Multiple Behavioral Risk Factor Interventions in Primary Care

Summary of Research Evidence

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Planning Committee of the Addressing Multiple Behavioral Risk Factors in Primary Care Project

Background: An important barrier to the delivery of health behavior change interventions in primary care settings is the lack of an integrated screening and intervention approach that can cut across multiple risk factors and help clinicians and patients to address these risks in an efficient and productive manner.

Methods: We review the evidence for interventions that separately address lack of physical activity, an unhealthy diet, obesity, cigarette smoking, and risky/harmful alcohol use, and evidence for interventions that address multiple behavioral risks drawn primarily from the cardiovascular and diabetes literature.

Results: There is evidence for the efficacy of interventions to reduce smoking and risky/harmful alcohol use in unselected patients, and evidence for the efficacy of medium- to high-intensity dietary counseling by specially trained clinicians in high-risk patients. There is fair to good evidence for moderate, sustained weight loss in obese patients receiving high-intensity counseling, but insufficient evidence regarding weight loss interventions in nonobese adults. Evidence for the efficacy of physical activity interventions is limited. Large gaps remain in our knowledge about the efficacy of interventions to address multiple behavioral risk factors in primary care.

Conclusions: We derive several principles and strategies for delivering behavioral risk factor interventions in primary care from the research literature. These principles can be linked to the “5A’s” construct (assess, advise, agree, assist, and arrange-follow up) to provide a unifying conceptual framework for describing, delivering, and evaluating health behavioral counseling interventions in primary healthcare settings. We also provide recommendations for future research.

Introduction

Lack of regular physical activity, an unhealthy diet, smoking, and alcohol misuse are leading causes of disease, death, and loss of functioning.1,2 Healthy People 2010 has designated tobacco use, physical activity, substance abuse, and overweight/obesity as four of the leading health indicators that will be closely monitored to reflect the health of the United States.1

Primary care clinicians have the potential to play an important role in addressing these key behavioral risk factors in the general population. For example, data from the 2000–2001 U.S. National Health Interview Survey indicate that 83% of the adults aged 18 to 64 years report that they have a usual source of care, a place where they usually go when they are “sick or ... need advice about health.”3 Moreover, the longitudinal nature of primary care provides multiple opportunities for clinicians to provide health behavior advice and counseling over long periods of time. According to recent data from a national sample of patients, >40% of patients aged >40 have had the same doctor for >5 years.4 Because a majority of adults in the United States have at least two of the four leading risk behaviors (see articles in this supplement by Fine et al.5 and Coups et al.6), strategies for addressing multiple risk behaviors within primary care settings are clearly needed. However, an important barrier to the delivery of health behavior change interventions in primary care settings is the lack of an integrated screening and intervention approach that can cut across multiple risk factors and...
help clinicians and patients to address these risks in an efficient and productive manner.\(^7,8\)

Although there is increasing evidence for the effectiveness of brief primary care–based interventions for changing individual health risk behaviors (e.g., tobacco use, risky drinking),\(^9\) few research trials in primary care settings have attempted to address multiple behavioral risk factors in a single intervention.\(^10\) In this paper, we will first review the evidence for interventions that separately address these four health behaviors in primary care settings. Then, because of the dearth of research evidence on multiple behavioral risk factor interventions in general populations of patients, we will review evidence for interventions that address multiple behavioral risks drawn primarily from the cardiovascular and diabetes literature. This is followed by suggestions for principles for delivering multiple behavioral risk factor interventions in primary care settings based on extrapolations from single risk factor evidence, the limited evidence from multiple behavioral risk factor interventions and other current data. We conclude with recommendations for future research.

**What Do We Know About Single Behavioral Risk Factor Interventions in Primary Care?**

The United States Preventive Services Task Force (USPSTF), which relies on rigorous systematic evidence reviews demonstrating high-quality evidence of clinically significant benefits on health outcomes to recommend clinical preventive services,\(^11\) has recently published revised recommendations and associated systematic reviews addressing physical activity,\(^12,13\) dietary counseling,\(^14,15\) obesity,\(^16,17\) smoking,\(^18\) and risky and harmful drinking.\(^19,20\) To address smoking, we also utilized the *Clinical Practice Guideline for Treating Tobacco Use and Dependence*, published by the U.S. Public Health Service (PHS) in 2000.\(^21\)

To complement the evidence gathered by the USPSTF and PHS, we have also reviewed evidence-based recommendations for population-based health activities, including environmental and health system interventions, for these behaviors from the Task Force on Community Preventive Services (Community Task Force) *Guide to Community Preventive Services: Systematic Reviews and Evidence-Based Recommendations*.\(^22\) Although Community Task Force recommendations are based on systematic reviews of research evidence from interventions outside the realm of primary care, these community-based interventions can complement, extend, and even support primary care interventions.\(^7,23,24\) Evidence reviews and the associated recommendations by the Community Task Force for addressing tobacco control and physical activity have been published.\(^25,26\)

The reviews and recommendations for community-based dietary improvement are expected in 2004 while the Community Task Force systematic review and recommendations for alcohol use and abuse are expected at a later date.

**Physical Activity**

In August 2002, the USPSTF found insufficient evidence (an “I” recommendation) to recommend for or against behavioral counseling in primary care settings to promote physical activity (Table 1).\(^15\) The USPSTF evidence-based review that generated this recommendation included controlled trials and observational studies in which; (1) a primary care clinician performed some of the counseling intervention; (2) physical activity outcomes were reported; and (3) the study was of “good” or “fair” quality, according to criteria developed by the USPSTF.\(^12\) Eight trials involving 9054 adults met inclusion criteria.\(^12\) The “I” recommendation was based on the mixed quality of the reviewed trials and the limited evidence for a sustained effect on physical activity.\(^12\) Most of the studies reviewed by the USPSTF reported nonsignificantly increased physical activity outcomes in the intervention groups 6 to 24 months after follow-up. Most of these studies compared brief, minimal, and low-intensity interventions, such as 3 to 5 minutes of counseling in the context of a routine clinical visit, with or without short-term follow-up mailings, telephone calls, or visits with usual care controls.

The Community Task Force has strongly recommended several evidence-based strategies to increase physical activity.\(^25\) Members reviewed three broad approaches to increasing physical activity: (1) informational approaches to change knowledge and attitudes about the benefits of and opportunities for physical activity; (2) environmental and policy approaches to change the structure of physical and organizational environments to provide safe, attractive, and convenient places for physical activity; and (3) behavioral and social approaches to assist individuals to adopt and maintain increased physical activity.\(^25,27\) The authors of the Community Task Force review found two informational approaches, one environmental and policy approach and three behavioral and social approaches to be effective.\(^27\) Within the category of behavioral and social support approaches, the Community Task Force strongly recommended tailoring behavioral interventions to the individual’s specific interests, preferences, and readiness for change and strategies to build community-based social support for physical activity.\(^25,27\) Programs that were effective in producing positive physical activity outcomes (i.e., time spent in physical activity, energy expenditure, or aerobic capacity) incorporated the following behavioral approaches: (1) goal setting for physical activity and self-monitoring of progress toward goals; (2) garnering social support for new physical activities; (3) self-reward and positive self-talk to reinforce physical activity; (4) structured problem solving to help maintain increased physical
Healthy Diet

In January 2003, the USPSTF found insufficient evidence (an “I” recommendation) to recommend for or against behavioral counseling to promote a healthy diet in unselected patients in primary care settings (Table 1). According to USPSTF standards, there was fair evidence that brief low- to medium-intensity (single or limited multiple contacts lasting <30 minutes) dietary counseling in primary care produces small to medium

Table 1. Evidence linking single health risk behavior counseling to health behavior change

