Evaluating Feasible and Referable Behavioral Counseling Interventions

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The U.S. Preventive Services Task Force (USPTF) recognizes that behaviors have a major impact on health and well-being. Currently, the USPSTF has 11 behavioral counseling intervention (BCI) recommendations. These BCIs can be delivered in a primary care setting or patients can be referred to other clinical or community programs. Unfortunately, many recommended BCIs are infrequently and ineffectually delivered, suggesting that more evidence is needed to understand which BCIs are feasible and referable. In response, the USPSTF convened an expert forum in 2013 to inform the evaluation of BCI feasibility. This manuscript reports on findings from the forum and proposes that researchers use several frameworks to help clinicians and the USPSTF evaluate which BCIs work under usual conditions. A key recommendation for BCI researchers is to use frameworks whose components can support dissemination and implementation efforts. These frameworks include the Template for Intervention Description and Replication (TIDieR), which helps describe the essential components of an intervention, and pragmatic frameworks like Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) or Pragmatic–Explanatory Continuum Indicator Summary (PRECIS), which help to report study design elements and outcomes. These frameworks can both guide the design of more-feasible BCIs and produce clearer feasibility evidence. Critical evidence gaps include a better understanding of which patients will benefit from a BCI, how flexible interventions can be without compromising effectiveness, required clinician expertise, necessary intervention intensity and follow-up, impact of patient and clinician intervention adherence, optimal conditions for BCI delivery, and how new care models will influence BCI feasibility.

Introduction

Unhealthy behaviors are an important cause of excess morbidity and premature mortality—potentially more significant than genetic, biological, or environmental factors.1–4 Government, employers, and health plans are squarely focused on addressing lifestyles as a means to curb the chronic disease epidemic and spiraling healthcare costs. Primary care clinicians are uniquely situated to play a pivotal role in helping patients improve health behaviors through behavioral counseling interventions (BCIs).5–8 This role is facilitated by the Affordable Care Act of 2010, which requires insurers to cover BCIs that are recommended and given a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).9

The USPSTF has long recognized the importance of BCIs in primary care and has developed an analytic framework to evaluate the evidence supporting them.10–12 The USPSTF evaluation assesses

1. whether an intervention in the clinical setting influences patients to change behaviors; and
2. whether changing behaviors improves health outcomes with minimal harms.

Although the USPSTF has recommended the provision of a growing number of BCIs, many are not routinely offered to the patients who need them or are poorly delivered and fail to result in meaningful health behavior changes.13–17 Research is needed to improve the design and evaluation of BCIs so that they can be more effectively delivered in primary care and the community.
This manuscript reports on the perspectives of a BCI Expert Forum convened by the USPSTF on November 26, 2013 to better advance the evidence and evaluation of BCIs to ensure their feasibility. Participants included stakeholders from the USPSTF, federal agencies, research community, and primary care community.

**Feasible and Referable Behavioral Counseling Interventions: Definitions and Challenges**

USPSTF behavioral counseling recommendations focus on interventions that are feasible for primary care to deliver or that are available by referral from primary care. The USPSTF has provided preliminary definitions for the feasibility of delivering and referring patients to BCIs. Interventions are considered feasible to deliver in primary care if they can be implemented as reported in published studies and achieve similar health behavior changes that result in improved mortality, morbidity, and quality of life. Many currently recommended BCIs are brief, require minimal specialized training, and are flexible in how they are delivered. Not all BCIs can or should be delivered in primary care. Some may be more effective if delivered in another clinical setting or in a community setting where patients live, work, or learn. For these BCIs, clinicians can play a role in identifying unhealthy behaviors, encouraging and supporting patients to make changes, and referring patients for interventions. The USPSTF considers it feasible to refer a patient for a BCI if it could reasonably be conducted in another healthcare setting outside of primary care or if it is widely available in communities and primary care clinicians are able to refer the patient for the service.

