Behavioral Counseling in Primary Care to Promote a Healthy Diet: Recommendations and Rationale

U.S. Preventive Services Task Force

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This statement summarizes the U.S. Preventive Services Task Force (USPSTF) recommendations on counseling to promote a healthy diet in primary care patients and the supporting evidence, and it updates the 1996 recommendations contained in the *Guide to Clinical Preventive Services,* second edition.[1] Explanations of the ratings and of the strength of overall evidence are given in Appendix A and Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is available in the Systematic Evidence Review[2] on this topic, which can be obtained through the USPSTF web site (www.preventiveservices.ahrq.gov) and through the

National Guideline Clearinghouse™ (http://www.guideline.gov). The summary of the evidence and the recommendation statement are also available in print through the AHRQ Publications Clearinghouse (call 1-800-358-9295 or e-mail ahrqpubs@ahrq.gov).

To address whether to recommend counseling to promote a healthy diet among primary care patients, the USPSTF reviewed the evidence on nutritional and behavioral counseling by a variety of practitioners (physicians, nurses, nutritionists, dietitians, health educators) and in a variety of clinical settings (eg, primary care practices, specialty clinics). In updating its recommendations, the USPSTF did not reevaluate the benefits of a healthy diet, which are detailed in many other reports. Instead, it focused on new controlled studies of the efficacy of counseling for changing dietary behavior in patients similar to those found in primary care practices. The review did not include studies of dietary interventions for specific chronic illnesses (eg, heart disease, diabetes, renal failure) but included studies enrolling patients with common risk factors such as elevated cholesterol, hypertension, obesity, or family history of heart disease. Counseling interventions with a primary focus on weight loss, weight management, and/or the treatment of obesity are covered in a separate review[3] and are outside the scope of this recommendation. Studies of diet interventions focusing on lowering cholesterol levels in patients with elevated cholesterol or other lipid abnormalities are addressed in a separate USPSTF report entitled *Screening for Lipid Disorders in Adults*.[4] Studies of breastfeeding will also be addressed in a future USPSTF report. All published reports are available on the USPSTF Web site at: www.preventiveservices.ahrq.gov.

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SUMMARY OF RECOMMENDATIONS

- The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to recommend for or against routine behavioral counseling to promote a healthy diet in unselected patients in primary care settings. **I recommendation.**

  The USPSTF found fair evidence that brief, low- to medium- intensity behavioral dietary counseling in the primary care setting can produce small to medium changes in average daily intake of core components of an overall healthy diet (especially saturated fat and fruit and vegetables) in unselected patients (see "Scientific Evidence" for discussion of patient populations and intensity of interventions). *The strength of this evidence, however, is limited by reliance on self-reported diet outcomes, limited use of measures corroborating reported changes in diet, limited follow-up data beyond 6 to 12 months, and enrollment of study participants who may not be fully representative of primary care patients. In addition, there is limited evidence to assess possible harms* (see "Clinical Considerations"). *As a result, the USPSTF concluded that there is insufficient evidence to determine the significance and magnitude of the benefit of routine counseling to promote a healthy diet in adults. Although community-based studies have evaluated measures to reduce dietary fat intake in children, no controlled trials of routine behavioral dietary counseling for children or adolescents in the primary care setting were identified.*

- The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. **B recommendation.**

The USPSTF found good evidence that medium- to high-intensity counseling interventions can produce medium to large changes in average daily intake of core components of a healthy diet (including saturated fat, fiber, fruit, and vegetables) among adult patients at increased risk for diet-related chronic disease. Intensive counseling interventions that have been examined in controlled trials among at-risk adult patients have combined nutrition education with behavioral dietary counseling provided by a nutritionist, dietitian, or specially trained primary care clinician (eg, physician, nurse, or nurse practitioner). The USPSTF concluded that such counseling is likely to improve important health outcomes and that benefits outweigh potential harms. No controlled trials of intensive counseling in children or adolescents that measured diet were identified.[5,6]