<table>
<thead>
<tr>
<th>Behavior</th>
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<th>Community Task Force recommendation</th>
<th>Opportunity for primary care</th>
</tr>
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<tbody>
<tr>
<td>Healthy diet</td>
<td>B (Specially trained providers) I (Primary care providers) Behavioral counseling in primary care to promote a healthy diet; recommendation and rationale. Am J Prev Med 2003;24:93–100. Evidence review: Pignone MP, et al., Counseling to promote a healthy diet in adults; a summary of the evidence for the U.S. Preventive Services Task Force. Am JPrev Med 2003;24:75–92.</td>
<td>Recommendation expected in 2004</td>
<td>Intensity of intervention related to outcome Most studies of specialty-trained providers had a moderate level of intervention intensity (multiple intervention contacts, but fewer than six, generally &lt;30 minutes per contact) Use of self-help materials, tailored mailings, and telephone counseling along with brief provider advice were moderately effective</td>
</tr>
<tr>
<td>Obesity</td>
<td>B (Screening and offering intensive counseling and behavioral intervention to obese adults) I (Moderate or low intensity counseling and behavioral intervention for obese adults) I (Counseling for overweight adults) Screening for obesity in adults: recommendations and rationale. Ann Intern Med 2003;139:930–2 Evidence review: McTigue KM, et al., Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003;139:933–49.</td>
<td>No recommendation</td>
<td>Body mass index is reliable and valid for identifying individuals at increased risk Fair to good evidence that high intensity counseling with behavioral interventions produces sustained weight loss in obese individuals High intensity = more than one session per month for at least 3 months Effective interventions targeted both diet and physical activity and included elements that addressed skill development, motivation, and support Pharmacologic interventions can produce modest weight loss; should only be used as part of a program that includes behavioral intervention Surgical interventions should be reserved for those with Class III obesity</td>
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changes in self-reported dietary components. However, because this evidence is limited by reliance on self-reported diet outcomes, limited use of corroborating measures, limited follow-up data beyond 6 to 12 months, and enrollment of study participants who might not be representative of primary care patients, the USPSTF judged this evidence insufficient to determine the magnitude of benefit or the clinical significance of these changes.15

On the other hand, based on good evidence by its standards, the USPSTF gave a “B” recommendation for intensive behavioral dietary counseling for adult patients at high risk (i.e., patients with hyperlipidemia or other known risk factors for cardiovascular or other diet-related chronic disease).15 The USPSTF specified that intensive intervention could be delivered by specially trained primary care clinicians or other specialists (e.g., nutritionists, dietitians, health educators).15 The systematic evidence review on which the USPSTF based these recommendations identified 21 trials that met its inclusion criteria (i.e., randomized controlled trials of ≥3 months’ duration with measures of dietary behavior that were conducted in patient populations similar to those found in primary care practices).14

Studies that specifically recruited patients with chronic illnesses (e.g., heart disease, diabetes) or that required special diets were excluded, although studies that enrolled patients with known risk factors (e.g., elevated cholesterol, hypertension, obesity) were included. This review found good evidence that medium-to-high-intensity counseling interventions produced medium or large changes in average daily intake of saturated fat, fiber, and fruits and vegetables among high-risk patients.14 Moreover, higher-intensity interventions produced larger effects than studies using brief interventions.14 However, most of the studies using specialty-trained clinicians with high-risk patients actually had only a medium level of intervention intensity (i.e., between two and five) intervention contacts, with generally <30 minutes per contact).14 Because higher-intensity interventions were usually delivered in trials that utilized special research clinics and subjects

Table 1. (continued)

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<tr>
<td>Preventing/ceasing tobacco use</td>
<td>A</td>
<td>Strongly recommended:</td>
<td>Screening of tobacco use is essential</td>
</tr>
<tr>
<td>Risky/harmful alcohol use</td>
<td>B (Screening and behavioral counseling interventions)</td>
<td>No recommendation</td>
<td>Screening can accurately identify patients whose levels of alcohol use place them at risk for increased morbidity and mortality Brief 15-minute counseling interventions and follow-up produce sustained small to moderate reductions in hazardous drinking Effective interventions include feedback, advice, goal setting, and follow-up</td>
</tr>
</tbody>
</table>

Note: This table was adapted with permission from Whitlock, EP and Williams, SB. The primary prevention of heart disease in women through health behavior change promotion in primary care, Womens Health Issues 2003;13:122–41.

*Key to grade: A, strongly recommends; B, recommends; C, no recommendation for or against; D, recommends against routine provision to asymptomatic patients; and I, insufficient evidence.
who were selected because they were at risk for disease, the larger effects seen in these trials may have been related to selection bias. That is, subjects who agreed to participate in such trials may have been more motivated and thereby more likely to respond to the intervention than unselected patients who are offered an intervention within primary care settings.28 The USPSTF review panel partially addressed this limitation by conducting an analysis that explored the relationship between the risk status of the patients and the effect size achieved. After stratifying by intervention intensity, there was no clear relationship between patient risk status and the effect size achieved.14 However, other differences in the representativeness of the samples across the studies (e.g., motivation, willingness to be randomized to an intensive intervention condition) were not addressed in these analyses.

In a more comprehensive report on the effects of dietary counseling, the USPSTF panel identified the following components of dietary counseling that are associated with improved behavioral outcomes: using a dietary assessment, enlisting family involvement, providing social support, using group counseling, emphasizing food interaction, encouraging goal setting, and using advice tailored to the patient group being studied.29 Interventions including a greater number of these components have larger effects than those with fewer components, while interventions that added self-help materials and interactive communications (e.g., computer-generated tailored reports, telephone counseling) to brief provider advice produced “medium” effects.29 Two approaches were judged to be especially promising by the USPSTF: (1) medium-intensity face-to-face dietary counseling delivered by a specially trained clinician; and (2) low-intensity brief counseling (<5 minutes) supplemented by self-help materials, follow-up telephone counseling, or other interactive health communications.15 The latter approach to intervention was judged to be most feasible in primary care settings when system supports for their delivery are available.14 The medium intensity intervention would require either dissemination of training to develop the counseling skills of the primary care clinician or an effective hand-off between the primary care team and another specially trained clinician (e.g., dietitian, health educator, specially trained nurse).

Obesity

The USPSTF evidence-based review and recommendations on counseling to promote a healthy diet, discussed in the section above, excluded nutritional counseling that focused primarily on weight loss, weight maintenance, or obesity.14 Subsequently, in late 2003, the USPSTF recommended that clinicians screen all adult patients for obesity using body mass index (BMI) measurement and offer intensive counseling and behavioral interventions for those screening as obese (BMI>30kg/m²) (a “B” recommendation)17 (Table 1). The recommendation for screening was based on the USPSTF’s conclusion that there was good evidence that BMI, calculated as weight in kilograms divided by height in meters squared, validly and reliably identifies adults with increased risk for morbidity and mortality due to excess weight.16,17 The USPSTF’s recommendation to offer intensive intervention was based on finding fair-to-good evidence for moderate, sustained weight loss in obese patients receiving high-intensity counseling that addressed physical activity, dietary improvement, or both, in combination with behavioral intervention strategies to develop skills and motivations, and provide support.16,17 On the other hand, the USPSTF found insufficient evidence (an “I” recommendation) to recommend for or against low- or moderate-intensity counseling and behavioral interventions, and insufficient evidence (an “I” recommendation) regarding weight loss and maintenance following counseling and behavioral interventions of any intensity in adult patients who are overweight but not obese (BMI of 25 to 29.9 kg/m²).16,17

