



HHS Public Access

Author manuscript

Am J Prev Med. Author manuscript; available in PMC 2016 September 01.

Published in final edited form as:

Am J Prev Med. 2015 September ; 49(3 0 2): S184–S193. doi:10.1016/j.amepre.2015.05.015.

Enhancing the Evidence for Behavioral Counseling:

A Perspective From the Society of Behavioral Medicine

Carmela Alcántara, PhD¹, Lisa M. Klesges, PhD², Ken Resnicow, PhD³, Amy Stone, BA⁴, and Karina W. Davidson, PhD^{1,5}

¹Department of Medicine, Columbia University Medical Center, New York, New York

²School of Public Health, University of Memphis, Memphis, Tennessee

³School of Public Health, University of Michigan, Ann Arbor, Michigan

⁴Society of Behavioral Medicine, Milwaukee, Wisconsin

⁵New York Presbyterian Hospital, New York, New York

Abstract

U.S. Preventive Services Task Force (USPSTF) clinical guidelines at present rarely assign the highest grade recommendation to behavioral counseling interventions for chronic disease prevention or risk reduction because of concerns about the certainty and quality of the evidence base. As a result, the broad integration of behavioral counseling interventions in primary care remains elusive. Thus, there is an urgent need for novel perspectives on how to generate the highest-quality and -certainty evidence for primary care-focused behavioral counseling interventions. As members of the Society of Behavioral Medicine (SBM)—a multidisciplinary scientific organization committed to improving population health through behavior change—we review the USPSTF mandate and current recommendations for behavioral counseling interventions, and provide a perspective for the future that calls for concerted and coordinated efforts among SBM, USPSTF, and other organizations invested in the rapid and wider uptake of beneficial, feasible, and referable primary care-focused behavioral counseling interventions. This perspective highlights five areas for further development, including: (1) behavioral counseling-focused practice-based research networks; (2) promotion of USPSTF evidence standards and the increased use of pragmatic RCT design; (3) quality control and improvement procedures for behavioral counseling training; (4) systematic research on effective primary care-based collaborative care models; and (5) methodologic innovations that capitalize on disruptive

Address correspondence to: Carmela Alcántara, PhD, Center for Behavioral Cardiovascular Health, Department of Medicine, Columbia University Medical Center; PH-9, Room 9-319, 622 West 168th Street, New York NY 10032. ca2543@columbia.edu.

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

C. Alcántara led all aspects of manuscript development, and made substantial contributions to the conception, design, and writing of the manuscript. L.M. Klesges, K. Resnicow, and A. Stone made substantial contributions to the conception, design, and critical revisions to the manuscript for important intellectual content. K.W. Davidson served as senior author and made substantial contributions to the conception, design, and writing of the manuscript. All authors have read and approved the final version of the submitted manuscript.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

technologies and healthcare transformation. Collective efforts to improve the health of all Americans in the 21st century and beyond must ensure that effective, feasible, and referable behavioral counseling interventions are embedded in modern primary care practice.

Introduction

Recent transformations in healthcare such as the passage and implementation of the Patient Protection and Affordable Care Act have cemented the importance of primary care to public health in the 21st century.^{1–3} Although behavioral counseling interventions—preventive clinical services that help people engage in healthy behaviors and minimize unhealthy ones⁴—have been shown to be efficacious and effective at chronic disease prevention and related risk factor reduction,^{5–7} they rarely receive the highest grade recommendation in national clinical guidelines and their wide integration into primary care remains elusive. Indeed, national guideline developers such as the U.S. Preventive Services Task Force (USPSTF or Task Force) have assigned the highest grade recommendation (A) to only one of the 11 reviewed primary care–focused and referable behavioral counseling intervention topics because of a lack of high-quality direct or indirect evidence of the net benefit to public health.⁸

Now more than ever there is an urgent need for high-quality evidence of effective models of collaborative care that embed behavioral counseling in primary care and improve health in the general primary care population. Scientific societies, such as the Society of Behavioral Medicine (SBM) can take an active role in enhancing the evidence base of behavioral counseling interventions so as to facilitate their recommendation by national guideline developers such as the USPSTF when the evidence suggests substantial benefit for patients. Herein, we, as members of SBM, provide a brief history of SBM, review the USPSTF mandate and current recommendations for behavioral counseling interventions, and provide a perspective that calls for coordinated efforts among SBM, USPSTF, and other organizations invested in the rapid and wider uptake of beneficial, feasible, and referable primary care–focused behavioral counseling interventions.

History of the Society of Behavioral Medicine

The principles underlying behavioral medicine are likely thousands of years old,⁹ yet the field is relatively young. In 1978, Neal E. Miller, a behavioral scientist who conducted landmark studies on learning and biofeedback and who is frequently credited as the founder of behavioral medicine, along with David Hamburg, former president of IOM, convened a 2-day meeting of behavioral and biomedical scientists for a singular purpose: to establish a viable theoretic framework for integrating the behavioral and biological sciences. This meeting helped define the new field of behavioral medicine and spawned a scientific society intended to advance it, the SBM.

