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Systematic Evidence Review
Number 18

Counseling to Promote a Healthy Diet

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Preface

The Agency for Healthcare Research and Quality (AHRQ) sponsors the development of Systematic Evidence Reviews (SERs) through its Evidence-based Practice Program. With guidance from the third U.S. Preventive Services Task Force* (USPSTF) and input from Federal partners and primary care specialty societies, two Evidence-based Practice Centers—one at the Oregon Health Sciences University and the other at Research Triangle Institute-University of North Carolina—systematically review the evidence of the effectiveness of a wide range of clinical preventive services, including screening, counseling, immunizations, and chemoprevention, in the primary care setting. The SERs—comprehensive reviews of the scientific evidence on the effectiveness of particular clinical preventive services—serve as the foundation for the recommendations of the third USPSTF, which provide age- and risk-factor-specific recommendations for the delivery of these services in the primary care setting. Details of the process of identifying and evaluating relevant scientific evidence are described in the "Methods" section of each SER.

The SERs document the evidence regarding the benefits, limitations, and cost-effectiveness of a broad range of clinical preventive services and will help to further awareness, delivery, and coverage of preventive care as an integral part of quality primary health care.

AHRQ also disseminates the SERs on the AHRQ Web site (http://www.ahrq.gov/uspstfix.htm) and disseminates summaries of the evidence (summaries of the SERs) and recommendations of the third USPSTF in print and on the Web. These are available through the AHRQ Web site (http://www.ahrgq.gov/uspstfix.htm), through the National Guideline Clearinghouse (http://www.ncg.gov), and in print through the AHRQ Publications Clearinghouse (1-800-358-9295).

We welcome written comments on this SER. Comments may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 6010 Executive Blvd., Suite 300, Rockville, MD 20852.

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*The USPSTF is an independent panel of experts in primary care and prevention first convened by the U.S. Public Health Service in 1984. The USPSTF systematically reviews the evidence on the effectiveness of providing clinical preventive services--including screening, counseling, immunization, and chemoprevention--in the primary care setting. AHRQ convened the third USPSTF in November 1998 to update existing Task Force recommendations and to address new topics.

Abstract

Context: Diseases associated with overeating, undereating, and dietary or nutritional imbalance rank among the leading causes of illness and death in the United States. The relationships between specific dietary elements and specific health outcomes have been widely researched and are reasonably well understood; similarly, the role of primary care providers in providing or arranging for dietary counseling has been extensively investigated, but controversy exists about the magnitude of change than can be achieved and the effectiveness of different counseling strategies.

Objective: To update the chapter from the 1996 *Guide to Clinical Preventive Services* examining the effectiveness of counseling to promote a healthy diet and to assist the US Preventive Services Task Force in making recommendations on this topic.

Design and Data Sources: To produce this systematic evidence review, we developed an analytic framework and 7 key questions that represent the logical chain between dietary counseling (especially about intake of total and saturated fat, fruits and vegetables, and fiber) and health practices and outcomes, together with linkages between diet and nutritional constituents and health outcomes for a wide array of disorders (e.g., cardiovascular disease, cancer). To supplement citations from the 1996 *Guide*, we sought studies examining the effectiveness of dietary assessment and counseling using searches of MEDLINE for publications appearing from 1966 to 2000, by combining Medical Subject Headings related to diet and nutrition, primary care settings and practices, and counseling. We supplemented these searches with searches of the Cochrane Collaboration database and various bibliographies for recent systematic reviews and

meta-analyses on the link between dietary patterns and health outcomes or between counseling and dietary behaviors.

Study Selection: To examine the relationship with diet and health outcomes, we selected systematic reviews, observational studies, and randomized trials relating specific dietary patterns and health outcomes. For studies of dietary assessment, we selected studies that examined test accuracy compared with a criterion standard. For studies linking counseling interventions with dietary change, we selected randomized controlled trials with pre- and post-test measures.

Data Extraction: Trained reviewers and the authors abstracted data from the eligible articles onto evidence tables; the first authors checked all abstractions.

Data Synthesis: The relationships between dietary patterns and health outcomes have been examined in a wide range of observational studies. Few randomized trials have examined the effect of dietary interventions on health outcomes. The majority of studies show that persons consuming diets high in fruits, vegetables, fish, and whole grains or fiber and low in saturated and trans-unsaturated fats have lower rates of coronary heart disease and some forms of cancer. Similarly strong evidence supports the relationship between dietary intake of calcium and the risk of low bone mineral density. High intake of dietary sodium and low intake of dietary potassium are associated with higher blood pressure levels and increased incidence of hypertension. Efforts to reduce sodium intake and increase potassium have shown moderate effects on blood pressure, with greater effects seen in African-Americans and persons with hypertension.

Abstract

Several brief, valid dietary assessment instruments are feasible for the primary care setting. Although these instruments have not been evaluated as to their impact on health outcomes, they serve an important role of identifying dietary counseling needs and monitoring change over time. Many of these instruments are designed for specific patient populations or nutrients.

We identified 33 articles examining the effect of nutritional counseling in primary care patients. Among primary care patients, nutrition counseling can produce modest improvements in saturated and total fat consumption, as well as fruit and vegetable consumption. The evidence is insufficient to determine the effectiveness of counseling in changing consumption of whole grains or fiber, calcium, sodium, or fish. Intensive interventions are more likely to produce large changes, but typical strategies pursued in primary care settings tend to be of lower intensity and produce smaller changes. Interventions using mailed or computer-generated materials appeared moderately effective, particularly in increasing fruit and vegetable consumption. Isolating the effect of a single counseling approach as more or less effective is made difficult by the tendency for counseling interventions to test multiple approaches simultaneously. Studies employing 3 or more well-proven counseling elements were more effective than those employing fewer elements.

Conclusions: Diets low in saturated and trans-unsaturated fat and high in fruits, vegetables, fish, and whole grains are associated with better health outcomes. Counseling patients can improve dietary behaviors, including reduction in dietary total and saturated fat and increases in fruit and vegetable intake. More intensive counseling and counseling directed to higher-risk patients have generally produced larger changes than less intensive interventions delivered to low-risk populations.

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Introduction

Diseases associated with dietary excess and imbalance rank among the leading causes of illness and death in the United States. Major diseases in which diet plays a role include coronary heart disease, some types of cancer, stroke, hypertension, obesity, osteoporosis, and non-insulin-dependent diabetes mellitus. All are major causes of morbidity and mortality in this country.

Although diet is associated with multiple health outcomes, the relationships between specific dietary elements and specific health outcomes have been studied extensively. The role of the primary care provider in either providing direct diet counseling or enlisting the help of other health professionals has been studied extensively, but controversy remains about the effectiveness of different strategies. In "Evaluating Primary Care Behavioral Counseling Interventions: An Evidence-based Approach," Whitlock et al. described a detailed framework for primary care counseling.[1]

To address the question of the role of diet in chronic disease as well as dietary assessment and counseling in primary care, staff of the RTI – University of North Carolina Evidence-based Practice Center undertook this systematic evidence review (SER) on behalf of the US Preventive Services Task Force (USPSTF). It updates the chapter on dietary counseling from the second edition of the Guide to Clinical Preventive Services.[2] In 1996, the USPSTF had recommended counseling adults and children over 2 years of age to limit intakes of fat and cholesterol, to maintain caloric balance in diets, and to emphasize foods containing fiber; the Task Force concluded then that the evidence was insufficient to recommend for or against counseling the general population to reduce dietary sodium. The Task Force also concluded that evidence was insufficient to show that nutritional counseling by physicians has any advantage over counseling

by dietitians or community interventions.[2] This SER enabled the USPSTF to reconsider the issues it addressed in the mid-1990s and to make recommendations concerning ways to promote healthy dietary practices in America.

Chapter II presents our conceptual framework and documents the literature search and synthesis approaches used in the work. Chapter III, on results, is organized in 2 parts. In the first part, we address the relationship between diet and health outcomes. In the second part, we address issues relating to the effectiveness of interventions to change dietary patterns, with the focus on dietary counseling. Chapter IV discusses these findings in more detail and presents our views of the necessary future research agenda. Tables and figures appear at the end of the chapters where they are first called out. Appendix A presents the acknowledgments for this report.

Methods

Analytic Framework and Key Questions

Staff of the RTI-University of North Carolina Evidence-based Practice Center (RTI-UNC EPC), together with 3 members of the US Preventive Services Task Force (USPSTF) who are authors of this systematic evidence review (SER), developed an analytic framework to guide the work of producing this systematic evidence review (Figure 1). It depicts the relationship between diet and health, feasible dietary assessment strategies, evidence that dietary interventions delivered through primary care are effective in promoting long- and short-term behavior change, adverse effects associated with dietary assessment or intervention, and system influences on the delivery of diet assessment and counseling.

To guide the work more precisely, we identified 7 key questions:

1. What is the relationship between dietary patterns and health outcomes?
2. What are valid, feasible tools for assessment of dietary risk?
3. What are the adverse effects of dietary assessment?
4. What is the efficacy of primary care counseling and dietary behavior change interventions?
5. What are the adverse effects and associated costs of dietary behavior intervention?
6. Which of the following system influences facilitate or impede dietary intervention:
   features of the health care team?
   features of the practice setting?
   features of the health care system?
7. Can dietary supplements improve nutrition in patients identified as undernourished?

Literature Search and Analysis Strategy

To identify studies examining the question of the relationship between diet and health, we identified existing systematic reviews from MEDLINE, the Cochrane Database of Systematic Reviews, and the University of York Database of Reviews of Effectiveness (DARE) from 1990 to the present; we did not conduct formal searches of the primary literature. When systematic reviews were unavailable, we also included representative individual observational studies and randomized trials.

To find articles relevant to the questions about dietary assessment and the effectiveness of diet counseling in the primary care setting, we searched the MEDLINE database for citations to articles published between 1966 and 2001. The information on searches provided below and in Chapter III pertains to those key questions about dietary behavior interventions.

We employed the following Medical Subject Heading (MeSH) terms for the 3 main types of searches (diet, primary care, and counseling):

- Diet: "diet," "nutrition," "food frequency," “food habits," "dietary assessment," "diet records," "diet surveys," and "nutrition assessment”;
- Primary care: "family practice," "primary health care," "primary care setting";
- Counseling: "counseling," "dietary counseling" (textword), "diet counseling" (textword), and "nutrition counseling (textword)."

We carried out additional searches to identify articles regarding brief dietary assessment methodology and existing systematic reviews about dietary counseling interventions. We reviewed bibliographies of pertinent articles and consulted with experts in the field to assure completeness.

Inclusion and Exclusion Criteria

We limited all searches to "human" populations and "English language." For counseling interventions, we restricted searches to randomized controlled trials (RCTs).

For the diet counseling literature related to patient dietary outcomes, we included articles if they evaluated a nutrition intervention delivered to a primary care population either within a primary care setting or after referral. We included studies that assessed impact on dietary change among those at risk for chronic disease (e.g., elevated cholesterol). However, we excluded studies of individuals with a diagnosed illness that (a) might directly affect their dietary intake (e.g., cancer), (b) required a specialized diet (e.g., diabetes or renal disease), or (c) required entry into the study immediately following a life-threatening, disease-related event (e.g., during hospitalization for an acute myocardial infarction).

All included articles used a RCT design with baseline and follow-up measures of relevant dietary outcomes. We excluded studies that reported physiologic measures or biomarkers associated with dietary change (e.g., serum vitamin levels) but no direct measure of diet behavior. We also did not use studies in which the diet was externally controlled (provided by researchers or in a residential institution). To include a study we required that the retention rate be at least 50% and that studies be at least 3 months in duration.

We retained studies evaluating physician training programs to improve physician counseling practices if a control or comparison group was a part of the evaluation and if the counseling approach tested was relevant to the primary care setting.

Literature Synthesis

Senior investigators reviewed titles and abstracts to identify which full manuscripts to review and made the final decisions about inclusion or exclusion. Assisted by nutrition doctoral

students, they then reviewed individual articles and abstracted selected information onto evidence tables. Reviewers discussed any disagreements; the senior investigators made the final decisions.

We graded the quality of the articles, in terms of internal validity, as good or fair. We judged studies to be fair or good quality based on allocation concealment, blinding of outcomes assessment, and completeness of follow-up. Exclusion criteria eliminated articles that would be considered of poor quality.

We classified each study as having low, medium, or high external validity based on representativeness of the providers and patient population as well as feasibility of replicating the intervention in a primary care setting without additional research infrastructure. Two senior reviewers independently rated the intensity of the dietary intervention as low, medium, or high based on the number and length of counseling contacts, the magnitude and complexity of educational materials provided, and the use of supplemental intervention elements, such as support groups sessions or cooking classes. Low-intensity interventions generally involved 1 contact lasting less than 30 minutes. High-intensity interventions involved greater than 6 contacts, each lasting at least 30 minutes. Medium intensity was in between low and high.

Given the wide range of measurement and reporting strategies and the need to facilitate comparability across studies, we also classified the effect size achieved by each study. We developed specific cutpoints to define 3 effect size categories, denoted large, medium, or small, for dietary fat, fruit and vegetables, and fiber. For outcomes stated in percentage of calories from total or saturated fat, we defined effect sizes as follows: large, >10% change in total fat or >3% change in saturated fat; medium, >5% to 10% change in total fat or >1.3% to 3% change in saturated fat; and small, 0% to 5% change in total fat or 0% to 1.3% change in saturated fat.

We classified fruit and vegetable intake effect sizes based on the following categories: large, ≥ 1 serving change; medium, 0.2 to 0.9 serving change; and small < 0.2 serving change. For fiber, effect size definitions were as follows: large change, > 6 grams (g); medium change, 1 g to 6 g; and small change, < 1 g. When studies used outcomes such as amounts of intake (e.g., grams of fat), dietary risk scores, or changes in specific dietary behaviors, we classified effect size based on the relative change (net change divided by baseline values in controls) and by our own qualitative estimates; when the abstractors disagreed, they resolved the discrepancy by consensus discussion.

Preparation of Systematic Evidence Review

The authors presented the work plan and interim portions of this SER at several USPSTF meetings in 2000 and 2001; at those times the Task Force liaisons and the entire Task Force could discuss and clarify the breadth of the work. In particular, Task Force members encouraged the research staff to expand their examination and review of literature pertaining to linkages between diet and health outcomes (i.e., Key Question No. 1) and provide much more detailed data and analysis on the components of dietary intervention strategies than had originally been planned. The senior author, who had primary responsibility for materials relating to issues of counseling and dietary practices, also participated in teleconferences of the USPSTF Counseling and Behavioral Intervention Work Group. The draft SER was circulated for outside peer review in early June 2001 and revised appropriately for this final version.

Results

We present here the results of our systematic review for the US Preventive Services Task Force (USPSTF) of issues relating to promoting healthy diets; the chapter is organized in terms of the key questions introduced in our analytic framework (Figure 1) and the text of Chapter II. As explained in Chapter I, the first part of the results concerns the relationships between numerous dietary constituents and a variety of important health outcomes. The remainder of the chapter deals with questions about the efficacy or effectiveness of counseling activities to change dietary behaviors for the better, including the availability of reasonably brief instruments to assess dietary behaviors feasible for use in primary care settings and populations. Tables and Figure 2 can be found at the end of the chapter. A glossary defining all abbreviations and acronyms used in one or more of these tables is found just ahead of Table 1.

Key Question No. 1: Relationship Between Dietary Patterns and Health Outcomes

Our search of the Database of Reviews of Effectiveness for systematic reviews using the key word "diet" produced 215 results. Through this search and subsequent targeted MEDLINE searches, we identified 58 references on the diet-health relationship that we included in our final review.

Eating habits over a lifetime can have a significant impact on the incidence and severity of many health disorders. The complete body of literature regarding the health effects of foods is beyond the scope of this report and has been the subject of extensive reviews.[3]

A direct relationship exists between nutritional risk factors and certain key diseases. We focus here on the relationship between several different dietary elements and the risk of important health outcomes. When data on health outcomes are lacking but reasonable surrogate measures exist, we examine the surrogate measures instead. For each dietary element, we first consider the epidemiologic evidence regarding the association between that element and various health studies. Next, we consider any studies that examine the effect of change consumption of the dietary element and change in health states or a well-validated surrogate outcome. Another USPSTF review will address the crucial question of the effect of diet on obesity.[4]

Effects of Diets High in Fat Intake

The effects of dietary fat intake, including the effect of changes in the subfractions of saturated, polyunsaturated, and monounsaturated fats, have been examined in relation to a wide range of health outcomes using a variety of study designs. Whether dietary goals should recommend limiting total fat intake or should keep the total proportion of dietary fat constant while changing the balance of subfractions remains a topic for substantial debate and research. This debate has not been fully elucidated through research comparing the two approaches; its full description is beyond the scope of this review.[5] Nevertheless, we will attempt to summarize current findings with respect to the relationship between dietary fat intake and important health outcomes such as those relating to coronary heart disease (CHD), stroke, or cancer.

