sciences Research (Curry and Whitlock in this supplement) and others.

An agreed-upon definition of behavioral counseling in primary care specifically also does not exist. The USPSTF adopted IOM’s definition of “primary care” and considers interventions that are feasible to be delivered in primary care settings or are judged to be feasible for referral from primary care. The intervention could target patients seeking care in primary care settings, and the skills to deliver the intervention are or could be present in clinicians and related staff in the primary care setting, or the intervention could generally be ordered or initiated by a primary care provider. In general, for behavioral counseling to be delivered effectively in often-busy primary care settings, it must be brief. Again, there is no standard definition of what constitutes a “brief” counseling intervention. The duration and intensity of counseling is highly dependent on the behavior(s) being targeted.
Frequently, the USPSTF is not able to find any direct evidence that demonstrates changes in patients’ health behavior leads to improvement in health or a reduction in risk factors, particularly over longer time horizons. In synthesizing the indirect evidence, problems include the fact that much of the literature features very tangentially related studies, resulting in a body of evidence that is too heterogeneous to quantitatively analyze. Follow-up periods in many studies are short, and effect sizes tend to wane over time, often leading to the need for “booster” counseling sessions.

Issues in Referring for Behavioral Counseling Interventions

Although the USPSTF does not consider the costs of providing services in their review process, it is relevant to note that referrals for BCIs can be challenging because of the potential limited availability of services, coverage, or quality in communities. There is also a lack of research on what happens after a referral is made, particularly over the long term. Research is needed on effective linkage and continuity from the primary care setting where initial behavioral counseling may be delivered to community care, where people will have much more service exposure opportunities over time, particularly with Affordable Care Act health reforms.

To identify common research gaps across USPSTF BCI topics, the authors conducted a comprehensive review of all BCI evidence reviews and recommendation statements. In total, there are 11 active BCI topics in the USPSTF queue (see Table 1, in Curry and McNellis, in this supplement). For each BCI topic, the authors collected the final recommendation statements and final evidence review summaries. Two co-authors reviewed each of these documents, with particular focus on descriptions of research limitations and evidence gaps, and identified key themes. The most common research gaps that emerged from this review are described in the following pages and Table 1.

The Need for Subpopulation Studies

As indicated in Table 1, the most common research gap reported across the BCI topics is the need for subpopulation studies. The USPSTF and Evidence-Based Practice Centers (EPCs) conducting evidence reviews repeatedly noted that extrapolation of results was not possible given a lack of diversity in study populations. Commonly cited under-represented groups included racial/ethnic minority populations, low-SES groups, and varying age demographics including older and younger cohorts. In total, the need for subpopulation studies was identified as a key research gap for seven BCI topics.

Evaluation of Longer-Term Health and Social Effects of Behavioral Counseling Interventions

Greater evaluation and knowledge of the longer-term health and social effects of BCIs is another research gap. More research is needed to better understand the ultimate impact of behavior change on either intermediate or final health outcomes. This is true in the example of 2010 screening for Obesity in Children & Adolescents topic, where BCIs may improve intermediate outcomes such as BMI maintenance but there is little evidence on the effect of these interventions on longer-term morbidity, mortality, or quality of life. Although many BCIs can take 10 years before clinically meaningful health outcomes occur, it may be possible to demonstrate some linkages in shorter time frames. Funders could prioritize opportunities to fund follow-up studies from past successful RCTs of BCIs and phase IV study designs. Federal agencies such as the Agency for Healthcare Research and Quality (AHRQ) and NIH could turn these research gaps and priorities into funded studies. Potentially, longer follow-up time also could be achieved through the use of large data sets (e.g., insurance and employer data including those from self-insured employers) or through the use of electronic health record data, making use of big data analytics after a trial is completed. These electronic means of ascertaining important health outcomes are advancing such that the analyses can be nearly as valid as the type of primary outcome that is used in an RCT, but at much lower cost and with faster completion. Funders should consider incentivizing integration of primary research studies of BCIs with big data systems to follow up in health records for extended terms/durations.