Currently, the USPSTF has 11 BCI recommendations (Table 1). Some have sub-recommendations for different populations (e.g., adults versus adolescents) and different BCIs (e.g., brief versus intensive counseling). The evidence currently supports counseling for alcohol misuse in adults; breastfeeding promotion; weight loss counseling for obese children, adolescents, and adults; sexually transmitted infection prevention for adults and adolescents at risk; skin cancer prevention for individuals aged 10–24 years; tobacco use counseling for those who use tobacco products; and tobacco use prevention counseling in school-aged children and adolescents.

Helping patients to change ingrained and reinforced health behaviors is difficult. Accordingly, the designs of many effective BCIs are based on well-established behavior change models such as the health belief model, theory of reasoned action, stages of change, social cognitive theory, community organization building, and social marketing. These models help to explain the complex issues that effective BCIs must address such as knowledge, attitudes, motivations, self-confidence, skills, resources, and social support. These frameworks do not, however, account for many of the challenges experienced by clinicians in delivering BCIs. Not unexpectedly, clinicians struggle with routinely delivering BCIs, often lacking skills, time, and resources while addressing multiple competing demands.

**Behavioral Counseling Intervention Delivery Intensity and Setting**

The USPSTF has identified the 5A’s (Ask patients about unhealthy behaviors, Advise patients to change, Agree to next steps, Assist patients to make changes, and Arrange follow-up) as one framework for understanding BCI delivery. This is exemplified by two stories of tobacco use counseling. In one, a clinician provides some or all of the 5A’s in a single encounter. In a more intensive example, a clinician provides the first three A’s and then refers smokers to a quit line for more intensive assistance and follow-up.

BCI delivery can be categorized based on intervention intensity (spectrum of brief to intense) and where the intervention is delivered (clinical setting or community) (Table 2). The USPSTF has identified brief counseling as adequate to help patients improve health behaviors for only four services—alcohol misuse, skin cancer, tobacco use, and tobacco prevention counseling; although these brief interventions are effective, more-intensive interventions are more effective. The remaining services require more-intense BCIs and often require multidisciplinary teams to deliver.

Brief counseling in the clinical setting is characterized by short motivational messages with supportive materials offered during an office visit. These BCIs are often easier to implement and broadly disseminate than intensive interventions. They typically take between 90 seconds and 30 minutes, can occur in a single or multiple sessions, require little specialized training, and their delivery is highly adaptable. As the USPSTF only recommends BCIs that result in meaningful behavior changes that improve health outcomes, it has only recommended four such brief interventions.

It can be difficult to define the difference between brief and intensive counseling. The distinction may depend on the setting, clinicians, and patients. In general, intensive counseling in the clinical setting lasts longer than 30 minutes, usually requires multiple sessions over time, benefits from a multidisciplinary team with specialized training, and may need local and personal tailoring balanced by adherence. This intensity is often required.
## Table 1. Behavioral Counseling Interventions Reviewed by the U.S. Preventive Services Task Force