Dietary Fat and Coronary Heart Disease

Observational studies. Observational studies of the relationship between the level of dietary saturated fat and the incidence of CHD and stroke have generally, but not always, found a positive association.[6] Much of this relationship appears to be mediated through total cholesterol

(TC) and low-density lipoprotein (LDL) cholesterol levels, which are related to both dietary saturated fat intake and the incidence of CHD events.[7] A recent development is the greater appreciation that another fat subtype, trans-unsaturated fats, which are commonly used in oils for fried foods, is also associated with unhealthy lipid levels and an increased risk of heart disease.[8,9]

Effect of interventions to change dietary fat on CHD and stroke. Hooper et al. reviewed the effect of dietary interventions to lower fat intake or the incidence of CHD.[10] They identified 26 randomized trials published through January 1999 that had been intended to modify fat or cholesterol intake, were not multi-factorial, and lasted at least 6 months. Their overall analysis found no effect on total mortality (relative risk [RR] 0.98; 95% confidence interval [CI], 0.86-1.12), a small, statistically nonsignificant effect on cardiovascular mortality (RR, 0.91; 95% CI, 0.77-1.07), and a 16% reduction in total cardiovascular events (RR, 0.84; 95% CI, 0.72-0.99). Most of the trials included patients with previous history of CHD; 2 included patients without known CHD living in institutional settings and being fed controlled diets. The data were insufficient to measure the effect of fat-restricted diets among free-living patients without previous CHD.[10]

The best data about the effect of dietary counseling on CHD incidence in persons without previously known CHD come from several large trials that addressed multiple CHD risk factors. Ebrahim and Smith performed a systematic review and meta-analysis of 14 such trials of at least 6 months' duration, including 5 major trials examining efforts to prevent CHD events through changes in dietary fat for high-risk patients with no previous history of CHD.[11] The dietary interventions were designed to improve serum lipid levels and reduce CHD events. Some of the trials also provided smoking cessation counseling or hypertension treatment. The summary effect on serum cholesterol was a reduction of 5.4 mg/dL (0.14 mmol/L), with a standard error of

0.38 mg/dl, (0.01mmol/L). Overall, the interventions did not have a significant effect on total mortality (odds ratio [OR], 0.97; 95% CI, 0.92-1.02), CHD mortality (OR, 0.96; 95% CI, 0.88-1.04), or nonfatal myocardial infarctions (OR, 1.0; 95% CI, 0.92-1.07).

The combined estimates, however, obscure some of the heterogeneity among individual trial results. The Oslo trial, in particular, tested a diet that reduced saturated fats and increased polyunsaturated fats.[12] The investigators found large reductions in total and LDL cholesterol, increases in high density lipoprotein (HDL) cholesterol, and decreased CHD events among patients assigned to the intervention. The patients in this trial, however, had very high cholesterol levels (average total cholesterol at entry, 327 mg/dl) and consumed diets very different from those consumed in the United States today. Hence, the results of the Oslo trial may not generalize well to US populations. The Multiple Risk Factor Intervention Trial (MRFIT) study in the United States did not find important reductions in CHD events, despite intensive dietary counseling consisting of 10 weekly group sessions followed by individualized counseling at least every 4 months thereafter.[13]

Dietary fat intake and CHD risk factors in children. The benefits of reduced dietary fat intake during childhood are uncertain. Some observational evidence suggests that high childhood serum lipid levels are associated with higher levels in adulthood, but the relationship is imperfect.[14] The effect of reducing dietary fat intake during childhood has been examined in a large RCT involving children ages 8 to 10 years at enrollment with LDL levels between about 115 mg/dl and 165 mg/dl. Intervention patients received a diet providing 28% of energy from total fat. Follow-up lasted a mean of 7.4 years.[15] The 3-year intervention included 18 individual and group sessions during the first year and 4 to 6 individual or group sessions in years 2 and 3, with monthly telephone contacts between sessions. Patients receiving the intervention were able

to reduce total fat intake by 2% to 4% and saturated fat intake by 1% to 2%. Patients had no adverse changes in mean height, ferritin levels, body mass index (BMI), or selected psychometric indices, but they also demonstrated little or no long-term change in serum cholesterol levels: differences in LDL cholesterol were 3% to 4% at 1 year but only 1% to 2% at the final follow-up visit.

Dietary Fat and Stroke

Gillman et al. examined the relationship between dietary fat intake and the risk of stroke in men using data from the Framingham Heart Study.[16] They found that increasing intake of dietary total and saturated fat was associated with lower risk of ischemic stroke (RR, 0.85 [95% CI, 0.78-0.94] for each 3% increase in total fat intake; RR, 0.91 [95% CI 0.85, 0.98] for each 1% increase in saturated fat). Adjustment for potential confounders did not affect the results. Insufficient data are available to examine the relationship among women.

Dietary Fat and Cancer

The relationship between dietary fat and cancer has been difficult to elucidate. Numerous observational studies have examined the intake of dietary fats, including total fat and the saturated and unsaturated subfractions, and different forms of cancer.[17] Most analyses have focused on the relationship between dietary fat and cancers of the prostate, breast, or colon. We examine these relationships in some detail here, but a full review of the topic is beyond the scope of this report.

Dietary fat and prostate cancer. Kolonel et al recently reviewed the relationship between dietary fat and prostate cancer.[18] They examined English language studies from MEDLINE (search dates not reported) on the relationship between dietary fat (or fat-containing

foods) and incidence or mortality from prostate cancer. Ecologic and case-control studies generally supported a relationship between dietary total or saturated fat and prostate cancer; cohort studies have had conflicting results.

Dietary fat and breast cancer. Hunter et al. performed a meta-analysis of 7 prospective cohort studies (including more than 337,000 women) that examined the relationship between dietary fat and breast cancer.[19] They found no significant association between dietary fat consumption and breast cancer (RR for highest versus lowest quartile, 1.05; 95% CI, 0.94-1.16). The lack of association persisted even when the subgroup of women with very low intake (less than 20% of calories from total fat) were compared with women in the highest quartile of intake.

Dietary fat and colon cancer. Some studies suggest that diets high in total fat increase the risk of colorectal cancer: relative risks for cohort studies have ranged from 1.3 to 2.2.[20] Animal fats seem to be most closely associated with risk. Other reviews have not identified a relationship between dietary fat and colorectal cancer once the investigators controlled for total caloric consumption.[21]

Effects of Diets High in Cholesterol

Dietary cholesterol intake appears to have at best modest effect on serum cholesterol levels once fat intake has been controlled for. No evidence exists to determine if reducing dietary cholesterol specifically reduces CHD events.[22,23]

Effects of Diets High in Fruits and Vegetables, Including Vegetarian Diets

Vegetarian Diets

To examine the relationship between a vegetarian diet and multiple health outcomes, Key et al. identified 5 large prospective cohort studies that drew their study populations from groups known to have a high proportion of vegetarians, defined as persons who reported not eating fish or meat.[24] These 5 studies examined health outcomes for more than 76,000 persons ages 16 to 89 years over a mean of 10.6 years, including 27,000 vegetarians. Using a random effects model meta-analysis to combine results from the 5 studies, they found that total mortality did not clearly differ between vegetarians and nonvegetarians (RR for death among vegetarians, 0.95; 95% CI, 0.82-1.11). CHD mortality, however, was significantly lower among vegetarians (RR, 0.76; 95% CI, 0.62-0.94). The relative risk reduction was larger at younger ages and among those following a vegetarian diet for more than 5 years. Risk reductions persisted after adjustment for potential confounders of age, smoking status, alcohol use, education level, exercise level, and body mass index. Summary risk ratios for death rates from colorectal, lung, breast, or prostate cancer did not differ, although the total numbers of events were small enough that excluding a modest protective effect with certainty was not possible. No effect was seen on stroke mortality.

Effects of Fruits and Vegetables on CHD and Stroke

Numerous observational studies have examined the effect of diets high in fruit and vegetables on CHD and stroke. Persons who report consuming high levels of fruits and vegetables appear to have a lower risk of heart disease and stroke than those who consume few

of these nutrients. The evidence from studies using the strongest design (cohort studies), however, have found mixed results for CHD.

In a systematic review of observational studies published through 1995, Ness and Powles examined the relationship between fruit and vegetable consumption and CHD or stroke.[25] They included studies that measured dietary intake directly and that examined the association between fruit and vegetable consumption (or a nutritional surrogate) and CHD or stroke incidence.

Almost half (8 of 19) of the cohort or case-control studies examining the relationship between fruit and vegetable consumption and CHD found a protective effect; most studies (6 of 9) examining stroke also found fruit and vegetable consumption protective. The authors did not combine effect estimates because of the heterogeneity of study designs and effect sizes. Inaccuracy and imprecision in measuring fruit and vegetable consumption may have hampered estimating the true effect of fruits and vegetables on cardiovascular events. In addition, separating the effect of fruits and vegetables from the impact of concurrent increases in dietary fiber and reductions in saturated fat and perhaps total calories is difficult.[25]

Law and Morris performed a similar systematic review of cohort studies published through 1996 that reported at least 50 CHD events;[26] 11 studies met their eligibility criteria. They re-analyzed the data from these studies and expressed the results as the relative risk of CHD for persons consuming fruits and vegetables at the 90th percentile compared with those the 10th percentile (about a 4-fold difference in consumption). They also examined several other markers of fruit and vegetable consumption such as potassium intake, fruit or vegetable fiber intake, or vitamin intake levels. The correlation among results was good regardless of how intake was measured. The median effect after adjustment for potential confounders was about a 15% lower risk of CHD events.

More recent cohort studies have found mixed results. Pietinen et al. studied 21,000 men 50 to 69 years of age enrolled in the Alpha Tocopherol, Beta-carotene Cancer Prevention Study.[27] Participants with high fruit and vegetable consumption (fourth and fifth quintiles) had relative risks for coronary death 15% to 40% lower than those controls whose consumption fell into the first or second quintiles of consumption over the 6-year study.

Mann et al. studied more than 10,000 British men and women ages 16 to 79 years who had no previous CHD over a mean of 13 years to examine the effect of various dietary elements on CHD death rates and total mortality.[28] Dietary patterns were measured using a semi-quantitative food frequency questionnaire administered at baseline. They found no protective effect against CHD death or total mortality among persons consuming large amounts of fruits, green vegetables, carrots, or dietary fiber. Increased consumption of dietary fat and cholesterol were both associated with increased risk of CHD death but not total mortality.

Key et al. examined the effect of different dietary elements within a cohort of 10,000 health-conscious persons in the United Kingdom recruited from health food stores, vegetarian societies, and magazines.[29] Dietary assessment involved a brief questionnaire at baseline; a subset of participants underwent a follow-up questionnaire to determine changes in dietary patterns. Outcomes (mean follow-up, 17 years) were tracked through the British National Health System. Mean age of the participants was 46 years; 43% were self-described vegetarians. Persons who reported consuming fresh fruit daily had 20% to 25% lower rates of CHD death and 30% to 40% lower rates of stroke death than those consuming these foods less often than daily. Total mortality was 20% to 25% lower as well. Raw salad consumption was associated with lower risk of CHD death but not stroke death. Eating whole grain bread was associated with a 10% to 15% lower total mortality rate but did not have a significant effect on CHD death or

stroke death. Reporting a vegetarian diet was not a significant predictor of decreased CHD mortality.

Joshipura et al. examined the relationship between fruit and vegetable intake and the risk of coronary heart disease using data from the Nurses' Health Study and the Health Professionals Follow-up Study.[30] They found, after adjustment for standard cardiovascular risk factors, that subjects in the highest quintile of intake of fruits and vegetables (9 to10 servings per day) had a relative risk of 0.80 (95% CI, 0.69-0.93) compared to those in the lowest quintile (2 to 3 servings per day). Each difference of 1 serving per day of fruit or vegetable was associated with a relative risk of 0.96 (95% CI, 0.94-0.99). The risk reduction was greater specifically for consumption of leafy green vegetable (RR, 0.77; 95% CI, 0.64-0.93).

Effects of Fruits and Vegetables on Blood Pressure

Observational evidence. Ascherio et al. examined the relationship between fruit and vegetable consumption and blood pressure in the Nurses' Health Study and found that fruit and vegetable consumption was associated with lower systolic and diastolic pressures.[31]

Dietary intervention trials. A recent large randomized trial (Dietary Approaches to Stop Hypertension [DASH]) examined the effect of a diet high in fruits and vegetables on blood pressure among volunteer subjects over 13 weeks at 4 centers in the United States. By design, a majority of the 412 participants (57%) was African-American; 57% were women; and the mean age was 48 years.[32] Patients were given specially prepared meals during the trial; this factor may limit the generalizability of this study with respect changing behavior, but it allowed the investigators to estimate ideal efficacy.

Eligible patients had a baseline systolic blood pressure between 120 and 159 mm Hg and a diastolic blood pressure between 80 and 95 mmHg. Subjects were randomized to a diet high in

fresh fruit and vegetables with typical dietary fat (35% total fat), a combination diet high in fresh fruits and vegetables plus low in dietary total and saturated fat (25% total fat), or a control diet for 13 weeks.

Compared to the blood pressures for controls, blood pressure was reduced most among those consuming the combination diet (a 5 mm Hg overall reduction in systolic pressure, 11 mm Hg reduction in hypertensive persons); smaller reductions were achieved for the increased fruit and vegetable/usual fat diet (3 mm Hg overall, 7 mm Hg among hypertensives).[32] Two older trials that randomized patients to a vegetarian diet low in saturated fats found similar reductions in systolic blood pressure.[33,34]

Effects of Fruits and Vegetables on Lipid levels

Most interventions designed to affect serum lipid levels have focused on reducing the amount of dietary total or saturated fat or increasing fiber consumption. Reducing dietary fat may entail increasing fruit and vegetable consumption, and they have in some cases successfully changed lipid levels. Zino et al. examined the specific effect of increasing fruit and vegetable consumption on lipid levels in an 8-week randomized trial in New Zealand.[35] Intervention subjects were asked to increase fruit and vegetable consumption from 3 or fewer servings per day to 8 servings per day but not to change consumption of nuts, oils, or butter. They found that participants were able to increase fruit and vegetable consumption 3-fold but that lipid levels did not change. The effect on the proportion of dietary fat intake was small (reduction from 35% to 32%).[35]

Effects of Fruits and Vegetables on Cancer

A large body of observational evidence suggests that persons who consume higher levels of fruits and vegetables are at lower risk for some forms of cancer, particularly gastrointestinal, lung, and endometrial cancers. Much of this evidence comes from either ecologic studies, which are subject to confounding, or from case-control studies, which may be subject to recall bias. Data from cohort studies, a design thought to be less susceptible to bias, are less suggestive of clear benefit for most types of cancer.[36] Two recent cohort studies found little effect of increased fruit and vegetable consumption on the incidence of lung or colorectal cancer.[30,37]

Smith-Warner et al. recently pooled data from 8 large cohort studies that had at least 200 incident cases of breast cancer.[38] Persons in the highest quartile of consumption of fruits and vegetables had risks for breast cancer that were only slightly lower than those risks among persons in the lowest quartile (RR, 0.93; 95% CI, 0.86-1.00). These results stand in contrast to those of another systematic review of observational data that identified 14 case-control and 3 cohort studies and found a significant risk reduction associated with higher vegetable consumption (RR, 0.75; 95% CI, 0.66-0.85).[39]

Effects of Legumes (Beans, Peas, and Nuts) on CHD

Bazzano and colleagues examined the relationship between consumption of legumes (beans, nuts, and peas) and the risk of CHD, using data from the National Health and Nutrition Examination Survey (NHANES) Epidemiologic Follow-up Study.[40] They measured legume consumption using a 3-month food frequency questionnaire and obtained data on CHD events from medical record review and death certificates. Persons consuming higher amounts of legumes had lower rates of CHD events. Compared to those consuming legumes less than once per week, those who consumed 4 or more servings of legumes per week had a relative risk for

CHD of 0.78 (95% CI, 0.68-0.90). Adjustment for potential confounders did not affect the magnitude of the estimate importantly (adjusted RR, 0.80; 95% CI, 0.69-0.91).

Effects of Diets High in Whole Grains and Fiber

Intake of dietary fiber, including whole grains, has been associated with a wide range of positive health outcomes, including lower mortality from CHD and cancer, lower rates of diabetes and obesity, and better gastrointestinal function.[41] In some cases, separating the effects of fiber and whole grains from other dietary constituents (e.g., fruits and vegetables, dietary fat) is difficult.

Whole Grains and All-cause Mortality

Jacobs et al. used data from the Iowa Women's Health Study to examine the relationship between whole grain consumption and all-cause mortality.[42] In this study, women were matched on total grain fiber intake but had varied levels of whole versus refined grains. Persons who consumed predominantly whole grains had a lower risk of mortality compared with those consuming refined grains (adjusted RR, 0.83; 95% CI, 0.73- 0.94). These data suggest that the type of grain fiber may be important to consider when examining diet-health relationships and that whole grains are more protective than refined grains.

Whole Grains and CHD

Several studies have examined the relationship between dietary intake of whole grains and risk of CHD. Jacobs and colleagues examined this relationship in the Iowa Women's Health Study, a prospective cohort study, and found that women who reported higher intake of whole grains had lower rates of fatal CHD events than those rarely consuming whole grains (adjusted

RR 0.71 for consumption of 1.2 servings per day compared with those consuming 0.2 servings per day).[42] More recently, Liu et al. used data from the Nurses' Health Study to examine the effect of whole grains on first CHD events (fatal and nonfatal).[43] Whole grain consumption was inversely related to CHD incidence (adjusted RR, 0.75; 95% CI, 0.59-0.95 for highest level of consumption [2.7 servings per day] versus the lowest level [0.13 serving per day]).