The systematic evidence review on which the USPSTF based its recommendations16 identified three prior well-done systematic reviews of counseling and behavioral interventions that reported on net mean weight change at 12 months (intervention minus control). The U.S. National Institutes of Health Review found a net mean weight change of −3.3 kg (range 1.9 to −8.8) for the 29 randomized controlled trials (RCTs) they reviewed, and also established that modest counseling-associated weight loss of 5 to 10 kg could improve blood pressure, glycemic control, and serum lipid levels.30 The United Kingdom National Health Service review found a net mean weight change of −3.0 kg (range 1.4 to −10.6) for 24 RCTs over 12 to 60 months.31 In a smaller review of six RCTs, the Canadian Task Force on Preventive Health Care found a net weight change of −2.1 kg (range −0.2 to −4.5) after 24 to 84 months.32 In addition, the systematic review conducted for the USPSTF identified 17 additional RCTs of high-intensity (more than monthly person-to-person contact in the first 3 intervention months), medium-intensity (monthly contact in the first 3 months), or low-intensity intervention (less than monthly interpersonal contact in the first 3 months)16. The most effective interventions were of high intensity and combined two to three components (nutrition education, diet and exercise counseling, behavioral strategies) to achieve weight loss of 3 to 5 kg at 1 year.16

Smoking

Clinician counseling of all patients to reduce or stop the use of tobacco products was the only primary-care counseling service given an “A” recommendation by
the USPSTF in 1996.33 In June 2000, the PHS strongly recommended clinician counseling for smoking cessation in its revised Clinical Practice Guideline for Treating Tobacco Use and Dependence (PHS Guideline).21 The PHS Guideline was cited as evidence for the USPSTF’s recently updated “A” recommendation for tobacco use screening and intervention in primary care.18 The PHS Guideline Panel and the USPSTF based their recommendations on evidence that minimal advice or counseling (≥1 to 3 minutes of person-to-person contact in a single session) significantly increases abstinence rates.21 Moreover, across 43 trials included in a PHS Guideline meta-analysis, there was a dose-response relationship between the intensity of smoking cessation intervention and smoking-cessation outcome.21 Thus, more intensive interventions (total contact of 30 to 90 minutes over two to eight contacts) are recommended for those patients who are willing to commit to intensive treatment. However, because only a small percentage of smokers are willing to accept intensive smoking-cessation treatment,34 brief primary care–based interventions have the potential to reach and assist a much larger proportion of smokers.35

Behavioral problem solving, assisting the patient to access social support, and providing the support element within the context of treatment were identified as effective intervention elements by the PHS Guideline panel.21 The PHS Guideline also recommended that clinicians offer effective pharmacotherapies (sustained-release bupropion or nicotine replacement therapy) for those patients attempting to quit, except when contraindicated.21 Also, interventions that are provided through three or four different formats (i.e., self-help, proactive telephone counseling, group counseling, and individual counseling) have higher abstinence rates than those limited to one format. The involvement of more than one provider in the delivery of interventions (e.g., physician and nurse) was associated with higher abstinence rates than interventions delivered by a single clinician, although this was a nonsignificant trend.21

The Community Task Force Guide to Community Preventive Services has strongly recommended two healthcare system interventions to increase or improve the delivery of smoking-cessation interventions in primary care: (1) Multicomponent systems that identify smokers, remind providers to intervene, provide access to patient educational materials, and train providers to both identify and counsel smokers; and (2) Telephone support to provide tobacco users with follow-up counseling in addition to other proven interventions.36 The PHS Guideline, the USPSTF, and the Community Task Force all strongly recommend that healthcare organizations adopt systems to support primary care–based assessment, advice, and brief counseling, as well as systems to link the primary care setting with community-based resources that might provide educational materials, follow-up counseling, and more intensive treatment, when desired. The Community Task Force also recommended reducing patient out-of-pocket costs for effective cessation therapies, as this has been shown to increase the use of these recommended therapies and to increase the total number of tobacco-using patients who quit.26

**Risky/Harmful Drinking**

In 1996, the USPSTF recommended screening for problem drinking (a “B” recommendation),39 and this recommendation was updated in 2004 to also recommend brief multicontact primary care interventions for risky and harmful drinkers who are identified through screening.19 The USPSTF found good evidence that screening in primary care settings can accurately identify patients whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence, but place them at risk for increased morbidity and mortality.19 This evidence included three good-quality systematic reviews of screening37–39 and two good-quality nonsystematic reviews.40,41 These reviews are examined in more detail elsewhere.42 Strategies for screening for alcohol misuse are discussed in the paper by Babor et al. in this supplement.43

The 2004 systematic review of behavioral counseling interventions that supported the new USPSTF recommendations considered 15 intervention conditions tested in 12 trials of brief primary care–based interventions for risky (hazardous) and harmful drinking.20 The authors of the review found that brief multicontact interventions (those with ≤15 minutes of initial contact and at least one follow-up) significantly reduced average drinks per week and increased the proportion drinking at moderate levels at 6 to 12 months of follow-up.20 Compared with control participants, intervention participants reduced their weekly drinking by 13% to 34%, and 10% to 19% more intervention participants reported moderate drinking patterns at follow-up.20 Results for trials testing briefer interventions (≤15 minutes of initial contact without any follow-up) tended to favor intervention conditions over controls, but were not generally statistically significant.20 All interventions with statistically significant improvements in alcohol outcomes had at least two of the following key intervention elements: feedback, advice, and goal setting.20

The findings in the USPSTF systematic review were supported by a meta-analysis, conducted by Moyer et al.,44 that found that brief interventions were especially effective for those patients with less severe drinking problems. The Moyer meta-analysis also found evidence for the efficacy of brief intervention in the subset of studies (n = 34) that identified subjects by “opportunistic” screening in primary care or emergency department settings.44 The USPSTF recommendations are also generally consistent with a 2001 World Health Organization report on brief medical care–based interventions for hazardous and harmful drinking.45
What Do We Know About Multiple Behavioral Risk Factor Intervention Trials in Healthcare Settings?

In order to review evidence available for multiple behavioral risk factor interventions in healthcare settings, we searched for systematic reviews published between 1990 and the present (2004) in MEDLINE, Cochrane Library, and the Database of Abstracts of Reviews of Effects (DARE). Systematic reviews were chosen because they generally define a systematic process for selection and evaluation of studies included, with quality of the studies taken into account in conclusions. We used the following search terms: risk factor, behavior risk, multiple risk factor, self-management, disease management, and health education. These terms were also cross-referenced with key words for two health conditions where multiple behavioral risk factors are commonly considered: cardiovascular disease and diabetes. Although we considered expanding our search to include other chronic conditions (e.g., asthma, cancer prevention), we elected to limit our search to cardiovascular disease and diabetes for several reasons: (1) we were aware of several recently published systematic reviews that addressed multiple risk behaviors in the cardiovascular and diabetes literature; (2) we had difficulty identifying systematic reviews that addressed multiple risk behaviors for other specific conditions; and (3) conducting a more exhaustive search was beyond the scope of this project. The reference lists of retrieved reviews were also searched. We found no reviews that were limited to primary care settings. The reviews retrieved were further scanned for inclusion of primary care settings in at least some of the studies included. As a result, we excluded reviews that were exclusively evaluating interventions in hospital, rehabilitation, or community settings. We also excluded reviews that did not describe risk factor change outcomes among the outcomes reported. Through this process, we identified three systematic reviews for cardiovascular disease interventions, and three systematic reviews for diabetes interventions. Since all of these reviews included intervention settings outside of primary care, we will focus on findings with greatest relevance to primary care and we will highlight specific studies that targeted multiple behavioral risk factors in primary care settings.