The SBM is a multidisciplinary organization composed of behavioral and biomedical scientists and practitioners from diverse professions including psychology, public health, medicine, and nursing. Its vision statement, “better health through behavior change,” aptly reflects the organization’s commitment to promoting the study of the interactions of

behavior, biology, and the built and social environment, and to applying that knowledge to improve the health of individuals, families, communities, and populations.¹⁰ Its annual meeting and its journals *Annals of Behavioral Medicine* and *Translational Behavioral Medicine*, as well as its 21 special interest groups, provide interactive forums for thousands of researchers and practitioners.

The SBM members, committees, and working groups have been at the forefront of the development, training, implementation, dissemination, and guideline development of evidence-based behavioral counseling interventions for children and adults. For example, committee members on behalf of SBM have published position statements and policy briefs on pressing national health issues such as healthcare coverage for diabetes self-management, the appropriate use of intensive behavior therapy for obesity, and correct implementation models for smoking-cessation programs.^{11–13} SBM members have also served as national experts in the USPSTF.

U.S. Preventive Services Task Force Mandate

As discussed in previous sections of this special issue, the USPSTF is an independent, volunteer panel of 16 national experts in preventive medicine. In 1984, the Task Force was created, 6 years after SBM, with the mandate to improve the health of all Americans by making evidence-based recommendations about clinical preventive services and health promotion; this is done to facilitate shared decision making among patients, their providers, and their families.¹⁴ Task Force recommendations focus on interventions to prevent or decrease the severity of disease, and these are applied only to patients without signs or symptoms of disease. USPSTF offers recommendations about services that are provided either directly to patients in the primary care setting or indirectly through referrals made by primary care practitioners. Thus, the primary care setting and its practitioners serve as the primary conduits for health promotion and disease prevention. Importantly, local policies within a given primary care setting and national healthcare policies also influence healthcare decisions shared among patients, their providers, and their families. To make these evidence-based recommendations, the USPSTF conducts a comprehensive and rigorous scientific assessment of the eligible evidence. Each of the recommendations are assigned a letter grade (A, B, C, or D) or are issued an I (insufficient) statement, based on an evaluation of the certainty of the evidence and on the balance of benefits and harms of the preventive or clinical service.¹⁵ Although not a focus of this review, USPSTF recommendations may also have important implications for both adoptability and also reimbursability of behavioral counseling practices in primary care.

U.S. Preventive Services Task Force Evidence Standards and Current Behavioral Counseling Interventions

The USPSTF has strict criteria and standards for what it considers evidence (see Section 1 of this special issue). As shown in Figure 1, both direct and indirect evidence of net benefit is considered within the context of an analytic framework that relates preventive clinical services to outcomes.¹⁵ USPSTF grade A or B recommendations are based on high-quality efficacy and effectiveness behavioral counseling trials that include an adequate

contemporaneous comparison group (for an illustrative example of eligible evidence for behavioral counseling interventions, see Lin et al.⁵). Direct evidence evaluates the effect of the clinical service on morbidity and mortality, whereas indirect evidence evaluates the effect of the clinical service on intermediate outcomes.

There are surprisingly few behavioral counseling interventions that have met the highest USPSTF evidence standards (grade A recommendation) and demonstrated substantial benefit to patients. In fact, only one of the USPSTF behavioral counseling intervention topics has received a grade A recommendation (Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women), five have received a grade B recommendation, and the remaining have received a grade C recommendation or a joint B and I recommendation (Table 1). The distribution of these letter grade recommendations reflect two salient realities in the field of behavioral medicine:

1. Most behavioral counseling interventions evaluate the indirect effect of the clinical service on intermediate outcomes (such as blood pressure, and so not on direct outcomes such as disease and mortality).
2. There are study design characteristics common to behavioral counseling intervention research that pose barriers to meeting the highest of USPSTF evidence standards.

Examples of these study design characteristics include^{4,8,16}:

1. RCTs are not powered to provide direct evidence of the effect of the behavioral counseling intervention on morbidity/mortality or even intermediary outcomes such as risk factors.
2. The selected population is not clearly described with respect to symptoms or risk status.
3. A usual care control condition is often not included.
4. The specific details of how to integrate tested behavioral counseling interventions within the primary care setting or create feasible referrals are not provided.
5. Multiple components or the active ingredients of interventions are not specified.
6. Standard metrics are not used or quantified (e.g., number of sessions, duration, outcomes).
7. A standard set of potential harms is not routinely collected.