<table>
<thead>
<tr>
<th>Topic</th>
<th>Current grade</th>
<th>Counseling description</th>
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<tbody>
<tr>
<td>Healthful diet and physical activity to prevent cardiovascular disease in at-risk adults (2014)</td>
<td>B: The USPSTF recommends offering or referring adults (aged ≥ 18 years) who are overweight or obese and have additional cardiovascular disease (CVD) risk factors (hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome) to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.</td>
<td>Individual or group counseling (on lifestyle, diet, and physical activity either alone or in combination); didactic education with additional support; audit and feedback; problem-solving skills; individualized care plans; medication adherence. Modalities: Face-to-face counseling (individual or group); phone counseling. Intervention intensity: low-intensity (&lt;30 minutes of interaction with clinician); medium-intensity (31–360 minutes of interaction with clinician); or high-intensity (&gt;360 minutes of interaction with clinician).</td>
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<tr>
<td>Primary care interventions to prevent tobacco use in children and adolescents (2013)</td>
<td>B: The USPSTF recommends that primary care clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use in school-aged children and adolescents.</td>
<td>Face-to-face counseling (individual, group, family); phone counseling; written materials; video with viewing guide. Intensity: ranging from no in-person interaction with a healthcare professional to seven group sessions totaling more than 15 hours.</td>
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<tr>
<td>Screening and behavioral counseling interventions in primary care to reduce alcohol misuse (2013)</td>
<td>B: The USPSTF recommends that clinicians screen adults aged ≥ 18 years for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse.</td>
<td>Brief advice, feedback, or motivational interviews; and cognitive–behavioral strategies (e.g., action plans, drinking diaries, stress management, or problem solving). Modalities: face-to-face sessions, written self-help materials, computer- or Web-based programs, or telephone counseling. Intervention intensity: very brief single contact (&lt;5 minutes); brief single contact (5–15 minutes); brief multicontact (each contact is 6–15 minutes); and extended multicontact (&gt;1 contact, each &gt;15 minutes).</td>
</tr>
<tr>
<td>Behavioral counseling to prevent skin cancer (2012)</td>
<td>B: The USPSTF recommends counseling children, adolescents, and young adults aged 10–24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.</td>
<td>Tailored risk feedback; cancer prevention– or appearance-focused messages (e.g., self-guided booklets, a video on photoaging, 30-minute peer counseling sessions, and UV facial photography); peer counseling. Modalities: face-to-face counseling (primary care and peer-to-peer); booklets; videos (computer-based); phone counseling.</td>
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<td>Healthful diet and physical activity for cardiovascular disease prevention in adults (2012)</td>
<td>C: Although the correlation among healthful diet, physical activity, and the incidence of cardiovascular disease is</td>
<td>Modality: Mailed materials; face-to-face counseling (individual or group); phone counseling.</td>
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<td>strong, existing evidence indicates that the health benefit of initiating behavioral counseling in the primary care setting to promote a healthful diet and physical activity is small. This applies to adults aged ≥18 years who do not have cardiovascular disease, hypertension, hyperlipidemia, or diabetes. Clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population.</td>
<td>• Intervention Intensity: low (1–30 minutes); medium (31–360 minutes); or high (&gt; 360 minutes) • Low-intensity: mailed materials or 1 or 2 single, brief sessions with primary care clinicians or other trained persons • Medium-intensity: a range of 3–24 phone sessions or 1–8 in-person sessions • High-intensity: a range of 3–24 phone sessions or 1–8 in-person sessions</td>
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<td>Screening for and management of obesity in adults (2012)</td>
<td>B: The USPSTF recommends screening all adults aged ≥18 years for obesity. Clinicians should offer or refer patients with a BMI of 30 or higher to intensive, multicomponent behavioral interventions.</td>
<td>• Modality: Group and individual sessions that set weight-loss goals to improve diet or nutrition; physical activity sessions; sessions address barriers to change, active use of self-monitoring, and strategies how to maintain lifestyle changes • Intervention intensity: high-intensity (12–26 sessions per year)</td>
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<tr>
<td>Screening for and treatment of obesity in children and adolescents (2010)</td>
<td>B: The USPSTF recommends screening all children aged ≥6 years for obesity and offer them or refer them to a comprehensive, intensive behavioral intervention to improve weight.</td>
<td>• Modality: Counseling and other interventions that target diet and physical activity, including behavioral management techniques, and involving the child and/or family. • Intervention Intensity: moderate to high-intensity (&gt;25 hours of contact over 6 months).</td>
</tr>
<tr>
<td>Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women (2009)</td>
<td>A: The USPSTF recommends that clinicians ask all adults ≥18 years about tobacco use and provide tobacco cessation interventions for those who use tobacco products.</td>
<td>• Face-to-face counseling including problem-solving guidance for smokers (to help them develop a plan to quit and overcome common barriers to quitting) and the provision of social support; telephone “quit lines.” Use of the “5-A” framework as a counseling strategy: o Ask about tobacco use. o Advise to quit through clear personalized messages. o Assess willingness to quit. o Assist to quit. o Arrange follow-up and support. • Modality: face-to-face and telephone counseling • Intensity: lower—brief one-time counseling; more-intensive—longer sessions or multiple sessions</td>
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<tr>
<td>Behavioral counseling to prevent STIs (2008)</td>
<td>B: The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and adults at increased risk for STIs.</td>
<td>• Modality: Face-to-face counseling (individual or group), distribution of self-help materials • Intensity: high-intensity interventions were delivered through multiple sessions, most often in groups, with total durations from 3 to 9 hours; moderate-intensity interventions were two 20-minute counseling sessions before and after HIV testing; low-intensity interventions were single-session interventions or interventions lasting less than 30 minutes</td>
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</table>
to modify ingrained and reinforced behaviors. There are several delivery variations for these intensive BCIs. Two established delivery models include referral from the primary care setting to a specialist (e.g., referral to a specialized pediatric obesity clinic) or group classes within a healthcare setting led by a trained specialist (e.g., breastfeeding classes in hospitals after delivery).28