Interventions to Address Multiple Behavioral Risk Factors in Cardiovascular Disease

A systematic review of the effectiveness of interventions targeting diet, physical activity, smoking cessation, and alcohol intake in reducing cardiovascular disease was published by Ketola et al. in 2000. The authors of this review identified 21 multiple risk factor intervention trials. Ten of these were secondary prevention studies (based on the presence of cardiovascular dis- ease before the intervention) and 11 were primary prevention studies. All studies were RCTs with follow-up for ≥1 year (range, 1 to 10.5 years). Outcomes reported included cardiovascular morbidity and mortality and change in risk factors. Among the eight primary-prevention, multiple risk factor studies that reported morbidity and mortality results, only two studies showed a significant effect on morbidity, and none on mortality. Among the five secondary prevention studies targeting multiple risk behaviors and reporting morbidity and mortality results, two demonstrated effects on mortality and one on cardiovascular morbidity. When both behavioral and physiologic (e.g., cholesterol, blood pressure) risk factor change outcomes were considered, both multiple risk primary prevention studies and multiple risk secondary prevention studies produced significant changes, although primary prevention studies were less likely to produce clinically significant change than secondary prevention trials. Significant changes in exercise, weight, and smoking were noted for both primary and secondary multiple risk factor prevention studies. One of three multiple risk secondary prevention trials targeting risky alcohol drinking produced a significant reduction in alcohol consumption, while the only multiple risk primary prevention trial targeting alcohol consumption did not have a significant effect on this outcome. The authors of this review conclude that multiple risk factor interventions should optimally be used for secondary prevention, rather than primary prevention, thus targeting patients with existing cardiovascular disease or those at high risk for cardiovascular disease (e.g., patients with existing hypertension, diabetes, hyperlipidemia).

The authors of a recent Cochrane review of primary prevention multiple risk factor intervention trials also concluded that there was little evidence for a clinically significant effect on cardiovascular disease outcomes. Physiologic risk factors (i.e., blood pressure and total blood cholesterol) as well as behavioral risk factors were included in this review. To meet inclusion criteria for this review, trials had to have each of the following elements: an RCT design; ≥6 months of follow-up; participants aged ≥40 years old and without clinical evidence of cardiovascular diseases; counseling or educational interventions, with or without pharmacologic treatment, that targeted more than one risk factor (i.e., smoking, physical inactivity, diet, blood pressure and total blood cholesterol); and outcomes that included risk factor changes. Of the 18 trials that met these eligibility criteria, ten reported both disease events and risk factors and only four were large enough to have sufficient power to demonstrate meaningful changes in clinical events. Follow-up periods ranged from 6 months to 11.8 years. Pooled effects across all studies revealed no effect on mortality.
or cardiac events, although a small benefit of treatment (about a 10% reduction in CHD mortality) may have been missed due to limitations in power and in the statistical approaches that were used.\textsuperscript{46} However, the pooled effects of intervention on changes in both behavioral and physiologic risk factors were significant, although modest, and were related to the amount of pharmacologic treatment (e.g., for hypertension or hyperlipidemia) included in the intervention. However, there was also evidence for the effectiveness of multiple risk factor counseling without pharmacologic treatments when high-risk hypertensive populations were targeted for intervention.\textsuperscript{46} In general, trials recruiting higher-risk individuals were more likely to produce beneficial intervention effects.\textsuperscript{46}

Results from PREMIER, a multicenter, multibehavioral risk factor intervention trial to address above-optimal blood pressure,\textsuperscript{93} were published in April 2003 and are not included in the Cochrane review. We have elected to describe the results of this trial because it meets the criteria for the Cochrane review and reports important and relevant findings. PREMIER investigators randomized 810 adults with above-optimal blood pressure (systolic 120 to 159 mm Hg and diastolic 80 to 95 mm Hg) to one of three conditions: (1) a behavioral intervention condition, which consisted of four individual counseling sessions and 14 group meetings with an “interventionist, typically a registered dietitian” to address weight, sodium intake, physical activity, and alcohol consumption; (2) the behavioral intervention plus the Dietary Approaches to Stop Hypertension (DASH) diet, which focused on adding increased consumption of fruits and vegetables and low-fat dairy products and decreased consumption of fat; and (3) an advice-only condition, which consisted of a single 30-minute individual session with an interventionist.\textsuperscript{93} At the end of the 6-month follow-up period, both behavioral interventions significantly reduced weight, lowered sodium intake and improved fitness, and the behavioral intervention plus DASH condition also increased fruit, vegetable, and low-fat dairy intake.\textsuperscript{93} Although all three interventions produced reductions in blood pressure and reductions in the prevalence of hypertension, both behavioral interventions produced significantly greater reductions in blood pressure than the advice-only group.\textsuperscript{93}

Additionally, at the end of the 6-month follow-up period, the two behavioral interventions significantly reduced the prevalence of both hypertension and above-optimal blood pressure compared to advice only.\textsuperscript{93} For example, 26% of the advice-only group was hypertensive at the follow-up point compared to 17% and 12% for the behavioral intervention and the behavioral intervention plus DASH groups, respectively.\textsuperscript{93} These changes in the prevalence and degree of hypertension, if sustained, would likely produce a substantial reduction in cardiovascular disease risk.\textsuperscript{93} Although the behavioral intervention plus DASH diet generally outperformed the behavioral intervention alone group, these differences were not significant.\textsuperscript{93} The results of the PREMIER trial extend the Cochrane review’s finding that multiple risk behavior interventions without pharmacologic agents are efficacious when delivered to hypertensive patients\textsuperscript{94} and to the broader population of patients with suboptimal blood pressure.\textsuperscript{94}

McAlister et al.\textsuperscript{48} reported results from a meta-analysis of 12 RCTs testing disease management interventions for coronary heart disease. The authors applied the following broad definition of disease management: “a combination of patient education, provider use of practice guidelines, appropriate consultation, and supplies of drugs and ancillary services.” Studies were included in the meta-analyses if they met the following criteria: were RCTs of interventions with at least two modalities (e.g., exercise element, telephone follow-up); addressed patients with existing cardiac disease; enrolled 50 or more patients; and were not inpatient based. All of the trials used a nurse or a multidisciplinary clinical team to deliver an intervention that included patient education and counseling, although the level and intensity of risk behavior counseling were not fully specified. The duration of the interventions ranged from 0.5 to 48 months. Two\textsuperscript{53,95,96} of the 12 trials\textsuperscript{53,57,62,93–104} identified patients from general practice settings, while the others recruited patients soon after a hospitalization or a visit to a chest pain clinic for a coronary artery disease episode or event.

One additional trial\textsuperscript{101} recruited patients from a hospital or chest pain clinic, but delivered a nurse-led intervention that coordinated and supported care within the primary care setting. Seven\textsuperscript{53,57,62,93–98,101} of the 12 trials tracked and addressed multiple behavioral risk factors, as well as physiologic risk factors (i.e., blood pressure, cholesterol).\textsuperscript{57,62,95–98} of the seven, including one\textsuperscript{95,96} of the three primary care-based trials, produced significantly greater improvements in risk factors than usual care interventions.\textsuperscript{48} The primary care-based study by Campbell et al.\textsuperscript{95} that was cited by McAlister et al.\textsuperscript{48} as having positive risk factor outcomes reported significant improvements in physical activity, diet, blood pressure management, and lipid management, although no effect on smoking cessation. Moreover, a second primary care–based trial\textsuperscript{53} included in the review produced significant improvements in exercise outcomes, although this finding was overlooked by McAlister et al.\textsuperscript{48} More details regarding these two primary care trials are provided below. Overall, across all 12 studies, McAlister et al.\textsuperscript{48} found significant improvements in processes of care for disease management interventions, although the risk ratios derived from the meta-analyses demonstrated no significant effect on recurrent coronary events or mortality. In summary, findings by McAlister et al.\textsuperscript{48} suggest that
nurse-led or multidisciplinary team–led secondary prevention programs that include multiple behavioral risk factor interventions can produce positive changes in behavioral risk factors, even when the intervention is delivered in primary care settings.