CLINICAL CONSIDERATIONS

- Several brief dietary assessment questionnaires have been validated for use in the primary care setting.[7,8] These instruments can identify dietary counseling needs, guide interventions, and monitor changes in patients' dietary patterns. However, these instruments are susceptible to the bias of the respondent. Therefore, when used to evaluate the efficacy of counseling, efforts to verify self-reported information are recommended since patients receiving dietary interventions may be more likely to report positive changes in dietary behavior than control patients.[9-12]
- Effective interventions combine nutrition education with behaviorally-oriented counseling to help patients acquire the skills, motivation, and support needed to alter their daily eating patterns and food preparation practices. Examples of behaviorally-oriented counseling interventions include teaching self-monitoring, training to overcome common barriers to selecting a healthy diet, helping patients to set their own goals, providing guidance in shopping and food preparation, role playing, and arranging for intra-treatment social support. In general, these interventions can be described

with reference to the 5-A behavioral counseling framework[13]: Assess dietary practices and related risk factors, Advise to change dietary practices, Agree on individual diet change goals, Assist to change dietary practices or address motivational barriers, and Arrange regular follow-up and support or refer to more intensive behavioral nutritional counseling (eg, medical nutrition therapy) if needed.

- Two approaches appear promising for the general population of adult patients in primary care settings: (1) medium-intensity face-to-face dietary counseling (2 to 3 group or individual sessions) delivered by a dietitian or nutritionist or by a specially trained primary care physician or nurse practitioner, and (2) lower-intensity interventions that involve 5 minutes or less of primary care provider counseling supplemented by patient self-help materials, telephone counseling, or other interactive health communications. However, more research is needed to assess the long-term efficacy of these treatments and the balance of benefits and harms.
- The largest effect of dietary counseling in asymptomatic adults has been observed with more intensive interventions (multiple sessions lasting 30 minutes or longer) among patients with hyperlipidemia or hypertension, and among others at increased risk for diet-related chronic disease. Effective interventions include individual or group counseling delivered by nutritionists, dietitians, or specially trained primary care practitioners or health educators in the primary care setting or in other clinical settings by referral. Most studies of these interventions have enrolled selected patients, many of whom had known diet-related risk factors such as hyperlipidemia or hypertension. Similar approaches may be effective with unselected adult patients, but adherence to dietary advice may be lower, and health benefits smaller, than in patients who have been told they are at higher risk for diet-related chronic disease.[14]

- Office-level systems supports (prompts, reminders, and counseling algorithms) have been found to significantly improve the delivery of appropriate dietary counseling by primary care clinicians.[15-17]
- Possible harms of dietary counseling have not been well defined or measured. Some have raised concerns that if patients focus only on reducing total fat intake without attention to reducing caloric intake, an increase in carbohydrate intake (eg, reduced-fat or low-fat food products) may lead to weight gain, elevated triglyceride levels, or insulin resistance. Nationally, obesity rates have increased despite declining fat consumption, but studies did not consistently examine effects of counseling on outcomes such as caloric intake and weight.
- Little is known about effective dietary counseling for children or adolescents in the primary care setting. Most studies of nutritional interventions for children and adolescents have focused on non-clinical settings (such as schools) or have used physiologic outcomes such as cholesterol or weight rather than more comprehensive measures of a healthy diet.[5,6]

SCIENTIFIC EVIDENCE

Epidemiology and Clinical Consequences

Consuming a healthy diet is associated with lower risks for chronic disease morbidity and mortality. Four of the 10 leading causes of death—coronary heart disease, some types of cancer, stroke, and type 2 diabetes—are associated with unhealthy diets.[2] The relationships between dietary patterns and health outcomes have been examined in a wide range of observational studies and randomized trials with patients at risk for diet-related chronic disease. The majority of studies show that people consuming diets that are low in fat, saturated fat, trans-fatty acids, and cholesterol and high in fruits, vegetables, and whole grain products containing fiber have lower rates of morbidity and mortality from coronary heart disease, and possibly several forms of cancer. In addition, one needs to balance calories with physical activity to maintain a healthy weight. The Dietary Guidelines for Americans[18] recommend 3 to 5 daily servings of vegetables and vegetable juices, 2 to 4 daily servings of fruits and fruit juices, and 6 to 11 daily servings of grain products, depending on caloric needs. In addition, they recommend a diet that contains less than 10% of calories from saturated fat, no more than 30% of calories from total fat, and limited consumption of trans-fatty acids.