Whole Grains and Stroke

Liu et al. also examined the relationship between whole grain consumption and risk of ischemic stroke in the Nurses' cohort.[43] Higher consumption was protective against stroke as well (adjusted RR, 0.72; 95% CI, 0.53-1.00) for the second lowest quintile [0.43 servings per day] versus the lowest quintile [0.13 servings per day] of consumption).

Fiber and CHD

Many observational studies have found lower rates of CHD in those persons who consume large amounts of dietary fiber compared with those who consume little fiber.[41,44] However, a large trial examining the effect of fiber on CHD events among middle-aged men who had recently had a myocardial infarction found no protective effect from advice to eat more fiber, despite fiber intakes that were twice that of control subjects.[45] The relative risk for total mortality among those randomized to fiber was 1.23 (95% CI, 0.95-1.60).

Fiber and Lipid Levels

Soluble fiber intake of 3 grams (g) per day (roughly 3 servings of 28 g of oatmeal per day) has been shown to reduce serum cholesterol levels by 2% to 4%, based on data from recent systematic reviews and meta-analyses.[46,47]

Fiber and Blood Pressure

The independent relationship between a high fiber diet and reductions in blood pressure has been difficult to study because high fiber diets often contain large amounts of fruit, are high in potassium, and have low levels of sodium. All these factors may also positively influence blood pressure. He and Whelton reviewed studies of the relationship between dietary fiber and blood pressure,[48] although they did not describe search methods or eligibility criteria. Persons consuming diets high in fiber were at lower risk for developing hypertension than those consuming lower levels of fiber. Relative risks were 0.76 for women and 0.64 for men when those with the highest consumption (greater than 25 g per day) were compared with those with the lowest (less than 10 to 12 g per day). They also identified 7 randomized trials of fiber supplementation published from 1986 to1992 that had blood pressure reduction as the primary endpoint.[48] Fiber supplements (average supplement, 14 g per day) were associated with a 1.6 mm Hg reduction in systolic blood pressure (95% CI, 0.4-2.7) and a 2.0 mm Hg reduction in diastolic blood pressure (95% CI, 1.1-2.9).

Fiber and Cancer

A wide range of studies has explored the relationship between dietary fiber intake and cancer. Some studies have detected an inverse association between fiber intake and cancer incidence. This finding has not been consistent, however, especially when higher-quality data from cohort studies are considered alone.[41]

For breast cancer, a meta-analysis of 12 case-control studies identified a modest decrease in breast cancer (RR, 0.85) with increased dietary fiber.[49] Newer studies (both case-control and cohort) have not found such an association.[41]

Numerous observational studies have examined the relationship between dietary fiber and colorectal cancer; recent reviews have attempted to summarize the data.[41,50] In general, case-control studies and ecological data support a strong association between dietary fiber and colorectal cancer (odds ratios of 0.50 to 0.65), but cohort studies generally have had mixed results and overall have found only modest decreases in risk (10% to 20%).[50] Two recent randomized trials of a high-fiber or fiber-supplemented diet for patients with previous colorectal adenomas did not find any change in the incidence of future adenomas with increased fiber.[51,52]

Data are not sufficient to determine the relationship between fiber intake and the incidence of cancer at other sites. In summary, current evidence is unclear with respect to the relationship between dietary fiber and cancer.

Effects of Diets High in Fish or Fish Oils on CHD

Marckmann and Gronbaek performed a systematic review of prospective cohort studies examining the relationship between fish consumption and the risk of coronary heart disease death.[53] Across 11 studies (a total of 116,764 persons), fish consumption was associated with a decreased risk of CHD death in high-risk but not low-risk populations.

The Diet and Reinfarction Trial (DART) examined the effect of different dietary recommendations on reinfarction and mortality among 2,033 men who had recently had a myocardial infarction.[45] Those assigned to eat more fish (or to take a fish oil supplement if they could not tolerate the fish) had a 29% reduction in total mortality over 2 years (95% CI, 7%-46%). In an older study of a post-infarction population, Singh and colleagues found similar results.[54]

The GISSI-Prevenzione trial (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico) examined the effect of fish oil supplements on the incidence of CHD

events in patients who had recently had a nonfatal myocardial infarction.[55] Mean lipid levels at entry were 210 mg/dl for total cholesterol, 137 mg/dl for LDL cholesterol, and 41 mg/dl for HDL cholesterol. The risk of the combined endpoint of death, nonfatal myocardial infarction, or stroke was reduced by 10% over a mean follow-up of 3.5 years (95% CI, 1%-18%); the absolute risk reduction was 1.3%, meaning that about 77 people would need to take fish oil supplements for 3.5 years to prevent 1 CHD event. Total mortality was reduced (RRR, 14%; 95% CI, 3%-24%), as were cardiovascular deaths (RRR, 17%; 95% CI, 3%-29%) but not nonfatal myocardial infarction. Numbers needed to treat for 3.5 years were 77 and 91, respectively. No change in lipid levels was noted.

No trial has examined the effect of a diet high in fish among lower-risk patients with no previous history of CHD.

Effects of Dietary Sodium on Blood Pressure

Observational Studies

Numerous ecologic and observational cohort studies have shown that dietary sodium intake and blood pressure are related. In general, the relationship between increasing levels of dietary sodium intake and blood pressure is linear.[56] The relationship is confounded somewhat by the effect of other dietary elements, such as dietary potassium, that may be correlated with sodium intake.

Interventions

Numerous trials in persons with or without previously diagnosed hypertension have addressed the effect of dietary sodium restriction on blood pressure. Two recent systematic reviews and meta-analyses have summarized this evidence.[57,58]

Midgley and colleagues systematically reviewed the literature from 1966 to 1994.[57] Reviewers identified 56 studies that randomized patients to sodium restriction or a control group, measured sodium excretion, and presented results for changes in both systolic and diastolic blood pressure. Patients with hypertension assigned to salt restriction averaged a 95 mmol/day reduction in sodium excretion. After adjustment for confounders, each 100 mmol reduction in daily sodium excretion was associated with a 3.7 mm Hg drop in systolic and a 0.9 mm Hg drop in diastolic blood pressure. For patients without hypertension, the mean decrease in sodium excretion was 125 mmol/day but the mean reduction in blood pressure per 100 mmol/day reduction in sodium excretion was only 1.0 mm Hg for systolic and 0.1 mm Hg for diastolic pressures. Decreases were larger for older patients with hypertension and smaller for free-living normotensive patients. The authors of the review concluded that sodium restriction was potentially useful for persons with hypertension but not for patients with normal blood pressure.

The Cutler team performed a similar systematic review in 1997, also covering literature published from 1966 to 1994.[58] They used slightly different entry criteria: studies had to be randomized trials, be free of obvious confounding, use reasonable sodium intake goals, report changes in sodium excretion, and present results for change in either systolic or diastolic blood pressure. Across 32 trials (2,635 subjects), they found slightly larger estimates of effect than had Midgley et al.[57] Among hypertensive persons, reductions in systolic and diastolic pressures per 100 mmol reduction in salt excretion were 5.8 and 2.5 mm Hg, respectively. Corresponding figures for normotensive persons were 2.3 and 1.4 mm Hg. They concluded that dietary sodium

reduction was valuable, as even the smaller reductions in blood pressure could prevent many events if implemented by the entire population.[58]

The DASH trial examined the effect of different levels of sodium intake in patients eating a controlled diet.[32] Patients were randomized to 1 of 3 levels of sodium intake: control (150 mmol [3.5 grams] of sodium), a 100-mmol sodium diet, or a 60-mmol sodium diet. They followed their initial sodium content for 30 days and then crossed over to the other 2 levels in consecutive 30-day periods. Patients' food was prepared and distributed at the study site; participants ate some meals at the study site but took others away to be consumed at home or work. The outcome of interest was blood pressure, measured at the study site. Sodium restriction reduced blood pressure for both the high fruit, vegetable, and fiber diet group and the control diet group. Participants on the control diet had a 6.7 mm Hg reduction in systolic pressure from high to low sodium, whereas those on the high fruit and vegetable diet had a 3.0 mm Hg drop.

The combined effect of eating a diet high in fresh fruits, vegetables, and fiber and minimizing salt intake reduced blood pressure more than either intervention alone. Low sodium intake had a greater effect in persons with hypertension, African-Americans, and women than it did in patients without hypertension, whites, or men.[32]

Trials of Hypertension Prevention

The Hypertension Prevention Trial, conducted in the mid-1980s, enrolled adults ages 25 to 49 with diastolic blood pressure between 78 and 89 mm Hg and no previous cardiovascular disease.[59] Participants were assigned to dietary counseling about sodium restriction (n = 196) or usual care (no counseling, n = 196). Counseling occurred weekly for 10 weeks, then every 2

weeks for a month, then every other month for three years. Blood pressure was assessed at 6 months and at 1-, 2-, and 3-year follow-up by personnel unaware of treatment status.

Urinary sodium excretion was reduced for intervention patients (net reduction: 3.3 mmol per 8 hours at 6-month follow-up and 5.0 mmol per 8 hours at 3-year follow-up). These outcomes suggested that counseling was effective in changing sodium consumption, but blood pressure did not differ between intervention and control groups at either the 6-month or the 3-year follow-up.

In the early 1990s, another hypertension prevention trial was conducted among a similar population of patients.[60] Eligibility criteria included diastolic blood pressure between 83 and 89 mm Hg and systolic blood pressure below 140 mm Hg. The goal of dietary counseling was to reduce sodium intake to 80 mmol/day (less than 2 g of sodium). Intervention patients received intensive counseling at 10 weekly group sessions followed by 4 monthly sessions, then 1 to 2 contacts per month for the duration of the trial. Participants kept logs of diet and activity and monitored urinary sodium excretion frequently. Control patients received usual care. Sodium excretion (mean 180 mmol/day at baseline) was reduced by 50 mmol/day for intervention patients and 10mmol/day for controls. Systolic blood pressure was reduced by a net 2.9 mm Hg at 6 months ($P < 0.001$) and 1.2 mm Hg at 3 years ($P = 0.02$). Development of hypertension, defined as systolic blood pressure greater than 140 mm Hg or diastolic blood pressure over 90 mm Hg or a new prescription for hypertension medication, was lower for intervention patients (RR = 0.82; $P = 0.05$).

Thus, intensive dietary counseling to reduce sodium intake among patients with high-normal blood pressure can apparently effectively reduce dietary sodium as measured by urinary

sodium excretion. However, it has little effect on mean blood pressure and only a small effect on number of abnormal blood pressure readings or initiation of antihypertensive medication.

The adverse effects of a low sodium diet have not been well studied. Data from systematic reviews of multiple trials have not identified important harms from sodium reduction other than its effect on food palatability, which has not been well investigated.

Effects of Dietary Potassium on Blood Pressure

Observational Studies

Several observational studies have examined the effect on blood pressure of diets high in potassium. They have generally found an inverse relationship between potassium intake and blood pressure. Separating this effect from the impact of other related components of the diet, including fiber, sodium, and the amount of fruits and vegetables, however, has been difficult.[61]

Interventions

Whelton et al. performed a systematic review of the effect of oral potassium supplementation on blood pressure, they identified 33 randomized trials published before July 1995 that involved a total of 2,609 subjects.[62] Using a random effects model, they found that supplementation led to mean decreases of 3.1 mm Hg (95% CI, 1.9-4.3) in systolic blood pressure and 2.0 mm Hg in diastolic blood pressure (95% CI, 0.5-3.4). Thus, supplementation with potassium does seem to improve blood pressure and lends support to observational evidence that diets high in potassium-rich foods also improve blood pressure.

Effects of Dietary Calcium

Effect of Dietary Calcium on Osteoporotic Fractures

Observational data. Population-based cohort and cross-sectional studies suggest that low calcium intake among young women leads to lower peak bone mass, a risk factor for postmenopausal osteoporosis. Data on the effect of calcium intake among middle-aged women are less clear. Feskanich et al. found that higher intake of dietary calcium was not associated with a lower risk of hip fracture in the Nurses' Health Study cohort of women ages 34 to 59 years.[63]

Whelton et al. performed a systematic review of 33 observational and interventional studies appearing between 1966 and 1994.[62] Their analysis focused on premenopausal adult women and adult men between the ages of 18 and 50 years. The authors examined the strength of the correlation between dietary calcium intake and bone mass and calculated a summary correlation coefficient (r = 0.13; 95% CI, 0.09-0.16) and a partial correlation coefficient (partial r = 0.08; 95% CI, 0.05-0.12) that were statistically significant. They also concluded that a difference of 1,000 mg per day of calcium intake (in the form of supplements) would prevent the additional loss of 1% of bone at all bone sites examined except the ulna.

Cumming examined the effect of calcium intake on osteoporotic fractures in postmenopausal women.[64] They performed a meta-analysis of 16 observational studies of dietary calcium that examined incidence of hip fracture. Pooling data from these 16 studies, the authors found an odds ratio for fracture of 0.88 (95% CI, 0.80-0.97) for 1,000 mg or less of higher intake of calcium. They concluded that modestly increased calcium intake among postmenopausal women appears to be associated with a small reduction in risk of fracture.

Intervention studies. Multiple randomized trials have examined the effect of increased calcium on bone mass or fracture risk. Heaney performed a systematic review of all studies relating calcium intake to bone health from 1977 to 1999 and identified 39 RCTs of the effect of calcium supplementation (33 with calcium supplements alone and 6 that used dietary sources alone or in addition to calcium).[65] Of the 39 trials, 37 showed a positive effect on bone mass; 5 showed reduced fractures (all among the elderly). The concurrent use of vitamin D in the intervention studies makes it difficult to estimate the effect of increased calcium alone.

Adverse effects. The potential adverse effects of recommending high calcium intake include (rarely) milk alkali syndrome and increased occurrence of kidney stones in a susceptible host. When dairy products are the source of calcium, other potential adverse effects include exacerbation of lactose intolerance or an increase in dietary fat intake if low-fat dairy products are not used. In men, prostate cancer risk may be increased with higher intake of dairy products, an effect that may be mediated through reduced circulating 1,25 vitamin D levels.[66] Available data are insufficient to estimate the risk of these complications.

Other Dietary Elements

Other USPSTF reviews will deal with other potentially important dietary elements such as dietary iron and folate. Other vitamins are examined in forthcoming work on vitamin supplements, and infant nutrition will be covered by the review of counseling about breastfeeding.

Special Populations

Pregnant Women

Nutritional status is especially important during pregnancy. Low birth weight and neonatal mortality are more common in pregnant women with very poor nutritional status[67,68] and in those who fail to gain adequate weight during pregnancy.[69,70] Factors other than nutrient intake *per se*, however, may account for these outcomes. Prenatal programs providing nutritional support for pregnant women have been associated with improved perinatal outcomes.

Pregnancy brings increased requirements for energy and specific nutrients, such as protein, calcium, folic acid, and iron.[70-72] Folate supplementation, which prevents neural tube defects, is being considered in the specific USPSTF review for that subject. Oral iron supplements may be beneficial in preventing iron deficiency anemia in pregnancy. They are often prescribed routinely as part of prenatal health care, along with vitamin supplementation. The evidence for iron supplementation will be covered in the separate review on screening for iron deficiency.

Older Adults

The elderly also have special nutritional issues. Undernutrition, common among the elderly, is associated with adverse health outcomes. Because clinical recognition of protein-calorie malnutrition, especially when manifested by clinically subtle findings, is often delayed among older adults, attempts have been made to screen older adults routinely (see Key Question No. 2, below). The effectiveness of screening and counseling persons at risk has not been well documented, but a systematic review about the use of nutritional supplements to treat undernutrition is considered in Key Question No. 7 (below).

Summary of the Evidence Regarding the Relationship Between Diet and Health Outcomes

Based on our review of the evidence relating various dietary elements with important health outcomes, we found reasonably good evidence that diets low in saturated and trans-unsaturated fats, and high in fruits, vegetables, fiber, and fish, are associated with better health outcomes. Diets high in calcium for women, and diets low in sodium for persons with hypertension or at high risk for developing it, are also associated with better surrogate health measures (bone density and blood pressure, respectively) that are correlated with improved health.

Key Question No. 2: Valid, Feasible Tools for Assessment of Dietary Risk and Patterns

We identified 18 articles related to dietary assessments designed to determine level of risk, to guide counseling, or both. We also identified assessment questions that can inform counseling by assessing mediators to dietary change, such as stage of readiness to change[73-90] (see Table 1).

Dietary assessment tools fall into 3 broad categories. First are age-specific general assessment tools, where attention is directed at issues relating to infants and toddlers, older children, adults, and the elderly. For children and adults, the particular concerns may involve assessing dietary behaviors most strongly identified with risk for chronic disease; for the elderly, unintentional weight loss associated with chronic illness, social isolation, or other factors linked with the aging process are of particular concern. The second category of assessments involves those that identify factors that foster or mediate dietary behavioral interventions. The third category includes assessment instruments to identify the presence of hunger and food insecurity.