Evaluation of the Effects of Individual Components of Multicomponent Programs

Many effective BCIs feature multiple components, such as face-to-face sessions with educational materials and telephone follow-up, among others. For example, the 2013 Screening & Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse evidence review included various counseling approaches (brief advice, feedback, or motivational interview) and cognitive behavioral strategies (self-completed action plans; written health education; or self-help materials, drinking diaries, or problem-solving exercises to complete at home). Without a clear understanding of the contribution of individual program components, practitioners are left with a “black box” understanding of underlying program effects. As a result, outstanding questions about program effectiveness across BCIs are numerous and include which individual components are essential to achieve a meaningful change in behavior; whether all the components are
really needed; comparative effectiveness of specific intervention components; and how to make the intervention more effective, efficient, and cost effective. Research is needed to better understand the effects of individual components of multicomponent interventions.

Relatedly, additional systematic research is needed to both describe adequately and to document effectiveness differences about the multiple modalities available to deliver behavioral counseling in primary care. These include use of information and communication technologies (eHealth) as well as face-to-face delivery to individuals or groups. Research that establishes the optimal effective duration of an intervention would be useful. At a minimum, studies should clearly report delivery modes so that the USPSTF and other reviewers can understand the logistics required to properly implement the protocol in a primary care setting, or to refer to this type of counseling from a primary care setting.
Research is needed to better understand the process and outcomes of referrals to BCIs from primary care.

**Examination of Heterogeneity of Intervention Intensity**

Examination of the effect of variation in intervention intensity also has been commonly cited as a research gap across BCIs. The intensity of an intervention is often correlated with the effectiveness of the intervention. However, in many studies, the most intensive interventions are often offered to the patients at highest risk for poor health outcomes. Few, if any, studies include a full spectrum of low-, middle-, and high-risk patients randomly assigned to an intervention. In addition, high-intensity interventions often require a high number of treatment sessions. Effective moderate- and low-intensity interventions are greatly needed to make delivery of behavioral counseling more widely feasible. Additional research is also needed to determine the level of intensity to achieve effectiveness taking into account the risk status of the patient.

**Examination of the Impact of Treatment Setting on Intervention Effectiveness**

The context of healthcare delivery in the U.S. is changing, from one focused on health facilities and providers to one that is community focused and that engages clients in their self-care. Research on the ways in which BCIs fit into this client-centered paradigm would be timely. For example, developing more-meaningful and patient-centered measures of quality of life by engaging patients in the research design and choice of patient-important outcomes is an emerging research priority. As noted in the Forum, quality of life often is narrowly defined, yet is enhanced by talking to patients themselves. The ultimate goal of health research and intervention delivery is for people to thrive, not just return to a homeostatic state of no negative outcomes. Funders can take an active interest in the patient perspective in the research they support, related not just to harm avoided but to achieving high acceptability of the interventions, in addition to including patient-important outcomes. New research funding, such as the Patient-Centered Outcomes Research Institute (PCORI), Clinical and Translational Science Award, and other initiatives, could be leveraged to aid primary care clinicians in their goal of providing patient-centered care that is informed by the best evidence. The USPSTF could join forces with PCORI as a research-supporting partner to accomplish this mission. As noted during the Forum, there are opportunities to examine linkages between primary care settings and public health/community settings and to create a scientific evidence base of these linkages in the context of effective behavioral counseling. It was noted that bringing together the work of the USPSTF and the CDC Community Preventive Services Task Force (CPSTF) also makes sense, given the respective foci on primary care and community settings. Behavioral intervention recommendations represent an important domain for both task forces, given the importance of behavior change in promoting healthful lifestyles. Opportunities to enhance behavioral counseling preventive services through closer coordination when developing and disseminating recommendations, as well as future collaboration between the USPSTF and CPSTF, are discussed by Grossman and Elder in this supplement.

**Other Identified Research Gaps**

A few additional gaps were also cited across BCI topics. These included evaluation of costs of interventions and cost effectiveness, examination of the impact of treatment setting on intervention effectiveness, and examination of the clinical utility of validated screening instruments. Also, it is rare that there are studies that address any potential harms associated with BCIs.

Finally, important implementation science research is needed on the feasibility of provider and health systems’ ability to integrate and deliver evidence-based BCIs at scale. Without this, empirically effective behavioral counseling sessions provided in a high-quality RCT with sufficient resources will never be available to the public through their primary care network, even though the counseling is known on net to be beneficial. This implementation science agenda includes weighing fidelity to the counseling intervention delivery versus the need to contextualize it to local conditions or populations, as well as operational challenges of determining which staff will deliver the intervention and ensuring quality so that there is no drift in BCI delivery over time. The utility of technology-enhanced intervention delivery such as computerized counseling, text messaging, and other approaches appears promising, but more research could inform how these can be effectively scaled up within primary care settings. More research is needed on how to best harness e-health and other information and communication technologies to help primary care providers as well as clients incorporate them in their daily lives outside of clinical settings.