Despite well-established benefits of consuming a healthy diet, more than 80% of Americans of all ages eat fewer than the recommended number of daily servings of fruit, vegetables, and grain products and more than the recommended proportions of daily calories from saturated fat and total fat.[19] In 1994-1996, 28% of people aged 2 years and older consumed at least 2 daily servings of fruit, 49% consumed at least 3 daily servings of vegetables, 51% consumed at least 6 daily servings of grain products, 36% consumed less than 10% of daily calories from saturated fat, and 33% consumed 30% or less of daily calories from total fat.[19]

Dietary counseling practices of primary care clinicians indicate limited attention to diet modification. In a 1999-2000 survey of U.S. adults, 33% of respondents reported past-year physician advice to eat more fruits and vegetables, and 29%

reported similar advice to reduce dietary fat.[20] In another recent survey, 25% of adult patients from four community-based group family medicine clinics indicated that their physicians had advised them to limit or reduce the amount of fat in their diets.[21]

Effectiveness of Dietary Counseling

The ideal evidence to support behavioral dietary counseling would link counseling directly to improved health outcomes in randomized controlled clinical trials. In the absence of such evidence, the clinical logic behind counseling is based on a chain of critical assumptions: (1) the clinician must be able to assess whether a patient is consuming a healthy diet, (2) critical components of counseling must be routinely replicable, (3) counseling must lead to sustained improvements in diet, and (4) the health benefits of these changes in diet must be established and known to exceed the potential harms of intervention.[13] A review conducted for the USPSTF identified 21 fair to good quality randomized controlled clinical trials of dietary counseling among patients without existing diet-related chronic disease (eg, coronary heart disease or cancer). Trials had to include follow-up of at least 3 months after intervention for at least 50% of the enrolled subjects and include measures of dietary intake. Studies that assessed only physiologic measures (eg, lipid levels, weight, or body mass index [BMI]) were not included. Additional details of the inclusion and exclusion criteria, and methods for assessing quality of studies, are described elsewhere.[2,22]

Most of these trials focused exclusively on dietary counseling, though some targeted diet as part of a broader risk-factor modification program that also addressed smoking and sedentary lifestyle.[23-26] Most studies targeted reductions in total fat or saturated fat intake (n=17).[9-11,15-17,23-35] Ten studies targeted increased fruit and vegetable intake[10,11,14,23,27-29,34,36,37] and 7 targeted increased intake of fiber and whole grains.[9,15,24,28,29,34,38] Most studies (n=11) focused on a single nutrient, although 10 focused on changes in 2 or more nutrients.[9-11,15,23,24,27-29,34]

Studies were classified by intensity of the interventions evaluated, based on the number and length of counseling sessions, the magnitude and intensity of educational materials provided, and the use of supplemental interventions such as support group sessions or cooking classes. Low-intensity interventions involved 1 contact lasting less than 30 minutes. High-intensity interventions involved more than 6 contacts lasting more than 30 minutes. Medium-intensity interventions fell between low- and high-intensity.

Effects of counseling were classified as “large,” “medium,” or “small” for each component of diet measured.[2] With reference to these specific, defined categories, the USPSTF concluded that large effects sustained over time were likely to produce important health benefits (reductions in morbidity and mortality).[39-43] Given the large attributable risk associated with these dietary components, it is possible that medium or even small changes in diet would yield important health benefits across a large population. However, to date, there is little direct evidence about the effect of small and medium dietary changes on the future risk for coronary heart disease, making it difficult to determine with certainty whether such changes will translate into changes in the incidence of chronic disease. Better data about these linkages are needed.