Assessment of Eating Patterns and Nutritional Factors in Selected Age Groups

Infant and Toddler Growth and Development

Comprehensive nutritional assessment includes multiple anthropometric and biochemical parameters in addition to estimations of dietary intake patterns. Most significant nutritional problems of infants and toddlers are manifested by a failure to follow predicted growth curves based on height for age and weight for stature. Therefore, growth charts are used to assess nutritional status and general health and well-being of infants, children, and adolescents. In May 2000, revised growth charts for the United States were released, representing the first major revision since the 1977 growth charts from the National Center for Health Statistics.[91] These revisions corrected many previous concerns with the existing charts, centered on the fact that the prior infant charts were developed from data based on a single longitudinal study of primarily formula-fed, white, middle-class infants from a limited geographic region.

Findings of small stature or low weight for height require further evaluation to assess organic problems versus inadequate dietary intake. Excess weight for height is most likely related to either excess calorie intake or inadequate energy expenditure. A review of feeding practices or a 3-day record of all dietary intake can help identify major dietary problems leading to inadequate or excessive intake, but no brief, validated assessment tool is currently available for this purpose.

The revised US growth charts include, for the first time, BMI-for-age charts, and all charts for children and adolescents now extend to 20 years of age. These updated instruments may improve detection and monitoring of pediatric obesity (which is expected to be covered in a separate USPSTF report). Dietary assessment for overweight children above the age of 2 years

should be conducted using tools available to assess dietary behavior associated with chronic disease outcomes.

A few brief diet and health screeners have been developed and evaluated as the first part of a 2-stage screening process to detect iron deficiency anemia in infants and toddlers. These measures are very sensitive (95%), but specificity is quite low (15% to 30%).[92-94]

Children

Assessing dietary intake of children becomes more difficult as they age. Parents have less control over intake and are less able to provide a complete and accurate picture of their children's food intake. In a review of dietary assessment instruments, Rockett and Colditz concluded that for children ages 9 years and older, food frequency questionnaires administered directly to children can provide a reasonably accurate picture of their usual patterns.[95] Correlations with criterion measures on a number of instruments range from about 0.46 to about 0.79, except for sodium intake for which the correlation coefficient was much lower (0.21). Although food frequency assessments are generally the most efficient way to estimate usual dietary intake, the majority of the instruments reviewed were quite lengthy and designed more for epidemiologic research than for rapid clinical assessment.

For children below the age of 9, dietary assessment relies on joint input from parents and children and can be supplemented by written or tape-recorded methods.[96,97] We identified no brief, validated diet screeners for this age group.

Adults

A recent review of practical nutrition assessment in primary care settings by Calfas et al. included brief instruments assessing primarily fat (various types) and, to a lesser extent, fruit and

vegetable intake as well as other nutrients.[98] Table 1 provides key descriptive information about various validated instruments and others identified from the literature. Most of these instruments can be self-administered, are easily scored, have fewer than 40 items, and take 10 minutes or less to administer. In contrast, dietary assessment tools designed for epidemiologic research generally require multiple 24-hour recalls, 7 days of food records, or food-frequency instruments with 60 to 100 items requiring 45 minutes or longer to administer.

Owing to the limited number of items in the shorter assessments, only selected nutrients found in a limited selection of foods can be assessed. These brief measures are usually compared against criterion measures using multiple 24-hour food recalls, records, or longer food-frequency instruments. Correlations with the criterion variable range from 0.37 to 0.60, with higher correlations for single nutrients such as calcium (0.79).[98]

In a recent study not included in the Calfas team's review, Little et al. validated 9 brief diet screener instruments commonly used in the United Kingdom against a 7-day weighted dietary record.[99] Having found reasonable correlations in a range similar to that for the instruments in Table 1, they concluded that brief assessment instruments perform well enough for clinical work. However, underreporting of absolute calorie intake was common, particularly among obese patients (60% of those with BMI ∃30).

Nutritional Assessment in the Elderly

Poor nutrition in the elderly is common: more than 25% of independent-living elderly and more than 80% of home-bound elderly have moderate to high risk of malnutrition and poor nutrition. This problem has been associated with increased mortality, more visits to physicians and hospital admissions, higher morbidity, higher costs, and longer lengths of hospital stay.[100] Risk factors for poor nutrition in older adults include low income, social isolation, loneliness,

concurrent illness, compromised functional status, and polypharmacy.[101] The challenge to primary care physicians is to identify elderly patients who would benefit from dietary intervention without subjecting all elderly persons to a battery of costly and time-consuming anthropometric, dietary, and laboratory tests.[102] However, few providers (10%) routinely assess patients for undernutrition.[103]

Several brief screening instruments have been developed to assess nutritional status in the elderly. Although many are designed for long-term-care patients,[104] some have been validated in community-living elderly and are intended for use by the primary care provider. Three extensively used and tested instruments are described here.

The Nutrition Risk Index (NRI) was derived initially from questions used in the first National Health and Nutrition Examination Survey (NHANES I). [105] Validity has been tested by the ability of the NRI to predict use of health services and correlations with a variety of anthropometric, laboratory, and clinical markers of nutritional status.

The DETERMINE instrument was developed as part of the Nutrition Screening Initiative – a 5-year campaign begun in 1990 to promote nutrition screening and better nutritional care among the elderly in the United States in response to the 1988 US Surgeon General's Workshop on Health Promotion and Aging.[106] This instrument has been validated against measures of depressive symptoms and functional disability.[104]

Probably the most extensively validated instrument is the Mini Nutritional Assessment (MNA).[102] Validation criteria include nutritional status determined by physicians using standard anthropometric, clinical, and dietary measures mortality, and hospital cost.

These instruments all consist of 18 or fewer yes/no checklist items and involve a weighted score. Nutrition factors common to all 3 instruments include unintended weight loss,

problems with chewing and swallowing, polypharmacy, and concurrent illness. The DETERMINE checklist and the MNA also include food access, social isolation, mobility, poverty, and intake of fruits, vegetables, and protein sources. The MNA includes questions to assess psychological problems, dementia, independent living status, and a self-assessment of nutrition problems and relative health status.[101,102,105]

Mediators of Dietary Change

In addition to assessing usual dietary behavior, providers are also encouraged to assess psychosocial factors that may mediate the effects of a counseling intervention. Such instruments have been developed primarily as evaluation measures in nutrition education intervention research.[107] A mediator frequently used to guide counseling for a variety of health-related behaviors is Stage of Readiness to Change.[108] This measure is used to determine the degree to which an individual is ready to begin counseling and how far he or she has advanced in the behavior change process. Several relatively brief and validated instruments assess stage of change for dietary fat intake; they can be implemented in the clinical setting.[109-112]

Table 2 lists additional mediating factors. These mediators have all been associated with success or lack of success in counseling interventions to promote dietary change.[113] Whitlock et al., in a report to the USPSTF, discuss mediators of behavioral change in greater detail.[1]

Food Insecurity and Hunger

Food insecurity and hunger is often overlooked as a nutrition concern. Food insecurity exists "whenever the availability of nutritionally adequate and safe foods or the ability to acquire acceptable foods in socially acceptable ways is limited or uncertain" (p.1560).[114] In 1995, the Current Population Survey (CPS) of the US Census Bureau documented that approximately 12%

of US households are “food insecure”; of these, 28% showed evidence of moderate hunger and 7% indicated severe hunger.[115,116] Extensive work had been done to develop and validate an 18-item assessment instrument for food insecurity in a nationally representative sample of nearly 45,000 households as part of the Food Security Measurement Project.[115]

A subset of 6 questions has shown acceptable accuracy and is more feasible for use in primary care than the original (longer) version.[76] Sample questions from this assessment include: "In the last 12 months, did you ever eat less that you felt you should because there wasn't enough money to buy food?" and "In the last 12 months, were you ever hungry but didn't eat because you couldn't afford enough food?" Patients identified as food insecure are likely to need referral to social services or other forms of assistance before they would be ready to attempt dietary changes to reduce chronic disease risk.

Key Question No. 3: Adverse Effects of Dietary Assessment

We did not identify any studies that document adverse effects of dietary assessment alone. Under Key Question 5, we discuss possible adverse effects of dietary counseling interventions.

Key Question No. 4: Efficacy of Primary Care Counseling and Dietary Behavior Change Interventions

Impact of Dietary Counseling

Overview

From 325 abstracts of articles, we identified 74 articles examining the effect of counseling on dietary behavior (Figure 2). We excluded 41 articles (see Table 3) from our analysis because of methodological and reporting problems, such as lack of a true control group, lack of pre- and post-intervention measures, or retention rates below 50%. We retained 33 articles – representing 29 unduplicated studies – that met our eligibility criteria. Of these 29 studies, 12 examined more than 1 nutrient or food group: dietary fat, 25 studies; fruit and vegetable intake, 11; and dietary fiber, 7. Based on randomized design, high retention rates, and use of appropriate outcome measures, we considered the included studies to be of good quality or fair quality (in the case of 1 study that had a higher and unequal loss to follow-up[117]).

Tables Reporting Study Design, Intervention Characteristics, Outcomes, Effect Sizes, and Other Information

Tables 4-6 on study design and outcomes. Three tables (found at the end of this chapter) present detailed information on the 29 studies that examine the impact of dietary counseling in the primary care setting. Specifically, Table 4 presents information on counseling to reduce dietary fat; Table 5, counseling to increase intake of fruits or vegetables; and Table 6, counseling to increase intake of fiber.

Each table has pairs of pages, such that any given study's information will be found on 2 adjoining pages. The first page presents information about the numbers and characteristics of the study population (including risk status), setting (and external validity of the study), the size and retention rates of the study, descriptions of the activities directed at the intervention and control groups, and the level of intensity of the intervention. The second page then presents information on outcomes, net changes between baseline and final follow-up measures for both intervention and control groups, differences between the intervention and control groups in net changes, and various statistical or effect size determinations.

Each separate row in a table represents a single study; if the study has multiple citations, they are provided in the first column. When studies have multiple arms, those are shown separated in the table by dotted lines; when studies simply have multiple outcome measures, such as outcomes related to total fat and saturated fat (in Table 4), those are given separately within the rows.

The study's setting, the means of performing the counseling, and the intensity and content of the intervention were considered especially significant variables in terms of understanding the feasibility of these types of interventions for primary care practice. Thus, we classified study settings (column labeled "Setting") in 1 of 4 ways:

1. primary care providers (counseling done by physician, physician assistant, nurse practitioner, or registered nurse [RN] in the course of his or her usual duties within the primary care setting);
2. primary care clinic referral (referral within a primary care practice, such as a registered dietitian [RD] or RN employed by the clinic or practice);
3. research clinic; or

4. mailings or computer-generated messages and intervention materials.

In addition, we noted other elements of interventions, including the intensity of the intervention (low, medium, or high) and whether the intervention components used had previously been shown to be associated with improved behavioral outcomes. We rated the study's external validity and feasibility for replication in routine primary care as high, medium, or low; in some studies, multiple intervention arms represented different levels of feasibility.

One column in the outcomes page of each table is entitled "Net Different in Change or Difference at Final Follow-up"; the net difference in change is calculated as the change from baseline to final follow-up for intervention groups minus the change for the control group and then presented in absolute terms. We also presented 2 calculated values in these tables. The "Relative Risk Reduction" is calculated as the absolute change in the intervention group from baseline to follow-up divided by the baseline value of the control group; although presented in arithmetic terms, it can be interpreted in percentage terms. The "Difference in Deltas" is calculated according to the following formula:

[(baseline intervention - follow-up intervention) / baseline intervention] –

[(baseline control - follow-up control) / baseline control] x 100.

Finally, using all information on study outcomes and changes from baseline to final measures for both intervention and control groups, we characterized the amount of dietary change in dietary behaviors, i.e., effect sizes, as small, medium, or large. The specific definitions for effect sizes are presented in the text below that deals in particular with the individual tables. Effect sizes for each study (including each arm or each separate outcome measure) appear in the last column of the table (on the second of the pair of pages).

Tables on interactions of variables and effect on dietary behaviors. Tables 7-12 deal in greater depth with results from reviewed studies concerning combined effects and relationships among, e.g., risk status of patients, intervention intensity, and number of components in the various interventions tested, setting and provider, and levels of effect size. Data are presented separately in some cases for fats, fruits and vegetables, and fiber.

Effect of Counseling on Intake of Total and Saturated Fat

We identified 25 studies examining the effect of counseling on dietary total or saturated fat (Table 4). For outcomes stated in percentage of calories from total or saturated fat, we defined effect sizes as follows: large, >10% change in total fat or >3% change in saturated fat; medium, >5% to 10% change in total fat or >1.3% to 3% change in saturated fat; and small, 0% to 5% change in total fat or 0% to 1.3% change in saturated fat. For comparison purposes, a daily reduction of 7% in percent of calories from fat represents, in food terms, foregoing a medium serving of fast-food French fries or 4 pats of butter per day. For other outcomes, such as those reported in grams of total or saturated fat, specific dietary behaviors, or various food or dietary risk scores, the senior authors independently estimated the magnitude of relative change and assigned effect size categories; disagreements were resolved with consensus discussion.

Of the 25 studies in Table 4, 17 studies reported the effect of counseling on the percentage of calories derived from total dietary fat or provided data permitting us to calculate this value (12 directly reporting percentages, and 5 reporting grams); 11 studies provided data regarding the effect of counseling on percentage of calories from saturated fat. We considered 6 studies to have achieved large effects on change in dietary fat (in at least 1 element of the study).[118-122] An additional 7 studies achieved medium effects (in at least 1 arm or outcome measure);[12,123-128] 1 achieved a medium effect size on the DINE fat score.[129] Finally, 13 studies

(one with 2 published articles) achieved small effects on dietary fat (in at least one part of the study).[13,119,123,130-140] Two studies had multiple study arms with different effect sizes.[119,123] A collection of 4 studies presents data from the Women's Health Trial (WHT), which achieved large effects during a 24-month intervention period that were maintained at the medium level effect size for another year without further intervention. [141-144] Coates et al. examined a minority subset of the WHT.[118]

Eleven studies specifically examined the effect of counseling on the percentage of calories from saturated fats, and the net differences in these percentage reductions between baseline and final measurement in these studies ranged from 0.9% to 5.3%.[13,118,120,122,125,133,134,136,138,139,141-144] Three other studies showed small or medium changes in other measures of saturated fats.[123,129,140]

Effect of Counseling on Fruit and Vegetable Intake

We identified 11 studies that examined the effect of counseling on fruit and vegetable intake (Table 5);[118,123,125,127,132-134,140,145-147] of these, 3 studies tested more than 1 type of intervention.[123,146,147] Eight studies reported their results in terms of the change in the number of servings of fruits and vegetables consumed per day and the differences between the intervention and control groups in their changes between baseline and the end of the study.[118,123,125,132,134,140,145,147] A serving of fruit and/or vegetables is one-half cup, the recommended intake is 5 servings a day, and the current US average is 2.5 to 3 servings per day. The mean increase in consumption seen with interventions ranged from 0 to 3.2 servings per day.

We defined effect sizes for studies reporting results in terms of increases in daily servings as follows: large, ∃1 serving; medium, 0.2 to 0.9 servings; and small, <0.2 servings. Across

these 8 studies, 1 study achieved a small effect;[123] 5 studies reported increases of medium size;[118,125,132,134,147] and 2 had large effect sizes. [140,145]

The studies by Cupples and McKnight[133] and Knutsen and Knutsen[127] each used the percentage of subjects increasing their consumption of fruits or vegetables (or both) above a defined threshold as the main outcome variable. Both teams found little or no change in intake of fruits or vegetables (net increases of 0 to 8 percentage points in the proportion of subjects meeting the defined goals depending on the group being studied); we classified these as having only a small effect size.

Finally, Siero et al. presented grams of fruits and vegetables per day as their outcome measure in a 2-arm study.[146] Group education alone achieved a 20 g increase in fruit and vegetable intake (small effect). By contrast, group education plus tailored messages resulted in a 99 g increase (medium effect); this is approximately equivalent to an increase of one-half serving per day.

Effect of Counseling on Fiber Intake

Seven studies, lasting from 3 months to 4 years, examined the effect of counseling on fiber intake (Table 6).[12,125,128,130,131,134,148] Of these 7 studies, 6 measured outcomes as grams of fiber per day;[12,125,128,130,134,148] 1 used grams of fiber per 1,000 calories (kcal).[131]

For these studies, we defined effect sizes as follows: large, ∃6 g increase in consumption of fiber per day; medium, 1 g to 6 g increase in daily consumption; and small, <1 g change in consumption. Putting these changes in context, the currently recommended daily intake (RDI) for fiber is 20 to 30 g per day; the average intake in the United States is 15 g. An apple has about 2 g of fiber.

Four studies yielded increases in the amount of additional fiber consumed (range: 0.6 g to 3.0 g) classified as medium effect size,[12,125,134,148] although Baron et al. reported differences in fiber intake between intervention and control groups of 2.7 g for men and 6.0 g for women at the 1-year follow-up point.[148] Two studies had only small effect sizes.[128,130] The single study with outcomes in terms of 1,000 kcal had only a small effect size (consensus decision by the senior authors).[131]

Factors Affecting Response to Dietary Counseling

We examined several factors that may affect response to counseling and feasibility in a primary care setting. These factors include risk status of the patient, intensity of the intervention, and the setting and intervention provider. We also examined whether use of a number of specific counseling aids and components would influence the magnitude of effect. Tables 7 and 8 provide more details on these topics. The findings presented relate to all studies combined (fat, fruits and vegetables, fiber), because the number of studies in each group was too low for us to make valid comparisons for each specific dietary constituent.