There are additional factors unique to behavioral counseling intervention research that make designing the appropriate RCTs to meet the highest USPSTF standards particularly challenging. For example, there is often no gold standard intervention to serve as the usual care comparison group for behavioral counseling, and often other active interventions end up as the control group (at the request of grant application reviewers) to control for attention effects and reduce threats to internal validity (as discussed in detail elsewhere^{8,16,17}). This leads to a situation where the impact of the behavioral counseling intervention compared with usual primary care practice is unknown, and so the net public health benefit cannot be determined. Though we acknowledge that powerful statistical techniques such as meta-

analysis can differentiate treatment–control and treatment–treatment effect sizes, with trials in an area that test against a usual care control group, these techniques do not overcome this research practice problem. Further, although behavioral counseling researchers are heavily concerned with theory building or mechanistic research to identify causal pathways, the extent to which theory is incorporated into intervention design and further its influence on treatment effectiveness is unclear.¹⁸ Additionally, until the publication of the behavior change technique taxonomy, deciding upon a behavior change target was often an unsystematic process because of the absence of a scientific classification and common nomenclature for behavior change targets.¹⁹ This in turn contributed to a research tradition in behavioral counseling intervention research of not specifying the active intervention ingredients or behavior change techniques that were used. And, without the ability to determine the active ingredients of the intervention, interpreting the evidence is a major challenge to meeting the highest USPSTF standards; however, recent scientific advances (behavior change technique taxonomy) may help address this research practice problem. Several research approaches have been offered to enhance the generalizability of the targeted behavioral counseling intervention, including recommendations for fewer eligibility restrictions, greater attention to external and internal validity, use of comparative effectiveness research designs, use of systematic reporting protocols (e.g., Pragmatic–Exploratory Continuum Indicator Summary, Reach, Effectiveness, Adoption, Implementation, and Maintenance, the 5R’s [Relevance, Rapidity, Rigor, Resource Reporting, and Replicability]), and, importantly, calls to design for the real world in the form of pragmatic clinical trials.^{20–24} In addition to these novel approaches, there is a pressing need for new perspectives about how to account for the significant role of guideline developers such as the USPSTF and how to propose adequate design features to satisfy their evidence standards, while appropriately testing the behavioral counseling intervention under investigation.

A Perspective for the Future From Members of the Society of Behavioral Medicine

We believe that a compelling new perspective for the future is needed that promotes the generation of relevant high-quality RCT evidence on integrated preventive and behavioral counseling interventions within primary care, and that capitalizes on the healthcare transformations and innovations of the 21st century in order to inform evidence-based clinical guidelines that have a direct influence on modern primary care practice. To advance this perspective, concerted and coordinated efforts from societies and organizations invested in preventive medicine such as SBM, USPSTF, and others are needed. We propose five strategies to achieve this aim.

1. Establish a Research Trial Infrastructure for Behavioral Counseling Interventions

Practice-based research networks (PBRNs) are primary care practices that work collectively to answer community-relevant healthcare questions and translate research results into practice.^{25,26} To register as a PBRN with the Agency for Healthcare Research and Quality, a practice must be composed of at least 50% primary care clinicians, include a minimum of five practice locations and 15 clinicians, and have a director and a mission statement.²⁷

PBRNs ensure that a representative set of patient, demographic, and contextual factors are included in these studies, thereby increasing the external validity and quality of the evidence base. PBRNs now exist nationwide and there is evidence to show that these networks can be the setting in which large, pragmatic cluster RCTs are conducted with success.^{28–30} However, there are challenges to conducting PBRN research, such as creating efficient processes for vetting research questions and study teams; managing multisite budgets, recruitment, and physician/staff training; and obtaining IRB approval for multicenter studies.³¹ In order to conduct the high-quality RCTs needed in behavioral medicine to inform clinical guidelines, we need to investigate exemplars of existing PBRNs, understand their funding opportunities, and establish a national network of behavioral counseling clinical and research experts who can partner with PBRNs. This process would establish the foundation for a sustainable learning system to continuously improve upon our conduct of excellent national studies. A behavioral counseling–focused PBRN would allow for the randomization of more than 1,000 primary care clinics, thereby providing the most comprehensive test of whether a behavioral counseling intervention improves outcomes and reduces risk; individual behavioral interventionists would never be able to accomplish this on their own. National scientific societies such as SBM could play a vital role in the creation and maintenance of a behavioral counseling–PBRN partnership, and provide a mechanism to conduct effectiveness, implementation, and dissemination research.

2. Promote Awareness of U.S. Preventive Services Task Force Evidence Standards and Promote Trails that Are Designed for Wide-Scale Implementation

Task Force methods and practices are often unknown to behavioral counseling interventionists. There is an urgent need to increase awareness of USPSTF evidence standards and more directed research training in how to improve the overall quality of the evidence base to inform national clinical guidelines and maximize the potential for implementation across contexts. For example, focused research training in how to conduct RCTs that are adequately powered to examine primary outcomes of relevance in primary care will enhance the quality and germaneness of the evidence base. Relatedly, many of our behavioral counseling interventions entail doses, training costs, implementation costs, and significant respondent burden that would prohibit their wide adoption.¹⁶ Thus, we need to learn how to design studies for real-world implementation.^{4,17} This includes not only raising awareness about the importance of reporting sufficient contextual factors for future implementation but also greater attention to moderating factors such as race/ethnicity, gender, and SES.^{16,21} Examples of existing training programs that address these training needs are the Office of Behavioral and Social Science Research intensive 2-week training on the Design and Conduct of RCTs Involving Behavioral Interventions, and the National Cancer Institute Summer Training Institute in Dissemination and Implementation Science. Partnering these research training programs with pragmatic, hands-on experience in the conduct of a large, multicenter trial could prove invaluable for sustaining a research workforce that is prepared to conduct the next trial.