As previously noted, few of the multiple health behavior intervention trials reported in the three cardiovascular disease reviews were conducted in primary care settings. However, two large primary care–based primary prevention trials and two primary care–based secondary prevention trials all conducted in the United Kingdom, were included in the reviews and are particularly relevant to this discussion. Details regarding these four trials follow below.

The OXCHECK study was conducted in five urban general practices the United Kingdom in the early 1990s. Final results (not included in the Ketola et al. review) described outcomes for 4121 subjects recruited from general primary-care practice registration lists and randomly allocated to an approximately 1-hour, nurse-led multiple risk factor counseling session and as needed follow-up or an assessment-only control condition. All registered patients aged 35 to 64 were targeted for recruitment, irrespective of cardiovascular disease or risk status and 80% of eligible patients were enrolled in the study. At the initial health check intervention session, nurses assessed smoking, diet, exercise, and alcohol consumption, and provided counseling with an emphasis on ascertaining the patient’s views on change and negotiating priorities and targets for risk reduction. Except for standardized protocols for follow-up of hypertension and hyperlipidemia, follow-up was by mutual agreement, although nurses were encouraged to set their own priorities in light of overall risk. After ≥3 years of follow-up, mean serum total cholesterol was 3.1% lower in the intervention group than in controls (difference 0.19 mmol/L; 95% confidence interval [CI] = 0.12–0.26); self-reported saturated fat intake was also significantly lower in the intervention group; and systolic and diastolic blood pressures and body mass index were respectively 1.9%, 1.9%, and 1.4% lower in the intervention group (p < 0.005 in all cases). There were no significant differences in the number of individuals with diastolic blood pressure > 100 mm Hg or BMI > 30 kg/m² and there were no significant differences between the two groups in smoking cessation or change in risky alcohol use. The authors concluded that the benefits of health checks were sustained over 3 years, but that the benefits of systematic health promotion in primary care must be weighed against the costs in relation to other priorities.

The British Family Heart Study was an RCT of nurse-led primary prevention screening and multiple health behavior intervention in families of general practices within 15 towns in Britain. The subjects were recruited by approaching families of all men, aged 40 to 59, who appeared on practice lists. The true response rate was 73%. Randomization of 12,472 subjects occurred at the practice level within towns. A second control group was obtained through randomization within intervention practices. Both patients in the practice and a family member (i.e., partner) were recruited into the trial. Research nurses were trained in client-centered counseling techniques and provided all elements of the intervention. The initial intervention was conducted with the couple and took approximately 90 minutes. Subsequent follow-up was based on a coronary risk score and occurred as frequently as every 2 months.

After 1 year, the cardiovascular risk factor score (Dundee) was 16% lower in the intervention group than in the control groups. The authors suggested adjusting the reduction in risk score to 12% to take into account those subjects who were lost to follow-up and not included in the final analyses (12% to 15% of the total sample). Change was greatest in those at the highest level of risk at baseline. Reduction in individual risk factors were quite modest in the intervention compared to controls (4% lower smoking rate, 1 kg mean weight reduction, 7 mm lower mean Hg systolic pressure, 0.1 mmol/L mean cholesterol lowering). Intervention nurses worked exclusively on providing screening, counseling, and follow-up, and each nurse was fully occupied providing care to an average of about 300 patients during the year.

In summary, the British Family Heart Study authors reported that nurse-led programs of cardiovascular screening and lifestyle intervention in general practice produced slightly lower weight, blood pressure, and blood cholesterol concentration in the intervention group at 1 year. If these reductions could be sustained, they would correspond to a 12% lower risk of coronary heart disease events. Based on these results, the authors concluded that this level of intervention in primary care was not justified and suggested that primary care practitioners alone cannot provide a population-based primary prevention approach to reduce cardiovascular disease risk. On the other hand, one might argue that a 12% reduction of risk at a population level is quite substantial and may even be cost-effective. Subsequent cost-effectiveness analyses conducted for both the OXCHECK and Family Heart Study concluded that the OXCHECK program would become cost effective if the effect lasted ≥5 years (an additional 2 years after the end of the study), while, for the British Family Heart study, the effect must last for about 10 years to justify the cost associated with the intervention delivered in that trial.

A primary care–based secondary prevention study, included in both the Ketola et al. and McAlister et al. reviews, targeted 688 patients with angina within 18 general group practices in Ireland. Patients were randomized to either a health education intervention...
condition or assessment only. The initial health education intervention was delivered by research staff either at the practice or at the subject’s home, and follow-up education was provided every 4 months for 2 years. At the end of 2 years, based on self-report, the intervention group was significantly more physically active, more likely to report healthy eating and was less likely to report restriction of activity by angina. However, were no significant differences in smoking, blood pressure, cholesterol concentration, or body mass index.53

Another primary care–based secondary prevention trial95,96 was reported in the McAlister et al.48 review. Over 1100 patients with known or suspected coronary heart disease were recruited from 19 general practices in Scotland. Nurses recruited from each of the study practices were trained by study staff to deliver the disease management intervention, which included health behavior counseling and review of cardiac medications. Patients randomized to receive the intervention attended an initial visit of approximately 45 minutes and were encouraged to attend follow-up visits every 2 to 6 months. The average intervention time over the 1-year intervention period was 1 hour and 22 minutes per patient.95,96 Significant improvements in diet and physical activity were found for patients in the intervention condition compared to the control group, along with improvements in medication use and blood pressure and lipid management.95,96 The initial report from this trial did not describe changes in cardiovascular events or mortality, which led to its exclusion from the Ketola et al.47 review.

In a recently published 4.7-year follow-up report of the Scottish primary care trial,108 investigators reported that all improvements noted at the end of the 1-year intervention, except improvements in exercise, were sustained over 4.7 years.108 The usual care control group also improved over the follow-up period, so differences in risk behaviors between intervention and control conditions were no longer significant at the final follow-up.108 However, the authors suggest that this loss of effect on risk behaviors over time was largely due to control subjects’ participation in secondary prevention programs that were available to all subjects during the follow-up period.108 Despite this crossover effect, a significant impact of the intervention on mortality and cardiac events was noted after 4.7 years, suggesting that the benefits produced during the 1-year intervention period impacted progression of cardiac illness over the subsequent 3 to 4 years.108

Interventions to Address Multiple Behavioral Risk Factors in Diabetes Care

Diabetes care trials provide another source of evidence for interventions targeting multiple health behaviors. These are considered to be secondary prevention trials because they target a subgroup of patients with pre-existing disease. In addition to targeting behaviors that are specific to diabetes (e.g., blood glucose monitoring, foot exams), diabetes care intervention trials usually also address diet and exercise and sometimes smoking cessation. We have identified three systematic reviews in diabetes care that have summarized the effectiveness of interventions targeting health behaviors and also meet our inclusion criteria.49–51 These reviews address a range of interventions, from those that emphasize providing patient education and self-management support, to more intensive interventions that involve case managers and include systems-level interventions that address the organization and delivery of care.109 We will describe the conclusions of these three reviews emphasizing, whenever possible, the interventions elements that are associated with improved outcomes.