Risk Status of Patients

Across all nutrient groups, studies of patients at average or low risk largely produced mainly small to medium effects on dietary behavior (Table 7). Studies of patients at moderate risk (1 or more identified risk factors, such as elevated cholesterol or hypertension) most frequently achieved small to medium levels of dietary change, but the amount of change tended to depend on the intensity of the intervention. Studies of high-risk patients (those with existing illnesses such as cancer or cardiovascular disease) were somewhat more likely to achieve large effects than studies of non-high-risk patients, but many studies in high-risk patients still produced only small or medium changes.

Intensity of the Intervention

As shown in Tables 4-6, we classified the intensity of each counseling intervention as low, medium, or high; the factors dictating this classification included the number and length of counseling contacts, the magnitude and complexity of educational materials provided, and the use of supplemental intervention elements such as support group sessions or cooking classes. Table 8 documents the relationship between the amount of change in dietary behavior (i.e., effect size, as recorded in Tables 4-6) and intensity of interventions (shown as low, medium, or high).

In our review, virtually all studies achieving large effect sizes fell into the high-intensity category. At the extreme is the study conducted by Ornish and colleagues.[121] In their study, high-risk selected patients were referred to a multi-component lifestyle modification program delivered in a retreat-like setting. Studies that combine very intensive interventions with high-risk patients tended to show the largest impact.

The vast majority of medium-intensity studies achieved small to medium effects. Low-intensity counseling interventions, such as those typically used in primary care settings, also achieved only small to medium effects on dietary behavior

Combined Effect of Risk and Intensity

Tables 9a through 9c (respectively for fats, fruits and vegetables, and fiber) show the effect of intervention intensity and risk status of subjects on the amount of change in dietary behavior. In these tables, studies with small effect sizes are shown in Roman (regular) type, studies with medium effect sizes in italics, and studies with large effect sizes in bold.

Across all risk groups (average/low, moderate, and high), more intensive interventions were somewhat more likely to produce larger changes in behavior than were less intensive interventions. Studies conducted in high-risk patients were also more likely to be of higher intensity and, hence, more effective.

Setting and Provider

As described above, we classified studies in terms of setting and provider and in terms of external validity. The latter classification – denoted, low, medium, or high – is based on representativeness of the providers and patient population and the feasibility of replicating the intervention in a primary care setting without the additional research infrastructure. Factors related to feasibility include training requirements of the providers as well as time and resource requirements of both patients and providers. (These data are recorded in columns labeled "Setting" and "External Validity" in Tables 4-6.)

Low-intensity interventions generally tended to be more feasible than higher-intensity efforts, and they tended to reflect counseling interventions that are implemented within the primary care setting today. However, some intervention strategies have achieved high levels of intensity while remaining feasible through the use of innovative, efficient strategies rather than relying on multiple clinic-based individual counseling sessions with the primary care provider. Examples include using office staff to deliver group-level interventions or follow-up telephone calls or mailings, computer-tailored newsletters or automated telephone systems to provide dietary feedback, goal setting, and reinforcement with very limited staff interaction time required.

In general, counseling provided by primary care providers had high external validity; primary care referral had medium external validity, as did mailed or computer-generated reminders. Research clinic settings had low external validity.

As shown in Tables 10a-10c and discussed in more detail below, studies conducted in primary care settings (by primary care providers or referrals) had small to medium effects,

computer-generated messages and mailings had medium effects, and efforts in special research clinics tended to have large effects.

Primary care provider studies. We reviewed a total of 8 studies in which a primary care provider in the office setting delivered the diet counseling intervention (2 for fat and fiber, 5 for fat only, and 1 for fiber only)(Tables 10a-10c).[124,126,129-131,137-139,148] Of these, 4 achieved small effects in dietary change and 4 achieved medium effects. All were considered to be of high feasibility and external validity.

Three evaluated interventions delivered primarily by physicians; 1 achieved medium-level effects,[126] and 2, small effects.[131,137,139] In the remaining 5 studies, the intervention involved distribution of print materials or counseling by a nurse employed by the primary care clinic. No study tested very brief advice by physicians against a control group receiving no such advice.

The studies that achieved medium-sized changes in dietary behavior used either medium-intensity[126,129,148] or high-intensity[123] interventions. Low-intensity interventions delivered to average-risk patients in primary care settings, although high in feasibility and external validity, produced only small changes in dietary fat consumption (1% to 2% reductions in total fat intake); changes in other dietary elements have not been studied.

Primary care clinic referral studies. An additional 6 studies in a primary care clinic used referral to a nutritionist, health educator, or other trained health professional (excluding nurses who were considered primary care providers when performing their usual duties) employed within that clinic.[12,127,128,133,135,146] These studies produced small to medium effects on dietary behaviors. The studies in this category were all deemed to be of low to medium feasibility and external validity.

Research clinics. The largest effects on dietary behaviors were seen in studies using special research clinics, many of which also involved high-risk patients. All 10 of these studies (7 examining dietary fat; 2 fruits and vegetables; 1 for both fat and fruits and vegetables; none for fiber) were classified as having low feasibility or external validity for the typical primary care practice setting because of the intensive nature of the intervention and because they often used very selected study populations.[13,118,120-122,125,136,140-142,145] Taking account of multiple dietary elements or study arms, 7 studies in research clinics achieved a large dietary behavioral effect, 1 a medium effect, and 3 a small effect.

Mailings and computer-generated messages. The health communications field is growing rapidly and has made use of various graphic and computer-based technologies to produce individually tailored counseling interventions that replace or supplement direct contact with providers. These interventions may be implemented alone or in conjunction with more conventional counseling strategies. We classified interventions in this category as largely having medium feasibility and external validity. As the technology evolves to provide "packaged" software tailoring programs, we anticipate that these interventions will become increasingly feasible for use within the primary care setting.

We identified 6 studies within this category, several of which tested multiple levels of computer tailoring.[119,123,125,132,134,147] All but 1 of these studies resulted in medium to small effect sizes; the exception reported a large change in fat consumption among the siblings and offspring of individuals with a history of myocardial infarction but was rated as only fair quality because of unequal loss to follow up.[119] More intensive tailoring seemed to result in greater dietary change, but the evidence was not conclusive.

Intervention Components

Several counseling intervention components have been shown to be associated with improved behavioral outcomes in other studies: a dietary assessment, family involvement, social support, group counseling, food interaction (such as taste testing or cooking), goal setting, and ethnic specificity. To characterize the investigations reported in this review at this level of detail, we abstracted data from each study to determine if the investigators used any of these 7 elements in their intervention; these data appear in Tables 11a, b, and c (fat, fruits and vegetables, fiber, respectively). The total number of components used ranged from 0 to 7, with a median of 2 components. Many authors did not describe their interventions in sufficient detail to assure that readers could determine the absence or presence of these study components.

As summarized in Table 12, studies employing 3 or more components were more likely to show a medium or large effect on dietary behaviors than studies using fewer than 3 components. Studies that did not report employing any of these specific components were more likely to have a small effect than studies using 1 or more components. The number of studies using each of the individual components was too low to permit us to determine with confidence whether the use of any given one component was associated with a greater change in dietary behavior.

Sample Studies Illustrating Counseling Approaches

To understand more about how different approaches to counseling may affect dietary change, applying the 5-A framework is a useful step. The 5-A construct was initially developed to describe the essential elements of brief provider interventions related to tobacco cessation.[149] Briefly, the 5-A framework includes *Assess, Advise, Agree, Assist*, and *Arrange*. Whitlock et al. describe it in more detail, provide an overview of counseling issues and approaches, and discuss

the systems support necessary to implement behavioral counseling activities in the primary care setting.[1]

We found that too few studies reported adequate detail about the intervention to use the 5-As as a guide for this analysis of counseling, but it offers a useful framework for describing various counseling approaches. To provide more information on counseling approaches, therefore, we describe here 4 studies that represent different counseling approaches within each of our 4 settings categories (described earlier) that we deemed to be of higher external validity than other investigations and that achieved a medium to high effect.

Primary care provider studies. Illustrative of studies in this category is work by Keyserling et al.,[126] who conducted a randomized trial in 21 community and rural health centers in the southeast. The main intervention was physician counseling, followed by a prompt for referral to a dietitian for patients not meeting their cholesterol-lowering goals after 6 months. Physicians *advised* patients with elevated cholesterol of the associated risks for cardiovascular disease. Patient diets were *assessed* using a 5- to 10-minute validated food frequency instrument. Providers were then trained to work with patients to *agree* on goals, provide counseling using low-literacy materials linked to the assessment (*assist*), and document the goals for follow-up at the next visit (*arrange/assist*). Before dietitian referral, the intervention resulted in a 3.3-point greater reduction in a dietary risk score for the intervention group than for control group ($P < 0.001$). When controlling for cholesterol-lowering medication use, reduction in total serum cholesterol was 5.5 mg/dl greater in the intervention group (95% CI, 0.3-10.7) than the control group. Ockene et al. tested a similar counseling intervention strategy by physicians in a group-model health maintenance organization supplemented with an office management system.[137] This work produced a modest but statistically significant reduction in percentage of

calories from saturated fat (1.1%), a reduction in weight of 2.3 kg, and a decrease of 3.8 mg/dl in LDL cholesterol. Dietary changes were not significant in the study arm that did not include an office management system.

Primary care clinic referrals. Siero and colleagues compared 3 2-hour group education classes only with an intervention arm including classes and a computer-tailored mailing.[146] Designed to promote a "Mediterranean-style" diet, this study was conducted in a low socioeconomic status community in the Netherlands. The authors did not mention whether the group sessions included an *assessment* of dietary intake or mediating factors. Group leaders *advised* participants about both the knowledge and the skills needed to implement the Mediterranean diet and *assisted* them in making the behavior changes with specific guidelines for food purchasing and preparation. Subjects randomized to the 2-part intervention also received a computer-generated personal letter tailored to attitude, self-efficacy, social norm, and stage of change based on an extensive *assessment* of dietary habits and related psychosocial factors. The investigators did not mention either identifying and *agreeing* on a set of goals or *arranging* for follow-up in either group. Results of the study showed an increase of 62 g in the consumption of fruits and vegetables (approximately 0.4 to 0.5 serving) in the group- session-only arm; the tailored letters conferred no significant additional benefit (99 g total increase).

Research clinics. In the study by Coates and colleagues,[118] dietitian-led group sessions were conducted weekly for 6 weeks, biweekly for another 6 weeks, and then monthly for 9 months. Study participants were ethnically diverse and were guided by group leaders to *assess* their dietary needs and then *agree* on specific changes to address the problems identified. Participants were advised by the group leaders regarding personal goals for grams of fat. The groups leaders then *assisted* participants with the lifestyle change process by teaching them

about low-fat substitutions, implementing a self-monitoring strategy using a specially designed tool, guiding them through role plays and problem solving, and providing individualized attention as needed. Because the groups met on a regular basis, arranging follow-up was not necessary. This intervention resulted in a medium effect for fruits and vegetables (an increase of 0.53 servings of fruit and 0.27 servings of vegetables) and a large effect for fat (net reduction of 3.5% calories from saturated fat and 11.6% calories from total fat).

Mailings and computer-generated messages. This emerging technology in nutrition counseling has the potential to tailor messages individually while requiring little time on the part of health care providers. Campell et al. devised computer-tailored newsletters to be mailed to family practice patients.[123] The study did fit into the 5-A framework. Diet was *assessed* using a self-administered food frequency instrument which provided the information needed to generate computer tailored nutrition messages mailed to participants. Although patients were not directly counseled by their physicians, the mailed materials helped to *advise* and *assist* them regarding recommended dietary change. The intervention did not *arrange* for any follow-up other than post-intervention measures. Relative to a control group, the tailored intervention resulted in a significant decrease in both total and saturated fat (9 g, $P = 0.03$ and 4.3 g, $P = 0.036$, respectively), whereas a nontailored newsletter did not show significant reduction in fat. Neither intervention arm achieved significant increases in fruit and vegetable intake.

Summary of the Effectiveness of Dietary Counseling

The existing literature examining the effect of dietary counseling for patients in primary care is complex. Differences in the risk status, intensity of the intervention, setting, use of effective counseling components, dietary element(s) targeted, and outcome measures used all

affect interpretation of data on the ability of counseling to change dietary behavior. We identified a large number of high-quality studies, many of which used patients and settings very similar to average US primary care clinics. We also identified several studies that take advantage of computerized or mailed information to supplement direct face-to-face counseling; these approaches are becoming more available with new advances in information technology dissemination.

Overall, dietary counseling produced modest reductions in the consumption of dietary total and saturated fat and modest increases in the consumption of fruits and vegetables. We did not identify sufficient evidence to make a conclusion about changes in other dietary elements. For studies conducted in primary care populations, interventions that were more intensive, conducted in patients at risk for chronic disease, or employed more of the effective "counseling elements" produce larger changes in dietary behavior. We did not identify enough studies to determine the individual effect of specific counseling techniques.

Other Systematic Reviews Related to the Effectiveness of Dietary Interventions

Several other systematic reviews of dietary interventions have involved either a broader or narrower range of studies relevant to primary care practice[150-153] In general, these reviews support our findings that a variety of counseling interventions result in meaningful dietary change in fat, saturated fat, fruits and vegetables, and fiber. As in this review, effect sizes vary widely and tend to be higher among those at higher risk for chronic disease. No clear consensus emerges from these reviews to suggest that certain intervention components are key to success.

Interventions to Enhance Dietary Counseling Behaviors Among Physicians

Of the numerous studies regarding efforts to increase dietary counseling interventions by physicians and their office staff, only a few have included a rigorous pre-post design with comparison groups. Kottke et al. documented an increase in reported diet counseling for cardiovascular disease risk reduction after serving (unbeknownst to the conference attendees) meals that qualified as the "prudent diet" at a family practice conference.[154] The proportion of physicians who reported that they considered the diet "very palatable" rose from 26% before the conference to 64% after they were told about the nature of the meals served. Several residency training programs were able to improve nutrition knowledge or increase dietary counseling behaviors (or both) through the use of a physician nutrition specialist (among other strategies).[155-157] Finally, a randomized trial demonstrated that computerized reminders increased physician dietary assessment and counseling along with other cancer prevention behaviors.[158]

Key Question No. 5: Adverse Effects and Associated Costs of Behavioral Interventions to Promote Healthy Diets

Concerns have been raised about the safety of reduced-fat diets for growing children.[159,160] Case studies have reported poor growth as a result of low-fat diets,[161,162] and experts have issued warnings of nutritional inadequacy for iron and calcium resulting from low-fat diets.[163] In reviewing evidence for detrimental consequences of dietary fat restriction for children, Kaplan and Toshima evaluated studies on secular trends, migration, and vegetarian diets.[164] They concluded that some evidence supports the contentions that dietary fat restriction may have minor effects on growth and that children who are placed on severe dietary restriction

during growth periods may experience growth stunting. They cautioned, however, that the majority of the studies reviewed had serious methodological limitations.

The DISC Study (Dietary Intervention Study in Children) is perhaps the only systematic attempt to evaluate the impact of a fat-reduced diet during puberty on anthropometric, biochemical, and dietary measures of nutritional adequacy and safety.[15] A recent publication from this study concluded that a cholesterol-lowering diet for children had no adverse effect on growth and development.[165]

Theoretically, assessing weight or dietary status or recommending dietary change to populations at high risk for eating disorders can pose some adverse effects. However, we are aware of no case reports or controlled studies regarding this issue.

Key Question No. 6: System Influences that Facilitate or Impede Dietary Intervention

Many patients look to their physicians as the most likely source of nutritional guidance and perceive the level of expertise of physicians as equal to or just below that of a dietitian.[166,167] Older national telephone surveys of practicing physicians and the adult public administered in 1983, 1986, and 1990 showed a steady increase in physician-provided diet counseling over time and a greater willingness to begin counseling at a lower serum cholesterol level.[168,169] Most surveys suggest that physicians believe in the importance of diet counseling and perceive it to be within their role.[170,171] However, counseling rates are still far from what is recommended by national guidelines.[172,173]

The epidemic of obesity in the United States is rising,[174] and the USPSTF is expected to address screening for obesity in 2 future reviews. Hiddink et al. examined surveys over a 5-year period (1992 through 1997) and demonstrated a trend that can be characterized only as disturbing

in this context, namely, a significant decrease in physician documentation and dietary counseling for obese patients.[175] In the same surveys, perceived self-efficacy for counseling dropped and time as a barrier increased. Physicians may find weight reduction counseling less rewarding because obesity is such a widespread and intractable diet-related problem.