3. Establish Quality Control and Improvement Procedures for All Behavioral Counseling Training

Behavioral counseling interventions may be delivered by providers from diverse professions such as psychology, medicine, social work, public health, or nursing. In the absence of standardized behavioral counseling training (as presumed in other fields of medicine), systematic profession-based variation in the type and quality of training received and services rendered may affect the overall quality of the evidence accrued for behavioral counseling. Although at least one study indicates that the type of profession (social work, mental health counseling) may not predict psychotherapy effectiveness at the patient level,³² additional research to determine whether profession-based variation in provider training influences the quality of the evidence base for behavioral counseling intervention research is warranted. Thus, there may be a great need to establish quality control and improvement procedures for the training of all behavioral counseling providers, including physicians, psychologists, social workers, nurses, and other practitioners that operate in the primary care setting. However, we recognize that a detailed discussion of the development of a behavioral health workforce competency strategy, including establishing competencies that differ by profession and illness domain, training, and staff development,^{33,34} is outside the scope of this manuscript.

Behavioral counseling requires a specific set of high-level skills that are not easily learned without adequate didactic and experiential training and supervision. National organizations such as SBM could partner with agencies such as the Accreditation Council for Graduate Medical Education (ACGME) to ensure that the general physician competencies related to prevention counseling are standardized, of relevance, and of high quality. Involvement with the ACGME now while there is an impetus to develop a common taxonomy of competency domains for health professionals and competencies for physicians³⁵ would ensure that high-quality behavioral medicine didactic and experiential training is included as part of the core competency physician training. Additionally, practicum and internship programs within multicenter research teams could then be developed to ensure a pipeline of excellently trained behavioral counseling providers. These opportunities would create a continuously learning healthcare system³⁶ in which our sophistication and ability to test new behavioral counseling interventions is constantly improving, and actively contributing toward the training of the next generation of behavioral providers as well as those who can aid in the dissemination of an evidence-based behavioral counseling intervention. Further, primary care patients expect that when a behavioral counseling intervention is recommended and is needed, that a qualified, competent provider can be located. Yet, there are no clear methods to identify said provider. Although there are existing credentialing bodies that facilitate identification of health educators (Certified Health Education Specialist³⁷), these models have not been widely adopted or proven effective. A potential solution is to create an easy-to-use web-based system for identifying these providers; such a system could be maintained by SBM and other organizations invested in its use.

4. Conduct Systematic Research on How Best and When to Integrate Primary Care Practitioners in the Delivery of or Referral to Behavioral Counseling Interventions

Although the importance of behavioral counseling interventions for chronic disease prevention is well established,³⁸ there remain outstanding questions such as how best to integrate primary care practitioners in the direct delivery of behavioral counseling interventions, when to have practitioners refer patients to behavioral counseling experts, how to make behavioral counseling experts integral to the primary care team, and how best to coordinate such care. Indeed, there is an urgent need for ongoing dialogue and research to determine under what conditions and for which populations primary care practitioners versus behavioral medicine experts should provide behavioral counseling and how to facilitate this integration and referral process; RCT designs could be used to answer these questions. It is plausible that the type of provider needed could be influenced by individual patient characteristics (disease entity, risk profile) or contextual characteristics (setting), but we do not have research or evidence to guide these clinical decisions currently. National organizations such as SBM and USPSTF could take a leadership role in facilitating this dialogue and conducting a programmatic inquiry (e.g., modified Delphi polls, commissioning an IOM report) to determine how best to establish, evaluate, disseminate, and implement these collaborative care models. Importantly, continued dialogue about best practices for dissemination and implementation could also inform the wider adoption of effective and referable behavioral counseling interventions in modern primary care practice.

5. Pioneer Methodologic Innovations and Disruptions that Capitalize on Current Healthcare Transformation

Healthcare transformation provides an exciting opportunity for rapid innovation and disruption in research priorities and evidence generation. Indeed, leaders in healthcare delivery and policy have identified research that aims to understand and compare the performance of new clinical organizations with physician practices and uses electronic data, rapid cycle research, and comparative effectiveness methods as their top research priorities for the next 3–5 years.³⁹ Wide adoption of these research priorities in behavioral medicine coupled with current methodologic innovations and technological disruptions have the potential to enhance the evidence base of behavioral counseling intervention research and the potential to inform national clinical guidelines such as those proposed by the USPSTF.