A 2001 report by the Alberta Heritage Foundation for Medical Research provided a review of reviews of diabetes education intervention trials.49 Included in this review were 17 reports, including three meta-analyses, seven systematic reviews, and seven additional trials with ≥1 year of follow-up and more than one patient contact. The authors concluded that although patient education is associated with short-term diabetes control, long-term outcomes have yet to be established.49 This report also concluded that providing patients with knowledge about diabetes is necessary, but insufficient to improve diabetes care. Goal setting, assessment of patient-specific barriers, and a focus on behavioral strategies and problem solving to address barriers appear to be important to produce an impact on diabetes outcomes.49

Norris et al.50 identified 72 RCTs in their systematic review of self-management training in people with type-2 diabetes. These authors defined self-management training as “the process of teaching individuals to manage their disease.”50 As the authors point out, the educational techniques used in these studies have shifted from didactic presentations and clinician-centered interventions to those involving patient activation and empowerment.110 Still, the interventions included in this review were extremely varied and included both didactic and collaborative approaches targeting a broad array of outcomes, including knowledge, skill development, lifestyle behaviors, physiological outcomes, and quality of life.50 Only 9 of the 72 studies focused on multiple behavioral outcomes (usually diet and exercise behaviors) and results of these were variable.50 Norris et al.50 conclude that evidence supports short-term effectiveness of self-management training, but there is insufficient evidence for sustained effects on glycemic control, cardiovascular risk factors, cardiovascular disease, and quality of life.50 However, the authors found that interventions with regular reinforcement were more effective than single sessions or only limited follow-up.50 Interventions that emphasized patient par-
participation or collaboration produced more favorable results on glycemic control, weight loss, and lipid profiles than didactic clinician-centered interventions. Group education appeared to be more effective for lifestyle interventions.

A systematic review of diabetes disease management, conducted by the Task Force on Community Preventive Services, reviewed 27 studies of disease management and 15 studies of case management. Although there was evidence for the effectiveness of disease management and case management on glucose control, the authors also concluded there was insufficient evidence for disease management or case management to determine the effectiveness on weight, BMI, blood pressure, and lipid concentration. They also noted that there is limited information about the relative value of specific components of disease management interventions, although providing patients with education, reminders, and support appear to be important.

Three recently reported trials, not included in the above reviews, provide new evidence regarding the impact of interventions targeting multiple behavioral risk factors in patients with diabetes as well as patients at risk for developing diabetes. The Diabetes Prevention Program (DPP) was a large multicentered RCT involving 3234 adults who were at risk for the development of type-2 diabetes. The DPP was designed to test whether a lifestyle intervention or metformin, an antihyperglycemic agent, would prevent or delay the onset of diabetes. The lifestyle intervention consisted of an individualized 16-lesson curriculum addressing diet, weight loss, physical activity, and behavior modification delivered by case managers on a one-to-one basis during a 6-month period. Follow-up individual sessions were held on a flexible schedule, usually monthly. Subjects, who all had evidence for impaired glucose tolerance that put them at greater risk for developing type-2 diabetes, were randomized to one of three conditions: standard lifestyle recommendations plus metformin, standard lifestyle recommendations plus placebo, or the intensive lifestyle intervention. After an average follow-up of 2.8 years, the lifestyle intervention reduced the incidence of diabetes by 58% compared with placebo (95% CI=48%–66%). Although metformin also significantly reduced the incidence of diabetes (by 31%, 95% CI=17%–43%), the lifestyle intervention was significantly more effective than metformin. The lifestyle intervention also produced significantly greater changes in diet, significantly greater weight loss, and significantly greater increases in physical activity than metformin or placebo. The authors calculated that the effect of the multiple-risk-behavior lifestyle intervention translates to one case of diabetes prevented per seven persons treated for 3 years.

Another recent RCT tested the effects of an intensive multifactorial intervention (that included behavioral risk factor intervention) on cardiovascular mortality in 160 adult patients with type-2 diabetes. The intensive intervention, delivered by a multidisciplinary team (physician, nurse, dietitian) in a Danish Diabetes Center, employed behavioral modification strategies to target diet, exercise, and smoking cessation in individual consultations every 3 months. The intensive intervention also included stepwise implementation of pharmacologic therapy targeting hyperglycemia, hypertension, dyslipidemia, and microalbuminuria, as well as aspirin therapy. The control condition received primary care–based treatment informed by conventional guidelines. After a mean follow-up of 7.8 years, subjects in the multifactorial intervention had an approximately 50% reduction in cardiovascular and microvascular events compared to conventional treatment. However, effects of the multifactorial intervention on behavioral risk factors were modest and only reduction in fat intake was significantly different between groups. Although the design of the study did not allow the investigators to identify which combination of interventions was responsible for the positive findings, the results of this study underscore several of the findings of the systematic reviews described above, including the value of a multidisciplinary team, combining medication with self-management education, targeting behavioral risk factors, and emphasizing goal setting and regular follow-up.

In the Finnish Diabetes Prevention Study, investigators randomly assigned 522 middle-aged overweight subjects (172 men and 350 women) with impaired glucose tolerance to seven individualized counseling sessions over 1 year with quarterly follow-up, or to a usual-care control condition with a diet/exercise pamphlet and general advice at baseline and annual follow-up. The counseling sessions were provided by nutritionists and focused on helping participants achieve a whole-grain, whole-foods, low-fat, and monounsaturated-fat diet, with intervention goals of reduced weight by >5%, reduction in total fat to <30% total energy, reduction in saturated fat to <10% energy, increased fiber, and moderate-intensity exercise of >30 minutes daily. After 1 year, the intervention group achieved a net weight loss of 3.4 kg (p <0.001) and the cumulative incidence of diabetes after 4 years was 11% (95% CI=6% to 15%) in the intervention group compared to 23% (95% CI=17% to 29%) in the control group. The risk of diabetes was directly associated with change in lifestyle, such that the more goals achieved by participants at 1 year, the lower the incidence of diabetes. Recent reports from the Finnish Diabetes Prevention Study investigators indicate that the intensive lifestyle intervention produced not only long-term (i.e., 3 years) beneficial changes in diet, physical activity, and weight, but also improvement in clinical and biochemical parameters of diabetes risk (e.g., glycemia, lipemia, and insulin sensitivity). Additional study-
ies by this research group from the National Public Health Institute of Finland are currently ongoing to determine how the techniques used in this clinical trial can be successfully implemented in primary care.

Summary of the Evidence

To address the health needs of the nation, there is clearly a mandate to focus on four key behavioral risk behaviors: lack of regular physical activity; unhealthy diet/obesity; smoking; and risky/harmful alcohol use. Our review of the evidence indicates that there are evidence-based single behavioral risk factor interventions that primary care clinicians can employ to reduce smoking,16,21 and risky/harmful alcohol use in unselected patients. These efficacious interventions include brief advice and counseling,18–21,44,45 interventions that are feasible in primary care settings. To address unhealthy diets, there is evidence for the efficacy of medium- to high-intensity dietary counseling delivered by specially trained clinicians to high-risk patients.14,15 There is also fair to good evidence that high-intensity counseling and behavioral intervention strategies that address physical activity, dietary improvement, or both, produce moderate, sustained weight loss in obese patients.16,17 Based on this evidence, the USPSTF has recently recommended: (1) screening for tobacco use,18 alcohol misuse,19 and obesity17; (2) brief primary care–based counseling for tobacco and alcohol misuse;18 (3) intensive behavioral dietary counseling for adult patients at high risk15; and (4) intensive counseling and behavioral interventions for obese patients.17 Although the evidence for the efficacy of physical activity interventions in primary care is limited,12,13 evidence-based recommendations for community activities and supports for regular physical activity help fill current evidence gaps.25,27 See Table 1 for a summary of the evidence linking single behavioral risk factor counseling to health behavior change.

However, large gaps remain in our knowledge about the efficacy of interventions to address multiple behavioral risk factors in primary care. The most promising evidence for addressing multiple behavioral risk factors comes from interventions that address secondary prevention among patients with existing cardiovascular disease or diabetes or patients who are at risk for these illnesses. Once illness is present, there is a growing body of evidence to support the impact of multitargeted multimodal risk factor interventions on a variety of outcomes, including change in health risk behaviors.46–51,93,108,111–113,116 Some of the most promising multiple behavioral risk factor interventions have been developed under the rubric of disease management, care management or self-management support.48–51 Since most adults aged >50 have one or more chronic conditions, a growing proportion of the population would benefit from multiple risk factor interventions that target patients with existing disease.