Assessing Dietary Behaviors in Primary Care Patients

A number of brief, validated dietary assessment instruments can identify dietary counseling needs, guide intervention, and monitor change among adult patients in primary care and other clinical settings. Most of these instruments can be self-administered, are easily scored, have fewer than 40 items, and take 10 minutes or less to administer. However, these instruments are susceptible to bias (ie, patients report healthier diets than they actually consume); some studies indicate that under-reporting of caloric intake is common, especially among obese patients.[12] When used to evaluate counseling efficacy, efforts to verify self-reported information are recommended.[9-12,15,26,44] For children aged 9 years and older, food frequency questionnaires administered directly to children can provide a reasonably accurate picture of usual dietary patterns, with correlations with criterion measures ranging from 0.46 to 0.79.[8] No brief valid dietary screening instruments were identified for children below the age of 9 years. The optimal interval for screening adults or children is not known.

Effectiveness of Routine Counseling in Primary Care

The USPSTF found 9 fair to good quality randomized controlled trials of behavioral dietary counseling in unselected populations in primary care settings. The majority of these interventions focused on change in more than one nutrient (ie, fat/saturated fat, fruit/vegetables, and/or fiber).[9,11,15,27-29,34] Most of these trials combined basic nutrition education with behaviorally-oriented counseling to help patients acquire the skills, motivation, or support needed to alter their daily eating patterns and food selection and preparation practices. Duration of interventions lasted from 1 week to 1 year. No controlled trials with children or adolescents were identified.

The 9 studies varied in the amount of face-to-face counseling involved. Two studies of medium-intensity interventions evaluated multiple face-to-face sessions of behavioral dietary counseling provided in the primary care setting by a dietitian or nutritionist, or by a primary care physician or nurse practitioner who had received brief training in dietary counseling.[34,38] These interventions involved 2 to 3 group or individual sessions lasting 30 minutes, with follow-up visits at 1 and 3 months. Baron et al reported an 84% patient recruitment/participation rate.[38]

Seven studies involved little or no face-to-face counseling and placed greater emphasis on patient self-help materials, manuals, and varied forms of interactive health communication. Two were studies of low-intensity interventions that combined brief (≤5 minutes) face-to-face counseling sessions with a primary care physician or nurse with self-help materials.[9,15] Three others were studies of low-intensity interventions that relied either on mailed self-help materials[27,36] or on health behavior change messages delivered via an automated computer-based voice system.[29] Campbell et al[27] found significantly greater benefits from tailored than non-tailored self-help materials; Lutz et al[36] did not. The remaining 2 were medium-intensity interventions that combined a computer-generated personalized letter and motivational phone call(s) from a trained health educator with a series of self-help mailings and newsletters.[11,28] Patient recruitment and participation in this second group of studies ranged from 16%[36] to 80%,[27] with most in the 40% to 70% range.

These studies in unselected populations produced mostly small (n = 9) and medium (n = 8) as opposed to large (n = 3) improvements in self-reported dietary behaviors, most of which were statistically significant. Most studies followed patients for 6 months or less post-intervention; 4 followed patients for as long as 12 months.[11,15,34,38] Only 2 of them assessed impacts on intermediate biological endpoints (eg, serum cholesterol, weight, or BMI), of which none reported significant treatment effects.[15,38] No studies examined adverse treatment effects.

The USPSTF also reviewed 2 additional studies that enrolled predominantly healthy premenopausal women, a large proportion of whom were overweight or obese. These studies employed high-intensity interventions involving multiple dietitian-led individual[14] or group[35] counseling sessions. One intervention extended over a 6-month period and aimed at increasing fruit and vegetable intake[14]; the other extended over a 5-year period and focused on dietary fat reduction. Both trials reported large treatment effects in self-reported dietary behavior at 6-month post-intervention follow-up, and both reported favorable changes in biological risk factors or markers. However, participants in these studies were highly selected and motivated volunteers. The USPSTF concluded that results could not be generalized to more representative primary care populations.