Disruptive technology, such as expanded clinical data systems and electronic registries, has the capability to collect high-quality standardized data across a large number of settings and patients. They introduce new resources for standardizing patient-reported data collection and new efficient means of establishing comparison groups to meet USPSTF evidence standards. As one example, registry-based randomized trials may provide a means to design large-scale trials by accessing potential participants at low cost from existing clinical systems and allowing for efficient clinical follow-up of morbidity and mortality.⁴⁰ Although relevant questions can be posed regarding this and other new trial recruitment, conduct, and outcome approaches, considering their potential benefit relative to recognized limitations in current clinical trial conduct seems worthy of the challenge. Embedding interventions within rapid learning systems of clinical care^{41,42} and capitalizing on the proliferation of e-health platforms has the potential to yield new types of study approaches and data structures.

In light of these innovations and disruptions, there is also a great need for dialogue on expanded definitions of rigor and quality. We do not propose to create standards of evidence that would favor behavioral counseling intervention research, but instead to encourage continued dialogue about the drawbacks and benefits of traditional RCT methods as typically implemented in behavioral medicine. For example, traditional RCTs are a strong method to account for confounding and many biases, but as they are classically conducted, they are problematic in terms of high cost, complexity in implementation and dissemination, and often inadequately representing a wide segment of a clinical population. The solution may be to identify methods and approaches that maintain the rigor of an RCT design to make qualified comparisons but an implementation and dissemination strategy that can improve our ability to address questions of generalizability. In other words, a potential solution may be to encourage research methods such as pragmatic randomized trials and comparative effectiveness trials that focus on enhancing the dissemination and implementation capacity of these interventions in real-world settings.⁴³

Emerging information technology such as the electronic health record (EHR) brings with it the potential for efficient access to standardized patient information⁴⁴ that can both enhance patient-centered care and clinical practice while supporting advances in behavioral counseling research. For example, many of the study design characteristics common to behavioral counseling research that often pose barriers to meeting the highest USPSTF evidence standards can be addressed by standardizing the electronic collection of a common set of patient measures such as health behaviors, psychosocial and psychological characteristics (that can later be used to tailor interventions and audience segmentation), behavioral intervention techniques or components, patient factors (demographics), and self-reported outcomes. Once standard data elements are clearly defined and consistently collected, we will gain the capability to compare measures of symptoms, health behaviors, and risk status across conditions and systems. Additionally, electronic coding systems could improve the collection of data around a standard taxonomy of behavioral counseling components (e.g., counts of reflective statements, open questions, feedback) and methods of quantifying intervention delivery. SBM in collaboration with the NIH, Patient-Centered Outcomes Research Institute, and other national organizations could help convene and coordinate an effort to evaluate and recommend common data elements for patient EHRs. This could extend work started by several institutes/offices from NIH with support from SBM that identified a core set of patient-reported measures of health behaviors and psychosocial factors for use in EHRs⁴⁴; the use of standardized data elements in EHRs is already being discussed to facilitate multisite clinical trial research in Europe.⁴⁵

Conclusions

USPSTF clinical guidelines currently have rarely assigned grade A recommendations to behavioral counseling interventions for chronic disease prevention or risk reduction because of concerns about the quality of the evidence base, and lack of certainty that substantial benefit would accrue to those who were offered these behavioral counseling interventions. Thus, there is an urgent need for concerted and coordinated efforts to enhance the quality of adequately powered RCTs testing feasible and referable primary care behavioral counseling interventions as a means to provide the most credible evidence on which to judge if certain

behavioral counseling interventions should be recommended for use in primary care settings. As members of the SBM, we present a perspective for the future to address this need that leverages the shared mission of SBM and USPSTF. We highlight five areas for further development, including: behavioral counseling–focused PBRNs, promotion of USPSTF evidence standards and pragmatic RCT methods, quality control and improvement procedures for behavioral counseling training, systematic research on effective primary care–based collaborative care models, and methodologic innovations that capitalize on disruptive technologies and healthcare transformation. If we are to improve the health of all Americans, we need to work collectively to ensure that effective, feasible, and referable behavioral counseling interventions are embedded in modern primary care practice.

Acknowledgments

The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of the Society of Behavioral Medicine, NIH, or the Patient-Centered Outcomes Research Institute. C. Alcántara is supported by HL115941-01S1 from the National Heart, Lung, and Blood Institute of NIH. K.W. Davidson is supported by NIH grants HL114924, HL115941, HL088117, and HL084034, and a grant from New York Presbyterian Hospital. L.M. Klesges is supported by R13HL123259 from the National Heart, Lung, and Blood Institute, and R01CA172253 from the National Cancer Institute of NIH, and IH-1304-6147 from the Patient-Centered Outcomes Research Institute.