Most of the studies that demonstrate the benefit of multiple behavioral risk factor interventions have been conducted in research clinics or specialty settings. Though the intensive interventions delivered in many of these studies would not be feasible in primary care settings, one might argue that they could be directly linked to primary care settings if they were available on a referral basis. Relatively little available evidence addresses the efficacy of multiple risk behavior interventions that are delivered within primary care settings, particularly for primary prevention, that is, for patients without an existing illness such as diabetes and cardiovascular disease.46–51

However, the few studies that have tested multiple risk behavior interventions in primary care have generally found significant but small effects on health behavior endpoints.53,63,76,95,96,105,108 One example is the 10% to 12% reduction in risk scores reported by researchers directing the British Heart Health Study.63 Although some have questioned the value of this modest reduction in risk, others have argued strongly that, from a population standpoint, this level of risk reduction, if sustained over time, would translate into highly significant and important changes in cardiovascular disease incidence as well as subsequent morbidity and mortality.117 The potential for realizing such benefits in patients with existing illness was recently bolstered by the publication of the long-term morbidity and mortality outcomes of the Scottish primary care–based secondary prevention trial.108 Although delivered in more intensive specialty clinic settings, the impressive reduction in cardiovascular disease events achieved by the Danish multifactorial intervention in patients with type-2 diabetes,112 and the marked reduction in the incidence of diabetes achieved by the DPP’s and the Finnish Prevention Study’s diet, exercise, and behavioral modification interventions,111,113 provide powerful examples of the potential of multiple behavioral risk factor interventions to prevent the incidence of disease.

Limitations of the Existing Evidence

A limitation of much of the research we have reviewed for this paper is reliance on results obtained among the subset of patients who are willing to participate in controlled clinical trials. This is especially true when testing interventions that require enrolled patients to undergo repeated demanding assessments and participate in intensive interventions over long periods of time. It is particularly problematic to compare effect sizes across studies that vary in the demands placed on subjects (e.g., brief counseling in primary care versus multiple and frequent intensive counseling sessions in a specialty setting), as these studies are likely to enroll samples with different levels of motivation as well other
variables that may influence responsiveness to an intervention. These limitations apply to the systematic reviews of dietary counseling interventions and obesity interventions conducted by the USPSTF. Moreover, intensive face-to-face intervention modalities will have limited impact if they cannot be delivered consistently to large segments of the target population.

On the other side of the coin, as noted previously, the smaller effects obtained by primary care–based interventions may actually produce greater impacts on the population level if they are able to reach a much larger proportion of the population of patients that would benefit from the service. One strategy for overcoming obstacles to increasing the reach of an intensive intervention is to consider how to facilitate “hand-offs” or referrals between primary care clinicians and specialty services or programs that can provide more intensive interventions. Harnessing interactive technology to help integrate more intensive interventions within primary care or community settings is another strategy for increasing the reach and impact of these interventions. See the article on interactive technology by Glasgow et al. in this supplement for further discussion of this promising approach. The article on translating what we have learned into practice by Glasgow et al. in this supplement highlights the challenges as well as the opportunities for translating research findings into real-world primary care settings.

Another important limitation of the body of research that we have reviewed is the lack of attention paid to the responsiveness of important subgroups of patients (e.g., patients from minority groups; older adults; patients with low literacy levels) to the interventions of interest. The lack of uniform inclusion criteria across the systematic reviews cited in this paper (e.g., some included only RCTs while others included other less tightly controlled designs; inclusion criteria regarding acceptable follow-up periods varied) is yet another significant limitation to our findings. This limitation is especially important when comparing the recommendations and findings that have emerged from the USPSTF and the Community Task Force. Also, several of the systematic reviews identified other methodologic issues that limited the quality of the body of research that was reviewed. These include lack of standard outcome measures (particularly for diet and exercise outcomes), failure to report intervention implementation rates (important to internal validity), and inability to determine the effects of individual elements of complex interventions. Moreover, we did not review behavioral risk factor interventions in pediatric and adolescent populations and we did not review the impact of interventions that are delivered primarily in community settings, such as peer-led interventions or those delivered in work sites and faith-based organizations.

**Intervention Elements Associated with Improved Health Behavior Outcomes**

What can we learn from existing intervention research about the intervention elements that are associated with improved health behavior outcomes? Although few studies have been designed to systematically address this question, the following intervention elements have been associated with positive outcomes in single behavioral risk factor intervention research:

- Assessment of patient characteristics and needs and subsequent tailoring of intervention elements to address assessment
- Behavioral interventions (especially those that include self-monitoring, collaborative goal setting and active problem solving)
- Combined behavioral and pharmacologic interventions
- Supportive elements (both within and outside of intervention)
- Use of multiple modalities
- Multiple contacts
- Inclusion of organizational or system elements to prompt patients and clinicians

Within multiple behavioral risk factor intervention trials, the relative importance and mix of specific intervention elements is less clear. The added complexity of addressing multiple behaviors may make it impossible, and even undesirable, to disentangle all intervention elements in controlled research trials. However, existing evidence from disease management and self-management research suggests that the following elements promote positive outcomes:

- Assessment and tailoring of the intervention to patient needs
- Greater effectiveness of interactive education and skill building compared to didactic education
- Self-monitoring, goal setting, identification of barriers, and problem solving
- Use of multidisciplinary teams or nurse-led programs
- Multiple follow-up contacts

**Recommendations**

**Recommendations: Principles to Guide Intervention**

As noted in the epidemiologic papers in this supplement by Fine et al. and Coups et al., a majority of individuals are at risk from more than one of the four behavioral risk factors that are the focus of this review. It is not reasonable to expect clinicians in primary care settings to deliver unique interventions for each of these four behavioral risk factor independently of the others, or independent of the long list of other preventive services that primary care clinicians are urged to
address. On the hand, the conceptual frameworks and intervention elements that are associated with health risk behavior change are not different for different behaviors.\textsuperscript{7,9,124,125} That is good news for clinicians and health systems who do not have to use a different intervention approach for each specific behavior. The USPSTF Counseling and Behavioral Interventions Work Group recently recommended adoption of the “5As” construct as a unifying conceptual framework for evaluating and describing health behavioral counseling interventions in primary and general healthcare settings.\textsuperscript{9} The 5A’s framework (assess, advise, agree, assist, arrange follow-up) is derived from the “4A’s” approach to smoking-cessation counseling developed by the National Cancer Institute in the late 1980s.\textsuperscript{126} This approach has also been applied to nontobacco health behaviors\textsuperscript{9,125,127–129} and the self-management component of chronic illness care.\textsuperscript{123,124} See Appendix A for a summary of the 5A’s construct, adapted from the USPSTF Counseling and Behavioral Interventions Work Group report.\textsuperscript{9}

We strongly recommend use of the 5A’s approach as a strategy for implementing evidence-based behavioral risk factor interventions across multiple counseling targets. Evidence supporting each of the elements of the 5A’s is noted below:

**Assess** refers to assessment of patient behaviors, and may also include assessment of patients’ knowledge, beliefs, attitudes, and preferences. This step is necessary to identify those in need of behavioral interventions and, when appropriate, to permit tailoring of a health behavior change intervention.\textsuperscript{14,16,20,25,29,45,49–51,122} See the assessment paper by Babor et al.\textsuperscript{43} in this supplement for a review of strategies and tools for assessing the four key risk behaviors. Assessment can be addressed in a number of ways to avoid overburdening the primary care clinician, including use of pre-visit health risk appraisal instruments, questionnaires, or interactive computer-based systems.\textsuperscript{130} See also the interactive technology article by Glasgow et al.\textsuperscript{120} in this supplement. Depending on the behavior addressed, assessment may also include identification of physiologic risk factors (e.g., hypertension, abnormal lipids, body mass index) and family history to guide decisions about the intensity of intervention and the use of pharmacologic interventions to address risk.