In the past, a key limitation with intensive primary care BCIs was that many practices lacked the required resources and expertise. However, new models of primary care are emerging that could better support intensive counseling, such as the integration of behavior counselors into primary care.

Some BCIs are more effective if delivered in a community setting. Most people spend relatively little time in clinical settings compared with the community

Table 1. Behavioral Counseling Interventions Reviewed by the U.S. Preventive Services Task Force (continued)

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<thead>
<tr>
<th>Topic</th>
<th>Current grade</th>
<th>Counseling description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counseling to promote breastfeeding (2008)</td>
<td>B: The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.</td>
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</table>

STIs, sexually transmitted infections; UV, ultraviolet; USPSTF, U.S. Preventive Services Task Force.

Table 2. Examples Intervention Delivery Models for U.S. Preventive Services Task Force-Recommended Behavioral Counseling Interventions as a Function of Intensity and Location

<table>
<thead>
<tr>
<th>Clinical setting</th>
<th>Shared setting</th>
<th>Community setting</th>
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<tbody>
<tr>
<td><strong>USPSTF recommended services benefiting from brief interventions—alcohol misuse, skin cancer, tobacco use</strong></td>
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<tr>
<td>Brief counseling interventions</td>
<td>Brief motivational and or educational messages with supportive materials offered during a visit:  - Clinician counseling about alcohol misuse, skin cancer prevention, or tobacco use23-25</td>
<td>Brief clinical and community interventions delivered independently in each setting Brief clinical and community interventions coordinated between settings</td>
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<tr>
<td></td>
<td></td>
<td>Brief motivational and or educational messages delivered in the community  - Informational messages about skin cancer prevention for visitors to outdoor recreational settings24</td>
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<tr>
<td></td>
<td></td>
<td>Community-based electronic screening and brief intervention (e-SBI):  - e-SBI for excessive alcohol use25</td>
</tr>
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</table>