References

1. Goodson JD. Patient protection and affordable care act: Promise and peril for primary care. *Ann Intern Med.* 2010; 152(11):742–744. <http://dx.doi.org/10.7326/0003-4819-152-11-201006010-00249>. [PubMed: 20404263]
2. Public Law 111-148 - The Patient Protection and Affordable Care Act, (March 23, 2010).
3. Hofer AN, Abraham JM, Moscovice I. Expansion of coverage under the patient protection and affordable care act and primary care utilization. *Milbank Q.* 2011; 89(1):69–89. <http://dx.doi.org/10.1111/j.1468-0009.2011.00620.x>. [PubMed: 21418313]
4. Curry SJ, Grossman DC, Whitlock EP, Cantu A. Behavioral counseling research and evidence-based practice recommendations: U.S. Preventive services task force perspectives. *Ann Intern Med.* 2014; 160(6):407–413. <http://dx.doi.org/10.7326/M13-2128>. [PubMed: 24723080]
5. Lin JS, O'Connor E, Evans CV, Senger CA, Rowland MG, Groom HC. Behavioral counseling to promote a healthy lifestyle in persons with cardiovascular risk factors: A systematic review for the u.S. Preventive services task force. *Ann Intern Med.* 2014; 161(8):568–568. <http://dx.doi.org/10.7326/M14-0130>. [PubMed: 25155549]
6. Leblanc ES, O'Connor E, Whitlock EP, Patnode CD, Kapka T. Effectiveness of primary care-relevant treatments for obesity in adults: A systematic evidence review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2011; 155(7):434–437. <http://dx.doi.org/10.7326/0003-4819-155-7-201110040-00006>. [PubMed: 21969342]
7. U S. Preventive Services Task Force. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: U.S. Preventive Services Task Force reaffirmation recommendation statement. *Ann Intern Med.* 2009; 150(8):551–555. <http://dx.doi.org/10.7326/0003-4819-150-8-200904210-00009>. [PubMed: 19380855]
8. Whitlock EP, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: An evidence-based approach. *Am J Prev Med.* 2002; 22(4):267–284. [http://dx.doi.org/10.1016/S0749-3797\(02\)00415-4](http://dx.doi.org/10.1016/S0749-3797(02)00415-4). [PubMed: 11988383]
9. Weiss, SM. Early developments in the field of behavioral medicine. In: Gellman, MD.; Turner, JR., editors. *Encyclopedia of behavioral medicine.* New York: Springer; 2013. p. 2044–2047.
10. About the Society of Behavioral Medicine. Society of Behavioral Medicine; 2014. www.sbm.org/about

11. Pagoto SL, Pbert L, Emmons K. The society of behavioral medicine position statement on the CMS decision memo on intensive behavior therapy for obesity. *Transl Behav Med.* 2012; 2(4): 381–383. <http://dx.doi.org/10.1007/s13142-012-0168-x>. [PubMed: 24073141]
12. Expand United States health plan coverage for diabetes self-management education and support: A position statement of the Society of Behavioral Medicine. 2014. www.sbm.org/UserFiles/file/diabetes-brief_statement_short.pdf
13. SBM and SRNT Urge increased funding of Quitlines and Research to Maximize Public Health Benefits of 1-800-QUIT-NOW on Cigarette Packs. Society of Behavioral Medicine; 2012. www.sbm.org/UserFiles/file/SBM_and_SRNT_Statement_for_web.pdf
14. About the USPSTF. U.S. Preventive Services Task Force; 2013. www.uspreventiveservicestaskforce.org/about.htm
15. Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D. Update on the methods of the U.S. Preventive services task force: Estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007; 147(12):871–875. <http://dx.doi.org/10.7326/0003-4819-147-12-200712180-00007>. [PubMed: 18087058]
16. Glasgow RE, Klesges LM, Dzewaltowski DA, Bull SS, Estabrooks P. The future of health behavior change research: What is needed to improve translation of research into health promotion practice? *Ann Behav Med.* 2004; 27(1):3–12. http://dx.doi.org/10.1207/s15324796abm2701_2. [PubMed: 14979858]
17. Rothwell PM. External validity of randomised controlled trials: “To whom do the results of this trial apply?”. *Lancet.* 2005; 365(9453):82–93. [http://dx.doi.org/10.1016/S0140-6736\(04\)17670-8](http://dx.doi.org/10.1016/S0140-6736(04)17670-8). [PubMed: 15639683]
18. Prestwich A, Sniehotta FF, Whittington C, Dombrowski SU, Rogers L, Michie S. Does theory influence the effectiveness of health behavior interventions? Meta-analysis. *Health Psychol.* 2014; 33(5):465–464. <http://dx.doi.org/10.1037/a0032853>. [PubMed: 23730717]
19. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Ann Behav Med.* 2013; 46(1):81–95. <http://dx.doi.org/10.1007/s12160-013-9486-6>. [PubMed: 23512568]
20. Gaglio B, Shoup JA, Glasgow RE. The re-aim framework: A systematic review of use over time. *Am J Public Health.* 2013; 103(6):e38–e46. <http://dx.doi.org/10.2105/AJPH.2013.301299>. [PubMed: 23597377]
21. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The re-aim framework. *Am J Public Health.* 1999; 89(9):1322–1327. <http://dx.doi.org/10.2105/AJPH.89.9.1322>. [PubMed: 10474547]
22. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): A tool to help trial designers. *CMAJ.* 2009; 180(10):E47. <http://dx.doi.org/10.1503/cmaj.090523>. [PubMed: 19372436]
23. Peek C, Glasgow RE, Stange KC, Klesges LM, Purcell EP, Kessler RS. The 5 r’s: An emerging bold standard for conducting relevant research in a changing world. *Ann Fam Med.* 2014; 12(5): 447–455. <http://dx.doi.org/10.1370/afm.1688>. [PubMed: 25354409]
24. Davidson KW, Goldstein M, Kaplan RM, et al. Evidence-based behavioral medicine: What is it and how do we achieve it? *Ann Behav Med.* 2003; 26(3):161–171. http://dx.doi.org/10.1207/S15324796ABM2603_01. [PubMed: 14644692]
25. Green LA, Hickner J. A short history of primary care practice-based research networks: From concept to essential research laboratories. *J Am Board Fam Med.* 2006; 19(1):1–10. <http://dx.doi.org/10.3122/jabfm.19.1.1>. [PubMed: 16491999]
26. Lindbloom EJ, Ewigman BG, Hickner JM. Practice-based research networks: The laboratories of primary care research. *Med Care.* 2004; 42(4 Suppl):III45–9.10.1097/01.mlr.0000119397.65643.d4 [PubMed: 15026664]
27. Register your network. Agency for Healthcare Research and Quality; 2014. <http://pbrn.ahrq.gov/register-your-network>