Barriers to dietary counseling by physicians are numerous. Some frequently reported barriers include perceived lack of preparation and confidence in their ability to help patients make lifestyle changes and a overall sense that their efforts are not successful.[170,171,175-177] Other frequently documented obstacles include lack of time, perceived lack of patient interest and nonadherence by patients, and lack of adequate educational materials.[170,171,177-180] Some weak associations between a physician's personal health habits and counseling behaviors seem to exist, and at least 1 study has shown that younger female physicians are more likely to be knowledgeable about diet and provide counseling than other physicians.[181,182]

In addition to the limited time available for preventive counseling, other system-level barriers exist. Many physicians cite the lack of nutrition training provided in medical school. Other describe challenges of reimbursement for physician or staff time spent on nutrition services,[179] as well as unavailability of referral sources and lack of supportive office systems to facilitate nutrition intervention and monitoring.[182]

Key Question No. 7: Nutritional Supplementation

Patients with poor nutritional status may benefit from nutritional supplementation. Potter et al. performed a systematic review of 32 studies of oral nutritional supplements.[183] Persons randomized to receive supplements showed consistently improved changes in body weight compared with controls (weighted mean difference, 2.1%; 95% CI, 1.6%-2.5%). Treatment patients were also at lower risk for death (OR, 0.66; 95% CI, 0.48-0.91). Too few data were

available to determine whether use of ordinary food in typical daily meals was superior or inferior to the generally more expensive prepared supplements.

Issues Relating to Quality and Strength of Evidence in this Body of Literature

The evidence for the different key questions ranges from fair to good. Articles we reviewed had to meet relatively strict inclusion criteria (to optimize internal validity), and we restricted studies to those conducted in primary care populations (to optimize external validity). Randomized trials directly measuring the effect of differences in dietary intake on health outcomes are rare because of the long lag time between dietary "exposure" and disease. Those who wish to examine these questions must rely on observational data or evidence relating dietary interventions to change in chronic disease risk factors.

Quality issues related to internal validity that we could not control through inclusion criteria included the degree to which the intervention can be correctly characterized from the published description and problems associated with self-report bias. External validity is more difficult to characterize, given the considerable room for interpretation as to whether an intervention delivered after referral to another health care provider is "generalizable" to the population and conditions of general primary care practice. Although this point is not strictly a quality issue for any one study, the tendency for counseling interventions to test multiple intervention strategies simultaneously makes it difficult to identify evidence regarding the effect of any one strategy.

Discussion and Conclusions

To provide information for the US Preventive Services Task Force (USPSTF) so that it can update its previous recommendations concerning counseling to promote a healthy diet, we conducted systematic reviews of 2 main bodies of literature and attempted to answer 7 key questions. The first main area included relationships between dietary behaviors and various health outcomes (the diet-health link) (Key Question No. 1 in Chapter III). The second broad area (the remaining key questions in Chapter III) dealt with various aspects of counseling interventions (chiefly in the primary care setting) intended to promote healthy diets (the counseling-diet link), starting with dietary assessment itself. These topics are briefly discussed in turn below.

Table 13 summarizes our judgments about the size and quality of the entire body of evidence. Harris et al.[221] provide USPSTF definitions for internal validity, external validity, and coherence (consistency) of bodies of evidence.

The Link between Dietary Patterns and Health Outcomes

Dietary patterns are important determinants of health status. A wide range of observational studies and selected randomized trials have documented the association between multiple dietary behaviors and various health outcomes. The evidence about some specific dietary relationships remains incomplete. Nonetheless, our review suggests that, in general, a diet high in fruits, vegetables, whole grains, fish, and calcium and low in saturated and trans-unsaturated fats is associated with better general health and lower morbidity.

Dietary Assessment

Dietary assessment is the first step in identifying patients in need of counseling and in guiding the practitioner to offer advice that is directly relevant to the patient's dietary habits and the factors that influence them. Only about 23% to 42% of physicians nationally counsel their patients about diet; 90% of primary care providers spend fewer than 5 minutes on dietary assessment.[181,222,223] Although few physicians conduct any sort of dietary assessment, those who do are significantly more likely to counsel a larger proportion of their patients.[179,224]

Although the independent effect of dietary assessment on health outcomes has not been well studied, such evaluations are the first step in nearly all studies that examine the effect of dietary counseling on behavior or health outcomes. To determine nutritional risk and need for counseling intervention, primary care providers need practical and valid means of assessing dietary intake.[225] Instruments that can be scored simply and that guide providers to offer food-based rather than nutrient-based counseling are particularly useful. We identified more than 15 validated and moderately feasible tools for carrying out dietary assessments in primary care patients and settings. Some are age-specific (infants and toddlers, children, adults, and the elderly), and others are designed for specific ethnic or cultural populations.

Assessment questions that can inform counseling by assessing mediators to dietary change (beliefs, barriers, or readiness to make dietary change) are also useful. However, they are only infrequently included in brief assessments.[109,111,112,226]

Counseling

Although primary care providers endorse the importance of dietary counseling as part of their professional role, counseling rates are far from what national guidelines recommend. [172,173]

Confidence among providers that they can have a positive impact on patient behavior has never been high, and it may be waning in the face of the growing obesity epidemic in this country.[166,170,171,177]

Impact of Counseling on Dietary Behaviors

Numerous interventions are available to help patients attempting to change their diets. We identified and reviewed a total of 29 separate studies. Nearly half of these dealt with more than one dietary constituent. In all, 25 of these addressed dietary fat; 11, fruit and vegetable intake; and 7, dietary fiber. Overall, such interventions had a modest effect in changing short-term dietary behavior, but the evidence about long-term change is less clear. Publication bias cannot be ruled out, but our findings and those of other systematic reviews support the conclusion that dietary counseling interventions with a wide range of patients and in a wide variety of settings can have a positive impact on dietary fat intake, on fruit and vegetable consumption, and on dietary fiber. These were reported in a total of 33 articles (12 articles dealt with 2 or 3 dietary constituents).

Among the factors affecting the response to dietary counseling, higher risk status of the patient was associated with somewhat greater changes in diet. High-intensity interventions were more likely to produce large changes than lower-intensity interventions, although many high-intensity interventions still produced only small or medium changes.

As expected, those interventions deemed most externally valid (most easily replicated in a standard primary care setting) achieved smaller effects: low- to medium-intensity interventions conducted by primary care providers in the course of their usual activities had only small effects on dietary behavior. Interventions using outside research clinic interventions were generally

more effective than those within a primary care clinic. No studies evaluated outside referral to individual counseling or group sessions independent of a research clinic. Computer or mailed interventions have promising effects, especially on consumption of fruits and vegetables. Studies using more counseling elements generally seen as proven to be effective had a greater impact in terms of dietary changes than those using fewer elements.

Only very limited data are available regarding the cost-effectiveness of different dietary intervention approaches. One study suggested that referral to a dietitian with brief physician reinforcement was more cost effective than referral alone.[200] Adverse effects other than costs associated with dietary assessment and /or counseling interventions appear to be limited.

Few dietary counseling interventions designed to reach primary care patients reported including a significant number of the behavior change strategies that we identified from the health behavior literature. This may be related in part to the inability of researchers fully to describe their intervention approach because of journal page limitations or other considerations. Interventions reporting the use of more components were more likely to produce large changes than those using fewer components.

Research Needs

Several areas of controversy remain in defining the relationship between diet and health outcomes. In areas such as cancer risk, further research would help resolve the discrepancies between case-control and cohort studies. More research is also needed to determine better the optimal amount and type of dietary fats that should be included in healthy diets.

Efficient but dietary assessment tools, particularly for children, should be developed and validated. Research is also needed to clarify and evaluate the linkages among dietary screening,

additional focused dietary assessment, and assessment-based counseling. Particularly important will be comparisons between these approaches and individual or population-level general dietary advice.

More in-depth examination of the effectiveness of specific components and intensities of dietary counseling is warranted. More theory-based studies will contribute to better understanding of immediate and long-term outcomes of dietary counseling. The lack of studies evaluating physician referral to health professionals outside their clinic setting for either one-on-one or group counseling is striking. Studies of dietary interventions delivered by special research clinics are common, but they are not representative of the resources commonly available to primary care providers. Cost-effectiveness studies comparing different intervention strategies relevant to primary care are lacking, but they will be particularly important in evaluating technology-based intervention strategies. Finally, as we move toward more environmental and policy-level interventions to support individual-level change, investigations should be carried out to evaluate the potential role and impact of the primary care provider in either stimulating or reinforcing these interventions.

References

1. Whitlock EP, Orleans CT, Pender N, Allan J. Behavioral Counseling Interventions for Health Promotion & Disease Prevention in Health Care Settings. *Overview Chapter Prepared by Oregon Health and Science University Evidence-Based Practice Center. Contract No. 290-97-0018. AHRQ Publications No. XX-XXX.* Rockville, Md.: Agency for Healthcare Research and Quality; In Press.

2. U.S. Preventive Services Task Force. Counseling to Promote a Healthy Diet. *Guide to Clinical Preventive Services (2nd Ed.)*. Baltimore: Williams and Wilkins; 1996:625-642.

3. U.S. Department of Agriculture and the U.S. Department of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. 5th ed. Washington, D.C.: 2000.

4. McTigue K, Harris R, Hemphill MB, Bunton A. Screening and Interventions for Overweight and Obesity in Adults. *Systematic Evidence Review No. X. Prepared by RTI-University of North Carolina at Chapel Hill Evidence-Based Practice Center. Contract No. 290-97-011. AHRQ Publications No. XX-XXX.* Rockville, Md.: Agency for Healthcare Research and Quality; 2002.

5. Katan MB, Grundy SM, Willett WC. Should a low-fat, high-carbohydrate diet be recommended for everyone? *N Engl J Med.* 1997;337.

6. Posner B.M., Cobb J.L., Bealnger A.J., Cupples L.A., D'Agostino R.B., Stokes J. Dietary lipid predictors of coronary heart disease in men. *Arch Intern Med.* 1991;151:1181-1187.

7. LaRosa JC, Hunninghake D, Bush D, et al. The cholesterol facts. A summary of the evidence relating dietary fats, serum cholesterol, and coronary heart disease. A joint statement by the American Heart Association and the National Heart, Lung, and Blood Institute. The Task Force on Cholesterol Issues, American Heart Association. *Circulation.* 1990;81:1721-1733.

8. Ascherio A, Katan MB, Zock PL, Stampfer MJ, Willett WC. Trans fatty acids and coronary heart disease. *N Engl J Med.* 1999;340:1994-8.

9. Oomen CM, Ocke MC, Feskens EJ, van Erp-Baart MA, Kok FJ, Kromhout D. Association between trans fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study. *Lancet.* 2001;357:746-51.

10. Hooper L, Summerbell C, Higgins J, et al. ver. Issue 3. Oxford: Update Software: The Cochrane Library; 2000.

11. Ebrahim S, Smith GD. Systematic review of randomised controlled trials of multiple risk factor interventions for preventing coronary heart disease. *BMJ.* 1997;314:1666-1674.

12. Hjermann I, Velve Byre K, Holme I, Leren P. Effect of diet and smoking intervention on the incidence of coronary heart disease. Report from the Oslo Study Group of a randomised trial in healthy men. *Lancet.* 1981;2:1303-1310.

13. Neaton JD, Broste S, Cohen L, Fishman EL, Kjelsberg MO, Schoenberger J. The multiple risk factor intervention trial (MRFIT). VII. A comparison of risk factor changes between the two study groups. *Prev Med.* 1981;10:519-543.

14. Webber LS, Srinivasan SR, Wattigney WA, Berenson GS. Tracking of serum lipids and lipoproteins from childhood to adulthood: The Bogalusa Heart Study. *Am J Epidemiol.* 1991;133:884-899.

15. Obarzanek E, Hunsberger SA, Van Horn L, et al. Safety of a fat-reduced diet: the Dietary Intervention Study in Children (DISC). *Pediatrics.* 1997;100:51-59.

16. Gillman MW, Cupples LA, Millen BE, Ellison RC, Wolf PA. Inverse association of dietary fat with development of ischemic stroke in men. *JAMA.* 1997;278:2145-50.

17. Lewis CJ, Yetley EA. Health claims and observational human data: relation between dietary fat and cancer. *Am J Clin Nutr.* 1999;69:1357S-1364S.

18. Kolonel LN, Nomura AM, Cooney RV. Dietary fat and prostate cancer: current status. *J Natl Cancer Inst.* 1999;91:414-428.

19. Hunter DJ, Spiegelman D, Adami HO, et al. Cohort studies of fat intake and the risk of breast cancer--a pooled analysis. *N Engl J Med.* 1996;334:356-361.

20. Lipkin M, Reddy B, Newmark H, Lamprecht SA. Dietary factors in human colorectal cancer. *Annu Rev Nutr.* 1999;19:545-586.

21. Howe GR, Aronson KJ, Benito E, et al. The relationship between dietary fat intake and risk of colorectal cancer: evidence from the combined analysis of 13 case-control studies. *Cancer Causes Control.* 1997;8:215-228.

22. Hopkins PN. Effects of dietary cholesterol on serum cholesterol: a meta-analysis and review. *Am J Clin Nutr.* 1992;55:1060-70.

23. McNamara DJ. Dietary cholesterol and atherosclerosis. *Biochim Biophys Acta.* 2000;1529:310-320.

24. Key T, Fraser G, Thorogood M, et al. Mortality in vegetarians and nonvegetarians: detailed findings from a collaborative analysis of 5 prospective studies. *Am J Clin Nutr .* 1999;70:516S-524S.

25. Ness AR, Powles JW. Fruit and vegetables, and cardiovascular disease: a review. *Int J Epidemiol.* 1997;26:1-13.

26. Law MR, Morris JK. By how much does fruit and vegetable consumption reduce the risk of ischaemic heart disease? *Eur J Clin Nutr.* 1998;52:549-556.

27. Pietinen P, Rimm EB, Korhonen P, et al. Intake of dietary fiber and risk of coronary heart disease in a cohort of Finnish men: the alpha-tocopherol, beta-carotene cancer prevention study. 1996;94: 11:2720-2727.

28. Mann JI, Appleby PN, Key TJ, Thorogood M. Dietary determinants of ischaemic heart disease in health conscious individuals. *Heart.* 1997;78:450-455.

29. Key TJ, Thorogood M, Appleby PN, Burr ML. Dietary habits and mortality in 11,000 vegetarians and health conscious people: results of a 17 year follow-up. *BMJ.* 1996;313:775-779.

30. Joshipura KJ , Hu FB, Manson JE, et al. The effect of fruit and vegetable intake on risk for coronary heart disease. *Ann Intern Med.* 2001;134:1106-1114.

31. Ascherio A, Hennekens C, Willett WC, et al. Prospective study of nutritional factors, blood pressure, and hypertension among US women. *Hypertension.* 1996;27:1065-1072.

32. Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. *N Engl J Med.* 1997;336:1117-1124.

33. Rouse IL, Beilin LJ, Armstrong BK, Vandongen R. Blood-pressure-lowering effect of a vegetarian diet: controlled trial in normotensive subjects. *Lancet.* 1983;1:5-10.

34. Margetts BM, Beilin LJ, Vandongen R, Armstrong BK. Vegetarian diet in mild hypertension: a randomized controlled trial. *Br Med J.* 1986;293:1468-1471.

35. Zino S, Skeaff M, Williams S, Mann J. Randomized controlled trial of effect of fruit and vegetable consumption on plasma concentrations of lipids and antioxidants. *BMJ.* 1997;314:1787-1791.

36. Steinmetz K, Potter J. Vegetables, fruit, and cancer prevention: a review. *J Am Diet Assoc.* 1996;96:1027-1039.

37. Feskanich D, Ziegler RG, Michaud DS, et al. Prospective study of fruit and vegetable consumption and risk of lung cancer among men and women. *J Natl Cancer Inst.* 2000;92:1812-1823.

38. Smith-Warner SA, Spiegelman D, Adami HO, et al. Types of dietary fat and breast cancer: a pooled analysis of cohort studies. *Int J Cancer.* 2001;92:767-774.

39. Gandini S, Merzenich H, Robertson C, Boyle P. Meta-analysis of studies on breast cancer risk and diet: the role of fruit and vegetable consumption and the intake of associated micronutrients. *Eur J Cancer.* 2000;36:636-646.

40. Bazzano LA, He J, Ogden LG, et al. Legume consumption and risk of coronary heart disease in US men and women: NHANES I Epidemiologic Follow-up Study. *Arch Intern Med.* 2001;161:2573-2578.

41. Kushi LH, Meyer KA, Jacobs DR. Cereals, legumes, and chronic disease risk reduction: evidence from epidemiologic studies. *Am J Clin Nutr.* 1999;70:451S-458S.

42. Jacobs DR, Pereira MA, Meyer KA, Kushi LH. Fiber from whole grains, but not refined grains, is inversely associated with all-cause mortality in older women: the Iowa women's health study. *J Am Coll Nutr.* 2000;19:326S-330S.

43. Liu S, Manson JE, Stampfer MJ, et al. Whole grain consumption and risk of ischemic stroke in women: A prospective study. *JAMA.* 2000;284:1534-1540.

44. Kromhout D, Bosschieter EB, de Lezenne Coulander C. Dietary fibre and 10-year mortality from coronary heart disease, cancer, and all causes. The Zutphen study. *Lancet.* 1982;2:518-522.

45. Burr ML, Fehily AM, Gilbert JF, et al. Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). *Lancet.* 1989;2:757-761.