| **USPSTF recommended services that require intensive interventions—breastfeeding, obesity (adults and children), sexually transmitted infections (STIs), healthy diet, and physical activity** |
| Intensive counseling interventions | Brief counseling in clinical setting and referral:  - Ask, Advise, Refer for tobacco use26  - Screening, Brief Intervention, and Referral to Treatment (SBIRT) for alcohol misuse30  - Referral to weight-loss program31 | Multi-component coaching or counseling interventions in the community:  - Diabetes Prevention Program37,38  - Commercial weight-loss programs39,40 |
| | | Worksite programs:  - Worksite nutrition and exercise interventions41 |
| | | Social support interventions:  - Social networks to promote physical activity42 |
| | | School-based interventions:  - School-based physical education43 |
| Referral from primary care to specialist for intensive counseling:  - Referral to a specialized pediatric obesity clinic | Behavioral counselors co-located within primary care settings:  - Ideal patient-centered medical home (PCMH) design46 | Integrated primary care and community-public health:  - Ideal integrated delivery model33-35 |
| Group classes within the primary care setting or health system:  - Group classes to promote breastfeeding or prevent STIs28 | Behavioral counselors located within the healthcare system:  - Ideal accountable care organization (ACO) design29 | |
where they make daily health behavior choices. BCIs often require social support from family and friends, and a built environment that facilitates access to resources. Brief community interventions have similar characteristics as brief clinical interventions, often consisting of educational messages, health risk screenings, or brief counseling events—like educational messages about skin cancer prevention at outdoor recreation centers.26,27

Intensive community interventions are multicomponent coaching or counseling interventions often delivered through established community, worksite, or school-based programs. Successful examples include programs provided by the YMCA, Weight Watchers, the Diabetes Prevention Program, worksite diet and exercise interventions, use of social networks, or school-based physical education.32,37–43,48 As the USPSTF does for primary care–based interventions, the Community Preventive Services Task Force reviews the evidence and makes recommendations about community-based interventions.27

The delivery of BCIs can also be shared across clinical and community settings (Table 2).33,34,49 Clinicians can identify patients in need of a BCI and refer the patient to the intervention—essentially a handoff. Alternatively, care can be integrated, coordinated, and reinforced across settings, allowing clinicians and community personnel to function within defined roles that build on individual strengths (Table 3). Shared interventions require personnel and infrastructure that span the settings. Examples of shared interventions include the Ask, Advise, and Refer campaign for smoking-cessation counseling and Screening, Brief Intervention, and Referral to Treatment (SBIRT) for alcohol misuse.30,31

Although there is great interest in creating truly integrated clinical–community BCIs, few sustainable examples have been implemented.

### Evaluating the Feasibility of Behavioral Counseling Interventions

Three general evidence needs emerged from the USPSTF Expert Forum and subsequent discussions to better understand whether BCIs are feasible and referable:

1. A template like the Template for Intervention Description and Replication (TIDieR) can help to better describe interventions.
2. More pragmatic trials are needed, and researchers should report study design elements and outcomes using pragmatic frameworks.
3. More evidence is needed to identify which BCI components are necessary to be effective and which components can be altered to improve feasibility.

### Describing Behavioral Counseling Interventions to Understand Feasibility

The traditional explanatory study is designed to evaluate whether an intervention can work under ideal conditions, whereas a pragmatic study is designed to evaluate whether an intervention works under usual conditions.50,51 Well-designed pragmatic studies have high external validity, and findings are more widely generalizable.52 Reporting the design and results for traditional RCTs is framed around the CONSORT criteria. Though essential for understanding internal validity, the CONSORT criteria do not provide sufficient detail on key
elements necessary to understand BCI feasibility such as setting context, local resources, and intervention flexibility. An extension of the CONSORT statement has been published to improve the reporting of pragmatic clinical trials with the goal of making it easier for decision makers to judge the applicability of trial results to their own conditions.\textsuperscript{53} Eight CONSORT checklist items were extended: study background, participants, interventions, outcomes, sample size, blinding, participant flow, and generalizability of the findings. As an example for generalizability of the findings, researchers are encouraged to “Describe key aspects of the setting which determined the trial results and discuss possible differences in other settings where clinical traditions, health service organization, staffing, or resources may vary from those of the trial.”