28. Resnicow K, McMaster F, Woolford S, et al. Study design and baseline description of the BMI2 trial: Reducing paediatric obesity in primary care practices. *Pediatr Obes*. 2012; 7(1):3–15. <http://dx.doi.org/10.1111/j.2047-6310.2011.00001.x>. [PubMed: 22434735]
29. Slora EJ, Wasserman RC. PROS: A research network to enhance practice and improve child health. *Pediatr Ann*. 2010; 39(6):352–361. <http://dx.doi.org/10.3928/00904481-20100521-07>. [PubMed: 20669890]
30. Wasserman RC, Slora EJ, Bocian AB, et al. Pediatric research in office settings (PROS): A national practice-based research network to improve children's health care. *Pediatrics*. 1998; 102(6):1350–1357. <http://dx.doi.org/10.1542/peds.102.6.1350>. [PubMed: 9832568]
31. Graham DG, Spano MS, Stewart TV, Staton EW, Meers A, Pace WD. Strategies for planning and launching PBRN research studies: A project of the academy of family physicians national research network (AAFP NRN). *J Am Board Fam Med*. 2007; 20(2):220–228. <http://dx.doi.org/10.3122/jabfm.2007.02.060103>. [PubMed: 17341759]
32. Kraus DR, Castonguay L, Boswell JF, Nordberg SS, Hayes JA. Therapist effectiveness: Implications for accountability and patient care. *Psychother Res*. 2011; 21(3):267–276. <http://dx.doi.org/10.1080/10503307.2011.563249>. [PubMed: 21623550]
33. Hoge MA, Paris M Jr, Adger H Jr, et al. Workforce competencies in behavioral health: An overview. *Adm Policy Ment Health*. 2005; 32(5–6):593–631. <http://dx.doi.org/10.1007/s10488-005-3259-x>. [PubMed: 16082798]
34. Marrelli AF, Tondora J, Hoge MA. Strategies for developing competency models. *Adm Policy Ment Health*. 2005; 32(5–6):533–561. <http://dx.doi.org/10.1007/s10488-005-3264-0>. [PubMed: 16082796]
35. Englander R, Cameron T, Ballard AJ, Dodge J, Bull J, Aschenbrenner CA. Toward a common taxonomy of competency domains for the health professions and competencies for physicians. *Acad Med*. 2013; 88(8):1088–1094. <http://dx.doi.org/10.1097/ACM.0b013e31829a3b2b>. [PubMed: 23807109]
36. Smith, M.; Saunders, R.; Stuckhardt, L.; McGinnis, JM., editors. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Washington DC: National Academy of Sciences; 2013. Committee on the Learning Health Care System in America.
37. National Commission for Health Education Credentialing, Inc. 2008. www.nchec.org
38. Fisher EB, Fitzgibbon ML, Glasgow RE, et al. Behavior matters. *Am J Prev Med*. 2011; 40(5):e15–e30. <http://dx.doi.org/10.1016/j.amepre.2010.12.031>. [PubMed: 21496745]
39. Gluck, M.; Radomski, L. *The Academy Health Listening Project Report: Improving the Evidence Base for Medicare Policymaking*. Academy Health; 2014. <http://academyhealth.org/files/publications/listeningprojectmedicare.pdf>
40. Lauer MS, D'Agostino RB Sr. The randomized registry trial--the next disruptive technology in clinical research? *N Engl J Med*. 2013; 369(17):1579–1581. <http://dx.doi.org/10.1056/NEJMp1310102>. [PubMed: 23991657]
41. Abernethy AP, Etheredge LM, Ganz PA, et al. Rapid-learning system for cancer care. *J Clin Oncol*. 2010; 28(27):4268–4274. <http://dx.doi.org/10.1200/JCO.2010.28.5478>. [PubMed: 20585094]
42. A Foundation For Evidence-Driven Practice: A Rapid Learning System For Cancer Care: Workshop Summary. Washington DC: National Academy of Sciences; 2010.
43. Selby JV, Beal AC, Frank L. The patient-centered outcomes research institute (PCORI) national priorities for research and initial research agenda. *JAMA*. 2012; 307(15):1583–1584. <http://dx.doi.org/10.1001/jama.2012.500>. [PubMed: 22511682]
44. Estabrooks PA, Boyle M, Emmons KM, et al. Harmonized patient-reported data elements in the electronic health record: Supporting meaningful use by primary care action on health behaviors and key psychosocial factors. *J Am Med Inform Assoc*. 2012; 19(4):575–582. <http://dx.doi.org/10.1136/amiajnl-2011-000576>. [PubMed: 22511015]
45. Doods J, Botteri F, Dugas M, Fritz F. A European inventory of common electronic health record data elements for clinical trial feasibility. *Trials*. 2014; 15:18. <http://dx.doi.org/10.1186/1745-6215-15-18>. [PubMed: 24410735]