**A Call for Action**

The gaps identified by the USPSTF in the course of its work, as well as during the 2013 Forum, lead us to suggest several concrete strategies that the USPSTF itself, as well as U.S. government bodies and funders, could take to improve the knowledge base and application of
effective BCIs in primary care. Priorities in this area include the need for a standardized list of criteria to define a BCI. An international group of scientists is developing a common descriptive framework for designing, describing, and using these behavior change techniques. They also have outlined the need for a standardization of other critical elements of any BCIs, and are working on a process to extend the CONSORT reporting guidelines to include some of this missing information about BCI research in general.

U.S. Preventive Services Task Force Purview

To address some of these systemic issues affecting the quality of BCI research, the USPSTF should disseminate a list of criteria used by the USPSTF EPCs in reviewing BCIs. This list can help inform ongoing trials by codifying what constitutes behavioral counseling and providing a more standardized definition.

The USPSTF includes a section on research gaps identified in each issued recommendation. Discussions of the evidence gaps in separate journal articles or editorials also could be important. The USPSTF should ask researchers to write accompanying articles for published recommendations, identifying research gaps, to call out the important next steps for the research community.

The USPSTF should include in its annual reports to Congress a standing section on research gaps related specifically to BCIs, including standardization for behavioral counseling and referrals, subpopulation considerations, and behavior as an outcome, as well as documented links to morbidity and mortality. The inclusion of these gaps in the congressional reports will reinforce the need for outside societies and funding entities to address these important gaps. This in turn would help to grow the scientific evidence base for how best to facilitate healthy behaviors, the foundation of individual and population health.

Funder Purview

Congress is provided information on research gaps and priorities to facilitate budget allocation decision and recommendations via entities including the NIH. As noted in the paper by Murray et al., increased collaboration of the NIH and other Federal partners with the USPSTF is an opportunity. The NIH is developing a plan with AHRQ and has identified many of places in the USPSTF’s process where NIH input could be helpful, for example, selecting members, topics, research plans, commenting on reports, and messaging of reports. The NIH has identified USPSTF liaisons at each of its institutes, and will continue to identify content experts for each active topic and “I” recommendations, and will produce annual reports on what each institute is doing to address “I” statements. The NIH can also help with interpretation of the recommendations by the public and work with the USPSTF to determine how many more of these trials are needed, of what quality, with what effects. The NIH Director has asked the institutes to address USPSTF-identified recommendations and gaps. We suggest that an annual report back from NIH representatives attending the USPSTF meetings be added to the agenda so that progress gets noted in the meeting records. The PCORI initiative also presents an opportunity to conduct pragmatic, community-focused trials of BCIs that may be highly relevant. Investigators considering the PCORI funding mechanism could reference the research gaps listed in BCI research by the USPSTF, and the PCORI institute also can consider them when crafting their funding calls.

Related agencies including the AHRQ research/action networks—though with more limited funding available than the NIH—also could consider the specific BCI gaps noted by the USPSTF. Additionally, foundations and corporate social responsibility units could consider investments in research areas that the USPSTF has identified as important for BCIs. Acting to fill these research gaps will improve evidence-based delivery of behavioral screening and counseling intervention delivery. This will in turn reduce the substantial preventable morbidity and premature mortality contributed by behaviors that can be addressed more effectively in primary care settings.

Implementation science funding is critical, and NIH and others should expand available funding streams for this key area of deepening the science of how to scale up efficacious BCIs into effective practice.

Finally, progress in evidence accumulation for BCIs could be aided by forming a multidisciplinary committee that establishes a set of standardized criteria and definitions to be used in BCI research and that provides guidance on the design elements and reporting criteria for BCIs to inform funding agency calls for proposals, as well as policy and review bodies such as USPSTF. Such work has started with reporting of behavioral trials more transparently in journals, using standard elements with definitions. This work needs to continue if we are to have the best BCIs available for the American public.

Publication of this article was supported by the Agency for Healthcare Research and Quality (AHRQ).

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that AHRQ support the operations of the USPSTF.

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 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.

Administrative and logistical support for this paper was provided by AHRQ through contract HHSA290-2010-00004i, TO 4.

No financial disclosures were reported by the authors of this paper.

References

11. USPSTF. Procedure Manual, Section 4.4.2.