46. Glore S, Van Treeck D, Knehans A, Guild. M. Soluble Fiber and serum lipids. *J Am Diet Assoc.* 1994;94:425-436.

47. Brown L, Rosner B, Willett WW, Sacks FM. Cholesterol-lowering effects of dietary fiber: a meta-analysis. *Am J Clin Nutr.* 1999;69:30-42.

48. He J, Whelton PK. Effect of dietary fiber and protein intake on blood pressure: a review of epidemiologic evidence. *Clin Exp Hypertens.* 1999;21:785-796.

49. Howe GR, Hirohata T, Hislop TG, Iscovich JM, Yuan JM, Katsouyanni K. Dietary Factors and Risk of Breast Cancer: Combined Analysis of 12 case-Control Studies. *J Nat Cancer Inst.* 1990;82:561-569.

50. Kim Y. AGA technical review: impact of dietary fiber on colon cancer occurrence. *Gastroenterology.* 2000;118:1235-1257.

51. Schatzkin A, Lanza E, Corle D, et al. Lack of effect of a low-fat, high-fiber diet on the recurrence of colorectal adenomas. Polyp Prevention Trial Study Group. *N Engl J Med.* 2000;342:1149-1155.

52. Alberts D, Martinez M, Roe D, et al. Lack of effect of a high-fiber cereal supplement on the recurrence of colorectal adenomas. *N Engl J Med.* 2000;342:1156-1162.

53. Marckmann P, Gronbaek M. Fish consumption and coronary heart disease mortality. A systematic review of prospective cohort studies. *Eur J Clin Nutr.* 1999;53:585-590.

54. Singh RB, Rastogi SS, Sircar AR, Mehta PJ, Sharma KK. Dietary strategies for risk-factor modification to prevent cardiovascular diseases. *Nutrition.* 1991;7:210-214.

55. GISSI-Prevenzione Investigators (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico). Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial. *Lancet.* 1999;354:447-455.

56. Law MR, Frost CD, Wald NJ. By how much does dietary salt reduction lower blood pressure? *BMJ.* 1991;302:811-815.

57. Midgley J, Matthew A, Greenwood C, Logan A. Effect of reduced dietary sodium on blood pressure: a meta-analysis of randomized controlled trials. *JAMA.* 1996;275:1590-1597.

58. Cutler J, Follmann D, Allender P. Randomized trials of sodium reduction: an overview. *Am J Clin Nutr .* 1997;65:643S-651S.

59. The Trials of Hypertension Prevention Collaborative Research Group. Effects of weight loss and sodium reduction intervention on blood pressure and hypertension incidence in overweight people with high- normal blood pressure. The Trials of Hypertension Prevention, phase II. *Arch Intern Med.* 1997;157:657-667.

60. Hypertension Prevention Trial Research Group. The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. *Arch Intern Med.* 1990;150:153-62.

61. Siani A, Strazzullo P. Dietary potassium and cardiovascular disease: clinical applications. *J Cardiovasc Risk.* 2000;7:15-21.

62. Whelton PK, He J, Cutler JA, et al. Effects of oral potassium on blood pressure. Meta-analysis of randomized controlled clinical trials. *JAMA.* 1997;277:1624-1632.

63. Feskanich D, Willett WC, Stampfer MJ, Colditz GA. Milk, dietary calcium, and bone fractures in women: a 12-year prospective study. *Am J Public Health.* 1997;87:992-997.

64. Cumming R. Calcium intake and bone mass: a quantitative review of the evidence. *Calcified Tissue International.* 1990;47:194-201.

65. Heaney RP. Calcium, dairy products and osteoporosis. *J Am Coll Nutr.* 2000;19:83S-99S.

66. Giovannucci E, Rimm EB, Wolk A, et al. Calcium and fructose intake in relation to risk of prostate cancer. *Cancer Res.* 1998;58:442-7.

67. Antonov A. Children born during the siege in Leningrad in 1942. *J Pediatr.* 1947;30:250-295.

68. Stein A, Susser M, Saenger G, et al. Famine and human development: the Dutch hunger winter of 1944/45. New York, NY: Oxford University Press; 1974.

69. Singer JE, Westphal M, Niswander K. Relationship of weight gain during pregnancy to birth weight and infant growth and development in the first year of life. *Obstet Gynecol.* 1968;31:417-23.

70. Institute of Medicine, Subcommittee on Nutritional Status and Weight Gain During Pregnancy. Nutrition during pregnancy. Washington, D.C.: National Academy Press; 1990.

71. Institute of Medicine. Preventing low birthweight. Washington, D.C.: National Academy Press; 1985.

72. National Research Council, Food and Nutrition Board. Committee on Dietary Allowances. Washington, D.C.: National Academy Press; 1989.

73. Ammerman A, Haines P, DeVellis R, et al. A brief dietary assessment to guide cholesterol reduction in low-income individuals: design and validation. *J Am Diet Assoc.* 1991;91:12385-1390.

74. Angus RM, Sambrook PN, Pocock NA, Eisman JA. A simple method for assessing calcium intake in Caucasian women. *J Am Diet Assoc.* 1989;89:209-214.

75. Block G, Gillespie C, Rosenbaum EH, Jenson C. A rapid food screener to assess fat and fruit and vegetable intake. *Am J Prev Med.* 2000;18:284-288.

76. Blumberg SJ, Bialostosky K, Hamilton WL, Briefel RR. The effectiveness of a short form of the Household Food Security Scale. *Am J Public Health.* 1999;89:1231-1234.

77. Conner SJ, Gustafson JR, Sexton G, Becker N, Artaud-Wild S, Conner WE. The diet habit survey: a new method of dietary assessment that relates to plasma choolesterol changes. *J Am Diet Assoc.* 1992;92:41-47.

78. Gans K, Sundaram SMJ, Hixson M, Linnan L, Carleton R. Rate your plate: an eating pattern assessment and educational tool used at cholesterol screening and education programs. *J Nutr Educ.* 1993;25:29-36.

79. Heller RF, Pedoe HD, Rose G. A simple method of assessing the effect of dietary advice to reduce plasma cholesterol. *Prev Med.* 1981;10:364-370.

80. Knapp JA, Hazuda HP, Haffner SM, Yonug EA, Stern MP. A saturated fat/cholesterol avoidance scale: sex and ethnic differences in a biethnic population. *J Am Diet Assoc.* 1988;88:172-177.

81. Kris-Etherton P, Eissenstat B, Jaax S, et al. Validation for MEDFICTS, a dietary assessment instrument for evaluating adherence to total and saturated fat recommendations of the National Cholesterol Education Program Step 1 and Step 2 diets. *J Am Diet Assoc.* 2001;101:81-86.

82. Kristal A, Shattuck A, Henry H, Fowler A. Rapid assessment of dietary intake of fat, fiber, and saturated fat: validity of an instrument suitable for community intervention research and nutritional surveilllance. *Am J Health Promot.* 1990;4:288-295.

83. Kristal A, Shattuck A, Henry H. Patterns of dietary behavior associated with selecting diets low in fat: reliability and validity of a behavioral approach to dietary assessment. *J Am Diet Assoc.* 1990;90:214-220.

84. Pietinen P, Hartman AM, Haapa E, et al. Reproducibility and validity of dietary assessment instruments. I. A self-administered food use questionnaire with a portion size picture booklet. *Am J Epidemiol.* 1988;128:655-666.

85. Peters JR, Quiter ES, Brekke ML, et al. The Eating Pattern Assessment Tool: a simple instrument for assessing dietary fat and cholesterol intake. *J Am Diet Assoc.* 1994;94:1008-1013.

86. Retzlaff BM, Dowdy AA, Walden CE, Bovbjerg VE, Knopp RH. The Northwest Lipid Research Clinic Fat Intake Scale: validation and utility. *Am J Public Health.* 1997;87:181-185.

87. Rifas-Shiman SL, Willett WC, Lobb R, Kotch J, Dart C, Gillman MW. PrimeScreen, a brief dietary screening tool: reproducibility and comparability with both a longer food frequency questionnaire and biomarkers. *Public Health Nutr.* 2001;4:249-254.

88. Roe L, Strong C, Whiteside C, Neil A, Mant D. Dietary intervention in primary care: validity of the DINE method for diet assessment. *Fam Pract.* 1994;11:375-381.

89. Serdula M, Coates R, Byers T, et al. Evaluation of a brief telephone questionnaire to estimate fruit and vegetable consumption in diverse study populations. *Epidemiology.* 1993;4:455-463.

90. Shannon J, Kristal AR, Curry SJ, Beresford SA. Application of a behavioral approach to measuring dietary change: the fat- and fiber-related diet behavior questionnaire. *Cancer Epidemiol Biomarkers Prev.* 1997;6:355-361.

91. Kuczmarski RJ, Ogden CL, Grummer-Strawn LM, et al. CDC growth charts: United States. *Adv Data.* 2000;1-27.

92. Boutry M, Needlman R. Use of diet history in the screening of iron deficiency. *Pediatrics.* 1996;98:1138-1142.

93. US Department of Health and Human Services. Recommendations to prevent and control iron deficiency in the United States. *Morb Mortal Wkly Rep.* 1998;47:1-29.

94. Bogen DL, Duggan AK, Dover GJ, Wilson MH. Screening for iron deficiency anemia by dietary history in a high-risk population. *Pediatrics.* 2000;105:1254-1259.

95. Rockett HR, Colditz GA. Assessing diets of children and adolescents. *Am J Clin Nutr.* 1997;65:1116S-1122S.

96. Van Horn LV, Gernhofer N, Moag-Stahlberg A, et al. Dietary assessment in children using electronic methods: telephones and tape recorders. *J Am Diet Assoc.* 1990;90:412-416.

97. Lytle LA, Nichaman MZ, Obarzanek E, et al. Validation of 24-hour recalls assisted by food records in third-grade children. The CATCH Collaborative Group. *J Am Diet Assoc.* 1993;93:1431-1436.

98. Calfas KJ, Zabinski MF, Rupp J. Practical nutrition assessment in primary care settings: a review. *Am J Prev Med.* 2000;18:289-299.

99. Little P, Barnett J, Margetts B, et al. The validity of dietary assessment in general practice. *J Epidemiol Commun Health.* 1999;53:165-172.

100. Johnsen C, East JM, Glassman P. Management of malnutrition in the elderly and the appropriate use of commercially manufactured oral nutritional supplements. *J Nutr Health Aging.* 2000;4:42-46.

101. Boult CB, Krinke UB, Urdangarin CF, Skarin V. The validity of nutritional status as a marker for future disability and depressive symptoms among high-risk older adults. *Am J Prev Med.* 1999;47:995-999.

102. Vellas B, Guigoz Y, Garry PJ, et al. The Mini Nutritional Assessment (MNA) and its use in grading the nutritional state of elderly patients. *Nutrition.* 1999;15:116-122.

103. Levine BS, Wigren MM, Chapman DS, Kerner JF, Bergman RL, Rivlin RS. A national survey of attitudes and practices of primary-care physicians relating to nutrition: strategies for enhancing the use of clinical nutrition in medical practice. *Am J Clin Nutr.* 1993;57:115-119.

104. Thomas DR, Ashmen W, Morley JE, Evans WJ. Nutritional management in long-term care: development of a clinical guideline. Council for Nutritional Strategies in Long-Term Care. *J Gerontol A Biol Sci Med Sci.* 2000;55:M725-M734.

105. Wolinsky FD, Coe RM, McIntosh WmA, et al. Progress in the development of a nutritional risk index. 1990;120:1549-1553.

106. Wellman NS. The nutrition screening initiative. 1994;52: 8:S44-S47.

107. Contento I, Randell J, Basch C. Review and analysis of evaluation measures used in nutrition education intervention research. *J Nutr Educ Behav.* 2002;34:2-25.

108. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. *Am Psychol.* 1992;47:1102-1114.

109. Greene G, Rossi S, Reed G, Willey C, Prochaska J. Stages of change for reducing dietary fat to 30% of energy or less. *J Am Diet Assoc.* 1994;94:1105-1110; quiz 1111-1112.

110. Greene G, Rossi S, Rossi J, Velicer W, Fava J, Prochaska J . Dietary applications of the stages of change model. *J Am Diet Assoc.* 1999;99:673-678.

111. Glanz K, Patterson RE, Kristal AR, et al. Stages of change in adopting healthy diets: fat, fiber, and correlates of nutrient intake. *Health Educ Q.* 1994;21:499-519.

112. Haire-Joshu D, Auslander W, Houston C, Williams J. Staging of dietary patterns among African American women. *Health Educ Behav.* 1999;26:90-102.

113. Contento I, Balch G, Bronner Y, et al. The effectiveness of nutrition education and implications for nutrition education policy, programs, and research: A review of research. *J Nutr Educ.* 1995;27.

114. Life Sciences Research Office, Federation of American Societies for Experimental Biology. Core indicators of nutritional state for difficult-to-sample populations. *J Nutr.* 1990;120 (Suppl):1559-1600.

115. Hamilton W, Cook J, Thompson W, et al. Household food insecurity in the United States in 1995: Summary report of the Food Security Measurement Project. Alexandria, VA: US Dept. of Agriculture, Food and Consumer Service; 1997.

116. Carlson S, Andrews M, Bickel G. Measuring food insecurity and hunger in the United States: development of a national benchmark measure and prevalence estimates. *J Nutr.* 1999;129 (Suppl):510S-516S.

117. Elkeles RS, Diamond JR, Poulter C, et al. Cardiovascular outcomes in type 2 diabetes: A double-blind placebo-controlled study of bezafibrate: the St. Mary's, Ealing, Northwick Park Diabetes Cardiovascular Disease Prevention (SENDCAP) Study. *Diabetes Care.* 1998;21:641-648.

118. Coates RJ, Bowen DJ, Kristal AR, et al. The Women's Health Trial Feasibility Study in Minority Populations: changes in dietary intakes. *Am J Epidemiol.* 1999;149:1104-1112.

119. Heller RF, Walker RJ, Boyle CA, O'Connell DL, Rusakaniko S, Dobson AJ. A randomised controlled trial of a dietary advice program for relatives of heart attack victims. *Med J Aust.* 1994;161:529-531.

120. Lee-Han H, Cousins M, Beaton M, et al. Compliance in a randomized clinical trial of dietary fat reduction in patients with breast dysplasia. *Am J Clin Nutr.* 1988;48:575-586.

121. Ornish D, Brown SE, Scherwitz LW, et al. Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. *Lancet.* 1990;336:129-133.

122. Simkin-Silverman LR, Wing RR. Management of obesity in primary care. *Obesity Research.* 1997; 5:603-612.

123. Campbell MK , DeVellis BM, Strecher VJ, Ammerman AS, DeVellis RF, Sandler RS. Improving dietary behavior: the effectiveness of tailored messages in primary care settings. *Am J Public Health.* 1994;84:783-787.

124. Campbell NC , Ritchie LD, Thain J, Deans HG, Rawles JM, Squair JL. Secondary prevention in coronary heart disease: a randomised trial of nurse led clinics in primary care. *Heart.* 1998;80:447-452.

125. Delichatsios HK, Friedman RH, Glanz K, et al. Randomized trial of a "talking computer" to improve adults' eating habits. *Am J Health Promot.* 2001;15:215-24.

126. Keyserling TC, Ammerman AS, Davis CE, Mok MC, Garrett J, Simpson RJ. A randomized controlled trial of a physician-directed treatment program for low-income patients with high blood cholesterol: the Southeast Cholesterol Project. *Arch Fam Med.* 1997;6:135-145.

127. Knutsen SF, Knutsen R. The Tromso Survey: the Family Intervention study--the effect of intervention on some coronary risk factors and dietary habits, a 6-year follow-up. *Prev Med.* 1991;20:197-212.

128. Lindholm LH , Ekbom T, Dash C, Eriksson M, Tibblin G, Schersten B. The impact of health care advice given in primary care on cardiovascular risk. CELL Study Group. *BMJ.* 1995;310:1105-1109.

129. Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *BMJ.* 1999;319:943-947; discussion 947-948.

130. Beresford SA, Farmer EM, Feingold L, Graves KL, Sumner SK, Baker RM. Evaluation of a self-help dietary intervention in a primary care setting. *Am J Public Health.* 1992;82:79-84.

131. Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH. A dietary intervention in primary care practice: the Eating Patterns Study. *Am J Public Health.* 1997;87:610-616.

132. Kristal AR, Curry SJ, Shattuck AL, Feng Z, Li S. A randomized trial of a tailored, self-

help dietary intervention: the Puget Sound Eating Patterns study. *Prev Med.* 2000;31:380-9.

133. Cupples ME, McKnight A. Randomised controlled trial of health promotion in general practice for patients at high cardiovascular risk. *BMJ.* 1994;309:993-996.

134. Delichatsios HK, Hunt MK, Lobb R, Emmons K, Gillman MW. EatSmart: efficacy of a multifaceted preventive nutrition intervention in clinical practice. *Prev Med.* 2001;33:91-98.

135. Hunt IF, Jacob M, Ostegard NJ, Masri G, Clark VA, Coulson AH. Effect of nutrition education on the nutritional status of low-income pregnant women of Mexican descent. *Am J Clin Nutr.* 1976;29:675-684.