As a means to improve the description of BCIs, a modified version of the TIDieR checklist (with less emphasis on theory and rationale) could be used to better describe interventions. TIDieR elements include descriptions of essential intervention elements, materials used in the intervention, procedures and processes used in the intervention, intervention providers and their expertise, modes of intervention delivery, locations where the intervention occurred, number of times and time period for the intervention, whether the intervention was personalized or adapted, how intervention adherence was assessed, and the extent to which the intervention was delivered as planned.\textsuperscript{54}

One useful framework for designing studies and reporting outcomes describes five domains of an intervention: Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) of interventions (Table 4).\textsuperscript{55–57} Another framework with similar utility is the Pragmatic–Explanatory Continuum Indicator Summary (PRECIS), which considers ten study design domains to understand how pragmatic versus explanatory study results may be. The domains include participant eligibility, intervention flexibility, intervention clinician expertise, comparison intervention flexibility, comparison intervention clinician expertise, follow-up intensity, primary outcome, patient compliance with intervention, practitioner adherence to study protocol, and analysis of outcomes (Table 4).\textsuperscript{50}

To disseminate evidence-based BCIs, clinicians need sufficient detail to replicate the intervention. TIDieR focuses on individual-level study reporting of intervention details and can illustrate exemplar interventions or summarize the range of effective interventions. Decision makers considering BCI implementation may also need to consider how challenging the intervention will be to deliver in their setting and how likely it will achieve similar results. PRECIS and RE-AIM introduce considerations of applicability and sustainability that may be particularly important for specific interventions or specific environments. For example, a study that provides trained research nurses to deliver an intervention is on the explanatory end of the spectrum and may not be feasible for non-research nurses given the additional time and skill requirements. Or, if an intervention depends on repeated interventions to produce a health benefit, RE-AIM may highlight the uncertainty as to whether an intervention will be acceptable to patients and sustainable over time.

**Key Behavioral Counseling Intervention Feasibility Considerations Identified by the U.S. Preventive Services Task Force Expert Forum**

Table 4 highlights specific considerations identified by the forum to better understand whether an intervention is feasible. Evidence must demonstrate that the intensity, duration, frequency, time course, and components of a BCI are appropriate for a clinical setting. The necessary resources and infrastructure to effectively deliver a BCI must be clearly defined, including personnel (clinicians, nurses, support staff, dietitians, personal trainers, patient educators); expertise (special knowledge, skills, training); tools (educational materials, communication supports, technologic supports); and information systems to identify patients, track progress, and monitor for relapse.

There are many different ways primary care is structured and reimbursed. What is feasible in one practice may not be in another. A greater understanding of the BCI adaptations necessary to comply with practice constraints without compromising effectiveness is needed. Offering a menu of effective BCIs may be most practical so that practices can choose what is most applicable. In traditional primary care practices, 2 minutes, not 15 or more minutes, would be considered a brief and feasible intervention for a clinician. But with the emergence of team-based approaches and technology-supported interventions, the clinician’s role may be more focused and other team members may be able to provide more intensive assistance. Accordingly, it is important to understand the influence of practice characteristics on BCI feasibility. What are the influences of workflow, team-based approaches, resource availability, culture, capacity to change, practice stress, and connections to a larger healthcare system and the community? To support consistency with reporting of this contextual information, more research is needed to develop measures for these variables.\textsuperscript{58} Forum participants also noted that because practice-based research networks (PBRNs) have the capacity to conduct research in a wide range of primary care settings, PBRN research can be helpful to determine the influence of practice characteristics on feasibility.