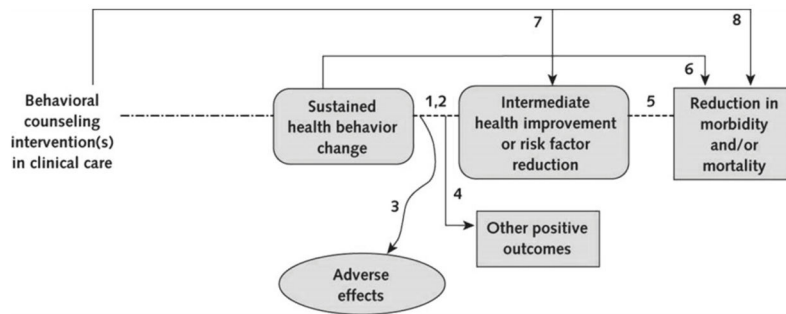


Figure 1.

Analytic framework for behavioral counseling interventions in clinical care

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, and 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 health care behaviors, improved function, and decreased use of health care resources)? 5. Is risk factor reduction or measured health improvement associated with reduced morbidity or mortality? 6. Is sustained health behavior change related directly to reduced morbidity 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 or mortality?

From *Annals of Internal Medicine*, Curry SJ, Grossman DC, Whitlock EP, Cantu A, Behavioral counseling research and evidence-based practice recommendations: U.S. Preventive Services Task Force perspectives, 160, 6, 407–13. Copyright © 2014 American College of Physicians. All Rights Reserved. Reprinted with the permission of American College of Physicians, Inc.

Table 1

Summary of USPSTF Grade Recommendations of Behavioral Counseling Interventions

Topic	RS Year	Current Grade
Healthful Diet and Physical Activity to Prevent Cardiovascular Disease in At-Risk Adults	2014	B: The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.
Primary Care Behavioral Interventions to Reduce Illicit Drug and Nonmedical Pharmaceutical Use in Children and Adolescents	2014	I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of primary care–based behavioral interventions to prevent or reduce illicit drug or nonmedical pharmaceutical use in children and adolescents. This recommendation applies to children and adolescents who have not already been diagnosed with a substance use disorder.
Primary Care Interventions to Prevent Tobacco Use in Children & Adolescents	2013	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.
Screening & Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse	2013	B: USPSTF recommends that clinicians screen adults aged 18 years or older for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse. I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening and behavioral counseling interventions in primary care settings to reduce alcohol misuse in adolescents.
Behavioral Counseling to Prevent Skin Cancer	2012	B: The USPSTF recommends counseling children, adolescents, and young adults aged 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer. I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of counseling adults older than age 24 years about minimizing risks to prevent skin cancer.
Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults	2012	C: Although the correlation among healthful diet, physical activity, and the incidence of cardiovascular disease is 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. Clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population.
Screening for and Management of Obesity in Adults	2012	B: The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m ² or higher to intensive, multicomponent behavioral interventions.
Screening for Obesity in Children and Adolescents	2010	B: The USPSTF recommends that clinicians screen children aged 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral intervention to promote improvement in weight status.
Counseling & Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults & Pregnant Women	2009	A: The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. A: The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy- tailored counseling for those who smoke.
Behavioral Counseling to Prevent STIs	2008	B: The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs. I: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of behavioral counseling to prevent STIs in non-sexually-active adolescents and in adults not at increased risk for STIs.
Counseling to Promote Breastfeeding	2008	B: The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.

Note: Behavioral counseling interventions may be delivered by practitioners as part of routine primary care practice or by behavioral counseling experts through a referral from a primary care practitioner.