**Advise** is supported by the evidence for the impact of brief clinician advice, especially when addressing tobacco use\textsuperscript{21,33} and risky alcohol use.\textsuperscript{19,20,44} However, for risky alcohol use, very brief or brief single contact interventions have limited efficacy.\textsuperscript{20} Advice is most effective when it is personalized and relates to a patient’s symptoms, values, and concerns.\textsuperscript{124,125,131}

**Agree** is the important step of collaboratively identifying behavioral and self-management goals. As noted, active participation of patients in the goal-setting process is associated with improved outcomes, particularly in studies of dietary\textsuperscript{14} and alcohol counseling\textsuperscript{42} and diabetes self-management education.\textsuperscript{20,49–51,124}

**Assist** includes providing behavioral counseling to help patients to develop a specific tailored action plan that includes helping them to identify, address and overcome barriers and develop the behavioral skills and confidence they need to successfully change and maintain health behaviors.\textsuperscript{14,16,21,29,42,45,49–51,122,124} The primary care clinician might hand-off this step to a nurse or other specially trained clinician, especially when addressing dietary change or obesity or when more intensive intervention is needed or desired.\textsuperscript{14,16,21,42,48–51,95,122,124}

**Arrange** includes making specific plans for subsequent contacts with the primary care team, as well as with clinicians with special expertise in addressing health risk behaviors and self-management.\textsuperscript{14,16,21,29,42,48–51} Follow-up might be provided through means other than face-to-face intervention, such as via telephone or interactive technology.\textsuperscript{120–122,133}

One of the key advantages of providing behavioral risk factor intervention in the primary care setting is the opportunity to take advantage of strong clinician–patient relationships, which have been linked with increased patient participation in health behavior change, as well as other aspects of care.\textsuperscript{125,134–136} The adoption of patient-centered, empowering, and collaborative approaches to behavior change counseling and self-management increase the influence and effectiveness of primary care clinicians’ counseling interventions.\textsuperscript{8,125,131,135,137–140} Another advantage of primary care is the longitudinal nature of primary care practice, which permits clinicians to deliver elements of the 5A’s through multiple contacts over time, while also taking advantage of teachable moments when new symptoms or patient concerns might be linked to problematic health behaviors or risks.\textsuperscript{141,142}

To take full advantage of interventions such as 5A’s counseling, we must recognize that they are delivered in a series of contexts, including (1) the systems that support the healthcare team (e.g., teamwork, provider training, reminders); (2) the healthcare delivery system (e.g., availability of referrals for more intensive dietary and obesity counseling); and (3) community resources (e.g., access to safe and convenient sites for physical activity, reminders to use them). The paper in this supplement on translating what we have learned into practice by Glasgow et al.\textsuperscript{121} describes and details the principles, practices, and systems that can be applied at the practice or health system level to promote successful adoption, implementation, and maintenance of multiple behavioral risk factor interventions in primary care settings. A brief list of contextual factors that

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74 American Journal of Preventive Medicine, Volume 27, Number 2S
influence successful implementation, based in part on evidence reviewed in the present paper, follows:

- System supports (e.g., computerized assessment; reminders, decision-support tools, feedback) clearly enhance the success of health behavior counseling interventions and are especially integral to the delivery of multiple risk behavior interventions. 14,20,21,109,122,124,133,143
- Use of multidisciplinary or nurse-led teams to share the responsibility and burden of delivering interventions, especially in the setting of chronic illness care or when more intensive levels of behavioral counseling are needed or desired.14,20,21,48–51,122,124,133,143
- Clinician and staff training is needed to optimize the delivery of effective patient-centered counseling.20,21,123,137,144,145
- Referral to or use of more intensive interventions may be needed when patients are alcohol dependent, fail initial treatment for tobacco dependence, or require intensive dietary or obesity counseling.14,16,20,44 Stepped care models such as the one proposed for tobacco dependence may prove valuable in addressing this need.35
- Use of community-based community approaches enhances smoking cessation and physical activity adoption, and may also improve other health behavior outcomes. 25,26,146

Recommendations: Future Research

The body of research conducted on multiple behavioral risk factor interventions is quite sparse, especially when considering studies performed within primary care settings. Much of the primary care research we cited was conducted in Western Europe and may not directly apply to U.S. healthcare systems and populations. Thus, there is a clear need to conduct controlled multiple risk factor intervention trials in primary care settings, especially in the United States. These trials should test interventions that can realistically be adopted, implemented, and maintained in primary care settings. Because of the wide variety of types of primary care settings in the United States (e.g., publicly supported community health centers, health maintenance organization, hospital-based clinics, private office practices), both generic interventions that would apply across type and specific interventions tailored to the type of setting need to be developed and tested. Many more narrowly defined questions remain about the efficacy and effectiveness of multiple behavioral risk factor interventions in primary care. These include questions about the relative importance of sequencing multiple behavioral risk factor interventions versus a simultaneous approach; strategies for balancing clinician and patient preferences; use of the physician (or nurse practitioner or physician assistant) to motivate and support versus personally deliver counseling interventions; use of multidisciplinary teams to share responsibility for intervention; use of telecommunications and/or interactive technology to support and extend primary care–based intervention; use of strategies to facilitate hand-offs or referral to more intensive programs; use of group formats and settings for delivering interventions; and assessing the needs and response of specific subpopulations.

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References


Appendix A

The Five A’s for Behavioral Counseling and Health Behavior Change

This version of the 5A’s was adapted by CJ Peek, PhD, and other members of the Planning Committee of the Addressing Multiple Behavioral Risk Factors in Primary Care Project from Whitlock P, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach, Am J Prev Med 2002;22:267–84.

Application: The content of each step in the Five A’s varies from behavior to behavior, but clinical intervention targeting any behavior change can be described with reference to these five intervention components.
### The Five A’s

| Assess | Ask about and assess behavioral health risks and factors that affect choice of behavior change goals and methods.  
|        | • Assessing behavioral risk factors identifies patients in need of intervention and provides basis for tailoring brief interventions for maximum benefit.  
|        | • Assess beliefs, behaviors, knowledge, motivation, and past experience.  
| Advise | Give clear, specific, well-timed, and personalized behavior change advice, including information about personal health harms and benefits.  
|        | • Clinician advice establishes behavioral issues as an important part of health care.  
|        | • Advise in a noncoercive, nonjudgmental manner that respects readiness for change and patient autonomy.  
|        | • Advice is most powerful when linked to the patient’s own health concerns, past experiences, family/social situations, and person’s level of health literacy.  
| Agree  | Collaboratively select appropriate goals and methods based on the patient’s interest in and willingness to change the behavior.  
|        | • Collaborate to find common ground and to define behavior change goals and methods.  
|        | • Shared decision making is especially recommended for interventions that involve significant risk-benefit tradeoffs.  
|        | • Shared decision making about behavior change results in a greater sense of personal control, choices based in realistic expectations and patient values, improved patient adherence, and time saved in the exam room.  
| Assist | Using self-help resources and/or counseling, help the patient to achieve goals by acquiring skills, confidence, and social and environmental supports for behavior change.  
|        | • Healthcare staff provide motivational interventions, address barriers to change, and/or secure support needed for successful change.  
|        | • Effective interventions teach self-management and problem-solving or coping skills that enable patients to take the next immediate steps toward targeted behavior change.  
|        | • An action plan is developed that lists goals, barriers and strategies, and specifies follow-up.  
| Arrange| Schedule follow-up (in person or by phone) to provide ongoing assistance and support and to adjust the plan as needed, including referral to more specialized intervention.  
|        | • Consider behavioral risk factors as chronic problems that change over time.  
|        | • Routine follow-up assessment and support through some kind of contact is usually necessary to promote and maintain behavior change.  