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<table>
<thead>
<tr>
<th>Domain</th>
<th>Characteristics of more pragmatic BCIs</th>
<th>Understanding if a BCI is feasible</th>
<th>Understanding if a BCI is referable</th>
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<tbody>
<tr>
<td>Patient eligibility (PRECIS)</td>
<td>Pragmatic BCIs include the patients with an unhealthy behavior that would be targeted for an intervention versus excluding those least likely to respond</td>
<td>What is the influence of patient readiness and motivation to change? How should multiple behaviors be prioritized? Should they be addressed simultaneously?</td>
<td>What is the influence of the referral process? What is the influence of clinician knowledge of the service?</td>
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<tr>
<td>Reach (RE-AIM)</td>
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<tr>
<td>Intervention flexibility (PRECIS)</td>
<td>Pragmatic BCIs have more flexible intervention components versus requiring strict adherence to intervention elements</td>
<td>What components are necessary for a BCI to be effective? How important is it for a BCI to be standardized?</td>
<td>What assurances are there that referred services use evidence-based strategies? What is the influence of communication on BCI delivery?</td>
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<tr>
<td>Implementation* (RE-AIM)</td>
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<tr>
<td>Clinician expertise (PRECIS)</td>
<td>Pragmatic BCIs can be delivered by individuals with a variety of backgrounds versus requiring delivery by highly trained individuals</td>
<td>Who should deliver the BCI? The primary care provider? Other team members? Staff with specialized training?</td>
<td>How do we ensure the quality of community-based BCI programs?</td>
</tr>
<tr>
<td>Outcome (PRECIS)</td>
<td>Pragmatic trials compare a BCI to an alternative intervention versus comparing a BCI to no intervention</td>
<td>What is the best intensity for a BCI? Brief? Intense?</td>
<td>Which setting is best for BCI delivery? Which community venue is best for BCI delivery?</td>
</tr>
<tr>
<td>Effectiveness (RE-AIM)</td>
<td>Pragmatic trials assess clinically significant outcomes assessed under usual care versus research outcomes not collected during routine care</td>
<td>How does making a BCI more feasible impact effectiveness?</td>
<td>How does making a BCI more referable impact effectiveness?</td>
</tr>
<tr>
<td>Patient compliance with intervention (PRECIS)</td>
<td>Pragmatic BCIs are effective with a naturally occurring range of patient adherence versus only being effective with strict intervention adherence</td>
<td>What is the influence of patient engagement?</td>
<td>What is the influence of patient willingness to be referred?</td>
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<tr>
<td>Clinician adherence to protocol (PRECIS)</td>
<td>Pragmatic BCIs are effective with a naturally occurring range of clinician adherence versus only being effective with strict intervention adherence</td>
<td>What adaptations can be made to a BCI? How is BCI quality assessed and maintained?</td>
<td>How is BCI quality assessed and maintained?</td>
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<tr>
<td>Adoption (RE-AIM)</td>
<td>Pragmatic BCIs include all settings that could deliver the intervention versus only including ideal settings</td>
<td>How replicable is the BCI in different practices? How do practice characteristics influence adoption? What is the influence of practice culture on adoption?</td>
<td>Do BCIs exist in the community? How accessible are community BCIs?</td>
</tr>
<tr>
<td>Maintenance (RE-AIM)</td>
<td>Pragmatic BCIs are self-sustaining versus only being sustainable of a study or with intensive support</td>
<td>Can staff and resources needed for a BCI be sustained?</td>
<td>Is coverage available for referred BCIs in the community?</td>
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*Implementation would also be included in the PRECIS domains of (1) clinician expertise; (2) follow-up intensity; (3) patient compliance; and (4) clinician adherence.

BCI, behavioral counseling intervention; PRECIS, Pragmatic–Explanatory Continuum Indicator Summary; RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance.
A critical feasibility concern unique to referring patients to a BCI is that a program must exist in the community. Referral to programs that exist in most communities (Weight Watchers, YMCA, Alcoholics Anonymous) is more feasible, and as such has been a component of the definition of primary care referable used by the USPSTF. Referring clinicians need to be aware of existing community interventions and have knowledge of what can be done in different settings. Thus, referable interventions must be describable, consistent, of quality, and accessible to patients. Evidence is needed about the influence of communication and coordination of care between settings, the benefits of integrating care between the clinical and community settings versus a referral model of care, how to help patients navigate between settings, and the influence of unique coverage issues when patients are referred outside of healthcare settings.