Effectiveness of Intensive Counseling in Patients at Risk for Chronic Disease

The USPSTF found 10 fair to good quality randomized controlled trials that tested whether medium- to high-intensity interventions delivered in primary care or other clinical settings led to improved dietary outcomes among adults who were identified as being at increased risk for diet-related chronic disease.[10,16,17,23-26,30-33,37] For 2 of these trials, 2 research reports for each were reviewed.[16-17, 30-31] No controlled trials with children or adolescents at risk for chronic disease were identified that reported dietary outcomes.

The interventions involved a two-step assessment: screening to identify a patient's risk status using chart audit/clinical exam/laboratory testing to screen for hyperlipidemia, hypertension, family history of heart disease or breast cancer, overweight, obesity, smoking status, and sedentary lifestyle, followed by assessment of dietary practices using a variety of dietary assessment tools and protocols (eg, food frequency questionnaires, 3-4 day food records, and brief dietary assessment instruments). Hyperlipidemia was included as a risk factor in most of these studies. Four trials addressed diet along with physical activity and/or smoking.[23-26]

Most of the trials tested multi-session group or individual counseling that combined nutrition education with behaviorally-oriented counseling. Most studies focused on reducing saturated fat and/or total fat intake; 2 of these studies also targeted fiber or fruit and vegetable intake,[23,24] and one focused on increasing fruit and vegetable intake only.[37] Most studies also reported intermediate health outcomes, such as serum lipid levels, blood pressure, weight, and/or BMI. Follow-up in most studies (n=6) was 12 months or longer, some as long as 4 to 6 years.[23-26,30-32]

Six of the trials took place outside of primary care settings, where counseling was provided by an experienced nutritionist, dietitian, and/or health educator in 8 to 20 sessions over a period ranging from 4 months to 5 to 6 years.[10,23,25,30,31,33,37] Four trials took place within primary care settings,[16,17,24,26,32] where counseling was provided by specially trained primary care physicians or nurses (training ranging from 60 minutes to 3 days) in 3 to 6 special sessions supplemented by follow-up phone calls and/or newsletters, and follow-up at routine visits over a period of 4 to 18 months. In two primary care-based

studies,[16,17,32] behavioral dietary counseling for patients with hyperlipidemia was supplemented, if needed, with lipid-lowering medication and/or referral to outside counseling by a dietitian. Ockene et al[17] found that implementing office-level systems supports (prompts, reminders, and counseling algorithms) significantly improved primary care provider adherence to the comprehensive dietary counseling.

In summary, interventions for patients at risk for chronic disease resulted in dietary behavior changes that were small (n=3),[16,17,23,24] medium (n=6),[10,23,24,26,32,37] and large (n=4),[10,25,30,33] most of which were statistically significant. The magnitude and duration of these changes were greater with higher intensity interventions than with interventions of lower intensity. More than one-half of these studies found that self-reported dietary changes were accompanied by significant improvements in serum lipids, weight, or BMI.[10,23,24,30-32] These findings help corroborate patients' self-reported dietary changes and confirm the overall health benefits of the observed changes in diet.

Discussion

Medium- to high-intensity behavioral interventions appear to produce consistent, sustained, and clinically important changes in dietary intake of total fat, saturated fat, fruit and vegetables, and fiber. However, these trials were generally either conducted with patients with known risk factors for diet-related chronic disease, or performed in special clinics with highly selected patients and specially trained providers. The most effective interventions generally combined education, behaviorally-oriented counseling, and patient reinforcement and follow-up. More intensive interventions, and those of longer duration, are associated with larger magnitude of benefit and more sustained changes in diet. Available studies do not, however, allow firm conclusions about the essential or most effective elements of these multi-component interventions, their relative effect on specific dietary constituents (eg, fat, fruit and vegetables, or fiber), or the relative efficacy of targeting single or multiple dietary risks or addressing diet in the context of broader lifestyle interventions. Although evidence is stronger for counseling patients who are at increased risk for chronic disease, such as those with hyperlipidemia, than for the general population of patients, it is not possible to disentangle the effects of patient risk status from the effects of intervention intensity. Adherence to these intensive interventions and the dietary changes they require may be dependent on patients' heightened perceived risk and motivation for change.