**New Opportunities to Make Behavioral Counseling Interventions More Feasible and Referable**

New healthcare developments may significantly improve the feasibility of BCIs. The Affordable Care Act’s expansion of health insurance options, combined with its mandated coverage of evidence-based preventive services, provides new resources and incentives to support BCI delivery. In 2014, close to 8 million Americans obtained health insurance coverage through the Health Insurance Marketplace and 4.8 million found coverage through Medicaid and the Children’s Health Insurance Program. Insurers are required to cover USPSTF-recommended BCIs and annual wellness visits. The Centers for Medicare and Medicaid Services mandates health risk assessments as part of an Annual Wellness Examination. These well-visit assessments may facilitate identification of previously unrecognized unhealthy behaviors. Collectively, this may result in a proliferation of BCIs in clinical and community settings. The opportunity cost of these interventions, if not done properly, could have negative unintended consequences.

New models of care delivery such as patient-centered medical homes and Accountable Care Organizations (ACOs) promote the establishment of multidisciplinary care teams with a range of skills to coordinate care across settings and fully use technology. These new models of care make BCIs more feasible and referable by integrating behavioral counselors, care coordinators, social workers, mental health providers, and other necessary behavioral health specialists (e.g., nutritionists, personal trainers, and others) into primary care practices or having them available within a healthcare delivery system. New staff can directly deliver care or help to coordinate care within primary care or across settings. It is unclear how best to integrate and fund this expanded primary care workforce. Examples currently seen in practice include consulting (primary care clinicians directly deliver BCIs with coaching from behavioral staff); co-located (behavioral staff and primary care clinicians share physical space with different degrees of connectivity); and embedded (behavioral staff work daily within primary care teams) models.

New payment mechanisms based on quality and financial performance are also emerging. A growing number of practices and ACOs are receiving direct financial support to create and maintain BCI resources. Delivery of BCIs can be further facilitated within these new models of care by the use of new technologies incentivized by the Health Information Technology for Economic and Clinical Health Act of 2009, including electronic health records, patient portals, and mobile applications. These technologies can facilitate patient–clinician communication, health behavior information sharing, delivery of educational materials, and automated delivery of some BCI components.

**Future Directions**

In order to effectively implement BCIs, practices and communities will need to operate differently. This has important consequences for healthcare delivery and community systems design in terms of where efforts are invested and potential opportunity costs incurred. To better guide these efforts, more evidence is needed about BCI characteristics and components that affect both the effectiveness and feasibility of interventions within various healthcare organization models, standardized metrics to report pragmatic contextual factors, and interventions to improve feasibility. Opportunities to fund such research should be prioritized by the Patient-Centered Outcomes Research Institute, NIH, Centers for Medicare and Medicaid Services Innovation Center, and Agency for Healthcare Research Quality.

For its part, the USPSTF can specify what is known about BCI feasibility in the clinical considerations of their recommendations and identify known evidence gaps. As the relationship between primary care and community care becomes increasingly important, there is a growing need for the USPSTF and the Community Preventive Services Task Force to collaborate in making recommendations about BCIs. National attention is needed to ensure quality and maintain evidence-based standards when delivering BCIs, similar to mechanisms in place to ensure the safety and quality of other preventive services. Health systems,
primary care practices, and community programs will need to evaluate whether they can overcome feasibility issues when deciding whether to implement new BCIs and monitor ongoing implementation to ensure that interventions are achieving their desired effect. Collectively, these efforts, coupled with advancing the evidence about whether BCIs are feasible and referable, will help to ensure the delivery of recommended interventions.

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

We would like to thank the attendees of the U.S. Preventive Services Task Force (USPSTF) Expert Forum, Susan Curry, PhD, Robert McNellis, MPH, PA, Evelyn Whitlock, MD, MPH, and Steven Woolf, MD, MPH, for their expert input and advice.

The 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 HHSAG290-2010-00004i, TO 4.

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

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