Existing trials of routine dietary interventions in unselected primary care populations have generally produced only small to medium changes in self-reported diet. Although direct comparisons cannot be made, results from medium-intensity, routine face-to-face counseling from nutritionists, dietitians, or specially trained primary care practitioners (physicians, nurses, or nurse practitioners) appear similar to those achieved through less intensive, minimal-contact interventions to supplement brief primary care provider advice/counseling. The consistently positive effects of such interventions on diet in unselected patient populations establish these interventions as highly promising as part of routine preventive care for patients at average risk for chronic disease. The USPSTF concluded, however, that existing studies do not provide sufficient evidence to recommend these interventions for widespread use due to a number of limitations such as modest overall patient recruitment/participation rates, reliance on self-reported outcome measures, relatively short follow-up periods, uncertainty about the health effects of small and medium changes in diet, and the lack of evidence about possible adverse effects of counseling. Two studies suggest high-intensity interventions can be effective in selected patients at average risk, but the applicability of these findings and the feasibility of these interventions in primary care settings are uncertain.[14,35]

RECOMMENDATIONS OF OTHERS

Dietary guidelines for the general population have been issued by the U.S. Department of Agriculture (USDA)[18] and the Department of Health and Human Services; specific dietary objectives for the nation are outlined in *Healthy People 2010*.[19] Guidelines from the American Heart Association (AHA) and the American Cancer Society (ACS) address diets that will lower the risk for heart disease and cancer, respectively.[45,46] These guidelines generally agree in recommending a diet that includes a variety of

fruit, vegetables, and grain products; is low in saturated fat and cholesterol and moderate in total fat; and balances calories with physical activity to maintain a healthy weight.

A variety of groups have recommended nutritional counseling or dietary advice for patients at average risk for chronic disease, including the American College of Preventive Medicine (ACPM), American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), and the American College of Obstetricians and Gynecologists (ACOG).[47-50] These recommendations are based primarily on the benefits of a healthy diet rather than on evaluations of the efficacy of counseling. The Canadian Task Force on Preventive Health Care (CTFPHC) concluded in 1994 that there was fair evidence to provide general dietary advice to all patients, based on a limited number of trials of counseling.[51]

Recommendations on nutritional counseling for patients at risk (eg, those who have hypertension or hyperlipidemia) have been issued by the American Dietetic Association (ADA) and two panels sponsored by the National Institutes of Health (NIH) National Heart, Lung, and Blood Institute. The ADA recommends that primary care providers screen for nutrition-related illnesses, prescribe diets, provide preliminary counseling on specific nutritional needs, follow up with patients, and refer patients to appropriate dietetic professionals when necessary.[52] Similarly, The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that dietary assessments be included as part of routine medical history and that physicians counsel patients on lifestyle modifications for the prevention and treatment of high blood pressure (lose weight if overweight, limit alcohol intake, reduce sodium intake, reduce saturated fat and cholesterol intake).[53] The National Cholesterol Education Program recommends that individuals with elevated levels of low density lipoprotein limit their intake of fats, particularly saturated fats, and cholesterol and increase dietary fiber.[54]

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APPENDIX A

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS AND RATINGS

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B. The USPSTF recommends that clinicians routinely provide [this service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C. The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

APPENDIX B

U.S. PREVENTIVE SERVICES TASK FORCE
STRENGTH OF OVERALL EVIDENCE

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.