136. Mojonnier ML, Hall Y, Berkson DM, et al. Experience in changing food habits of hyperlipidemic men and women. *J Am Diet Assoc.* 1980;77:140-148.

137. Ockene IS, Hebert JR, Ockene JK, et al. Effect of physician-delivered nutrition counseling training and an office-support program on saturated fat intake, weight, and serum lipid measurements in a hyperlipidemic population: Worcester Area Trial for Counseling in Hyperlipidemia (WATCH). *Arch Int Med.* 1999;159:725-731.

138. Roderick P, Ruddock V, Hunt P, Miller G. A randomized trial to evaluate the effectiveness of dietary advice by practice nurses in lowering diet-related coronary heart disease risk. *Br J Gen Pract.* 1997;47:7-12.

139. Ockene IS, Hebert JR, Ockene JK, Merriam PA, Hurley TG, Saperia GM. Effect of training and a structured office practice on physician-delivered nutrition counseling: the Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH). *Am J Prev Med.* 1996;12:252-258.

140. Masley S, Phillips S, Copeland JR. Group office visits change dietary habits of patients with coronary artery disease-the dietary intervention and evaluation trial (D.I.E.T.). *J Fam Pract.* 2001;50:235-239.

141. Henderson MM, Kushi LH, Thompson DJ, et al. Feasibility of a randomized trial of a low-fat diet for the prevention of breast cancer: dietary compliance in the Women's Health Trial Vanguard Study. *Prev Med.* 1990; 19:115-133.

142. Insull W Jr , Henderson MM, Prentice RL, et al. Results of a randomized feasibility study of a low-fat diet. *Arch Intern Med.* 1990;150:421-427.

143. Kristal AR, White E, Shattuck AL, et al. Long-term maintenance of a low-fat diet: durability of fat-related dietary habits in the Women's Health Trial. *J Am Diet Assoc.* 1992;92:553-559.

144. White E, Shattuck AL, Kristal AR, et al. Maintenance of a low-fat diet: follow-up of the

Women's Health Trial. *Cancer Epidemiol Biomarkers Prev.* 1992;1:315-323.

145. Maskarinec G, Chan CL, Meng L, Franke AA, Cooney RV. Exploring the feasibility and effects of a high-fruit and -vegetable diet in healthy women. *Cancer Epidemiol Biomarkers Prev.* 1999;8:919-924.

146. Siero FW, Broer J, Bemelmans WJ, Meyboom-de Jong BM. Impact of group nutrition education and surplus value of Prochaska- based stage-matched information on health-related cognitions and on Mediterranean nutrition behavior. *Health Educ Res.* 2000;15:635-647.

147. Lutz SF, Ammerman AS, Atwood JR, Campbell MK, DeVellis RF, Rosamond WD. Innovative newsletter interventions improve fruit and vegetable consumption in healthy adults. *J Am Diet Assoc.* 1999;99:705-709.

148. Baron JA, Gleason R, Crowe B, Mann JI. Preliminary trial of the effect of general practice based nutritional advice. *Br J Gen Pract.* 1990;40:137-141.

149. Fiore M, Bailey W, Cohen S, et al.; Treating Tobacco Use and Dependence. Clinical Practice Guideline. Rockville, Md.: US Department of Health and Human Services, PHS; 2000.

150. Ammerman A, Lindquist C, Hersey J, et al. Evidence report on the efficacy of interventions to modify dietary behavior related to evidence risk. Rockville, MD: Agency for Healthcare Research and Quality; 2001.

151. Mullen PD, Simons-Morton DG, Ramirez G, Frankowski RF, Green LW, Mains DA. A meta-analysis of trials evaluating patient education and counseling for three groups of preventive health behaviors. 1997;32:157-173.

152. Thompson R, Summerbell C, Hooper L, et al. Dietary advice given by a dietician versus other health professional or self-help resources to reduce blood cholesterol (Cochrane review). *The Cochrane Libray.* 2001.

153. Shannon BM, Tershakovec AM, Martel JK, et al. Reduction of elevated LDL-cholesterol levels of 4- to 10-year-old children through home-based dietary education. *Pediatrics.* 1994;94:923-927.

154. Kottke TE, Foels JK, Hill C, Choi T, Fenderson DA. Perceived palatability of the prudent diet: results of a dietary demonstration for physicians. *Prev Med.* 1983;12:588-594.

155. Jack BW, Gans KM, McQuade W, et al. A successful physician training program in cholesterol screening and management. *Prev Med.* 1991;20:364-377.

156. Lazarus K, Weinsier RL, Boker JR. Nutrition knowledge and practices of physicians in a family-practice residency program: the effect of an education program provided by a physician nutrition specialist. *Am J Clin Nutr.* 1993;58:319-335.

157. Kirby RK, Chauncey KB, Jones BG. The effectiveness of a nutrition education program for family practice residents conducted by a family practice resident-dietitian. *Fam Med.* 1995;27:576-580.

158. McPhee SJ, Bird JA, Fordham D, Rodnick JE, Osborn EH. Promoting cancer prevention activities by primary care physicians. Results of a randomized, controlled trial. *JAMA.* 1991;266:538-544.

159. Olson RE. The dietary recommendations of the American Academy of Pediatrics. *Am J Clin Nutr .* 1995;61:271-273.

160. Anderson G. Factors affecting nutritional lifestyle changes in children. *Prevention of Athersclerosis and Hypertension Beginning in Youth*. Philadelphia, PA: 1994:3-10.

161. Pugliese MT , Weyman-Daum M, Moses N, Lifshitz F. Parental health beliefs as a cause of nonorganic failure to thrive. *Pediatrics.* 1987;80:175-182.

162. Lifshitz F, Moses N. Growth failure. A complication of dietary treatment of hypercholesterolemia. *Am J Dis Child.* 1989;143:537-542.

163. Mauer AM. Should there be intervention to alter serum lipids in children? *Annu Rev Nutr.* 1991;11:375-391.

164. Kaplan RM, Toshima MT. Does a reduced fat diet cause retardation in child growth? *Prev Med.* 1992;21:33-52.

165. Obarzanek E, Kimm SY, Barton BA, et al. Long-Term Safety and Efficacy of a Cholesterol-Lowering Diet in Children With Elevated Low-Density Lipoprotein Cholesterol: Seven-Year Results of the Dietary Intervention Study in Children (DISC). *Pediatrics.* 2001;107:256-264.

166. Hiddink GJ, Hautvast JG, van Woerkum CM, Fieren CJ, van 't Hof MA. Information sources and strategies of nutrition guidance used by primary care physicians. *Am J Clin Nutr.* 1997;65:1996S-2003S.

167. Serra-Majem LL, Calvo JR, Male ML, Ribas L, Lainez P. Population attitudes towards changing dietary habits and reliance on general practitioners in Spain. *Eur J Clin Nutr.* 1999;53 Suppl 2:S58-S61.

168. Schucker B, Wittes JT, Cutler JA, et al. Change in physician perspective on cholesterol and heart disease. 1987;258: 24:3521-3526.

169. Schucker B, Wittes JT, Santanello NC, et al. Change in cholesterol awareness and action. Results from national physician and public surveys. *Arch Intern Med.* 1991;151:666-673.

170. Ammerman AS, DeVellis RF, Carey TS, et al. Physician-based diet counseling for

cholesterol reduction: current practices, determinants, and strategies for improvement. *Prev Med.* 1993;22:96-109.

171. Morris SE, Lean ME, Hankey CR, Hunter C. Who gets what treatment for obesity? A survey of GPs in Scotland. *Eur J Clin Nutr.* 1999;53 Suppl 2:S44-S48.

172. Zoorob RJ, Mainous AG3. Practice patterns of rural family physicians based on the American Diabetes Association standards of care. *J Commun Health.* 1996;21:175-182.

173. Rafferty M. Prevention services in primary care: taking time, setting priorities. *West J Med.* 1998;169:269-275.

174. Troiano RP, Flegal KM, Kuczmarski RJ, Campbell SM, Johnson CL. Overweight prevalence and trends for children and adolescents. The National Health and Nutrition Examination Surveys, 1963 to 1991. *Arch Pediatr Adolesc Med.* 1995;149:1085-1091.

175. Hiddink GJ, Hautvast JG, van Woerkum CM, van't Hof MA, Fieren CJ. Cross-sectional and longitudinal analyses of nutrition guidance by primary care physicians. *Eur J Clin Nutri.* 1999;53 Suppl 2:S35-S43.

176. Mann KV, Putnam W. Physicians' perceptions of their role in cardiovascular risk reduction. *Prev Med.* 1989;18:45-48.

177. Holund U, Thomassen A, Boysen G, et al. Importance of diet and sex in prevention of coronary artery disease, cancer, osteoporosis, and overweight or underweight: a study of attitudes and practices of Danish primary care physicians. *Am J Clin Nutr.* 1997;65:2004S-2006S.

178. Kottke TE, Foels JK, Hill C, Choi T, Fenderson DA. Nutrition counseling in private practice: attitudes and activities of family physicians. *Prev Med.* 1984;13:219-225.

179. Secker-Walker RH, Morrow AL, Kresnow M, Flynn BS, Hochheiser LI. Family physicians' attitudes about dietary advice. *Fam Pract Res J.* 1991;11:161-170.

180. Kushner RF. Barriers to providing nutrition counseling by physicians: a survey of primary care practitioners. *Prev Med.* 1995;24:546-552.

181. Shea S, Basch CE, Zybert P. Correlates of internists' practices in caring for patients with elevated serum cholesterol. *Nutrition.* 1990;4:421-428.

182. Glanz K. Review of nutritional attitudes and counseling practices of primary care physicians. *Am J Clin Nutr.* 1997;65:2016S-2019S.

183. Potter J, Langhorne P, Roberts M. Routine protein energy supplementation in adults: systematic review. *BMJ.* 1998;317:495-501.

184. Aubin M, Godin G, Vezina L, Maziade J, Desharnais R. Hypercholesterolemia screening. Does knowledge of blood cholesterol level affect dietary fat intake? *Can Fam Physician.* 1998;44:1289-1297.

185. Bakx JC, Stafleu A, van Staveren WA, van den Hoogen HJ, van Weel C. Long-term effect of nutritional counseling: a study in family medicine. *Am J Clin Nutr.* 1997;65:1946S-1950S.

186. Barratt A, Reznik R, Irwig L, et al. Work-site cholesterol screening and dietary intervention: the Staff Healthy Heart Project. Steering Committee. *Am J Public Health.* 1994;84:779-82.

187. Brannon SD, Tershakovec AM, Shannon BM. The cost-effectiveness of alternative methods of nutrition education for hypercholesterolemic children. *Am J Public Health.* 1997;87:1967-1970.

188. Caggiula AW , Watson JE, Kuller LH, et al. Cholesterol-lowering intervention program. Effect of the step I diet in community office practices. *Arch Intern Med.* 1996;156:1205-1213.

189. Crouch M, Sallis JF, Farquhar JW, et al. Personal and mediated health counseling for sustained dietary reduction of hypercholesterolemia. *Prev Med.* 1986;15:282-91.

190. DeBusk RF, Miller NH, Superko HR, et al. A case-management system for coronary risk factor modification after acute myocardial infarction. *Ann Intern Med.* 1994;120:721-9.

191. de Lorgeril M. [Oxidative stress and lipid-protein peroxidation after cardiac transplantation. New hypotheses for explaining pathogenesis of accelerated forms of ischemic heart disease]. *Arch Mal Coeur Vaiss.* 1994;87:1467-73.

192. Dyson PA, Hammersley MS, Morris RJ, Holman RR, Turner RC. The Fasting Hyperglycaemia Study: II. Randomized controlled trial of reinforced healthy-living advice in subjects with increased but not diabetic fasting plasma glucose. *Metabolism.* 1997;46:50-55.

193. Ershoff DH, Aaronson NK, Danaher BG, Wasserman FW. Behavioral, health, and cost outcomes of an HMO-based prenatal health education program. *Public Health Reports.* 1983;98:536-547.

194. Family Heart Study Group. Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. *BMJ.* 1994;308:313-320.

195. Fletcher V. An individualized teaching programme following primary uncomplicated myocardial infarction. *J Adv Nurs.* 1987;12:195-200.

196. Foreyt JP, Scott LW, Mitchell RE, Gotto AM. Plasma lipid changes in the normal

population following behavioral treatment. *J Consult Clin Psychol.* 1979;47:440-452.

197. George SM, Latham MC, Abel R, Ethirajan N, Frongillo EAJ. Evaluation of effectiveness of good growth monitoring in south Indian villages . *Lancet.* 1993;342:348-352.

198. Gosselin P, Verreault R, Gaudreault C, Guillemette J. [Dietary treatment of mild to moderate hypercholesterolemia. Effectiveness of different interventions]. [French]. *Can Fam Physician.* 1996;42:2160-2167.

199. Heller RF, Elliott H, Bray AE, Alabaster M. Reducing blood cholesterol levels in patients with peripheral vascular disease: dietitian or diet fact sheet? *Med J Aust.* 1989;151:566-568.

200. Henkin Y, Shai I, Zuk R, et al. Dietary treatment of hypercholesterolemia: do dieticians do it better? A randomized, controlled trial. *Am J Med.* 2000;109:549-555.

201. Howard-Pitney B, Winkleby MA, Albright CL, Bruce B, Fortmann SP. The Stanford Nutrition Action Program: a dietary fat intervention for low-literacy adults. *Am J Public Health.* 1997;87:1971-1976.

202. Kuehl KS, Cockerham JT, Hitchings M, Slater D, Nixon G, Rifai N. Effective control of hypercholesterolemia in children with dietary interventions based in pediatric practice. *Prev Med.* 1993;22:154-166.

203. Luepker RV, Smith LK, Rothchild SS, Gillis A, Kochman L, Warbasse JR. Management of hypercholesterolemia: evaluation of practical clinical approaches in healthy young adults. *Am J Cardiol.* 1978;41:590-596.

204. Lytle LA, Stone EJ, Nichaman MZ, et al. Changes in nutrient intakes of elementary school children following a school-based intervention: results from the CATCH Study. *Prev Med .* 1996;25:465-477.

205. Miettinen TA, Huttunen JK, Naukkarinen V, et al. Multifactorial primary prevention of cardiovascular diseases in middle- aged men. Risk factor changes, incidence, and mortality. *JAMA.* 1985;254:2097-2102.

206. Multiple risk factor intervention trial. Risk factor changes and mortality results. Multiple Risk Factor Intervention Trial Research Group. *JAMA.* 1982;248:1465-1477.

207. Naglak M, Mitchell DC, Kris-Etherton P, Harkness W, Pearson TA. What to consider when conducting a cost-effectiveness analysis in a clinical setting. *J Am Diet Assoc.* 1998;98:1149-1154.

208. Neil HA, Roe L, Godlee RJ, et al. Randomised trial of lipid lowering dietary advice in general practice: the effects on serum lipids, lipoproteins, and antioxidants. *BMJ.* 1995;310:569-573.

209. Neyses L, Dorst K, Michaelis J, et al. Compliance with salt restriction as a limiting factor in the primary prevention of hypertension. *J Hypertens Suppl.* 1985;3:S87-S90.

210. Nikolaus T, Schlierf G, Vogel G, Schuler G, Wagner I. Treatment of coronary heart disease with diet and exercise--problems of compliance. *Ann Nutr Metab.* 1991;35:1-7.

211. Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. *Am J Cardiol.* 1998;82:72T-76T.

212. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. Imperial Cancer Research Fund OXCHECK Study Group . *BMJ.* 1994;308:308-312.

213. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. Imperial Cancer Research Fund OXCHECK Study Group. *BMJ.* 1995;310:1099-1104.

214. Pritchard DA, Hyndman J, Taba F. Nutritional counseling in general practice: a cost effective analysis. *J Epidemiol Community Health.* 1999;53:311-316.

215. Ridgeway NA , Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J.* 1999;92:667-672.

216. Smith LK, Luepker RV, Rothchild SS, Gillis A, Kochman L, Warbasse JR. Management of type IV hyperlipoproteinemia. Evaluation of practical clinical approaches. *Ann Intern Med.* 1976;84:22-28.

217. Tershakovec AM, Shannon BM, Achterberg CL, et al. One-year follow-up of nutrition education for hypercholesterolemic children. *Am J Public Health.* 1998;88:258-261.

218. Tomson Y, Johannesson M, Aberg H. The costs and effects of two different lipid intervention programmes in primary health care. *J Intern Med.* 1995;237:13-17.

219. Waber DP, Vuori-Christiansen L, Ortiz N, et al. Nutritional supplementation, maternal education, and cognitive development of infants at risk of malnutrition. *Am J Clin Nutr.* 1981;34:807-813.

220. Winkleby MA , Howard-Pitney B, Albright CA, Bruce B, Kraemer HC, Fortmann SP. Predicting achievement of a low-fat diet: a nutrition intervention for adults with low literacy skills. *Prev Med.* 1997;26:874-882.

221. Harris RP, Helfand M, Woolf SH, et al. Current Methods of the US Preventive Services Task Force: A Review of the Process. *Am J Prev Med.* 2001;2 (3S):21-35.

222. Centers for Disease Control and Prevention. Physician advice and individual behaviors about cardiovascular disease risk reduction: seven states and Puerto Rico. *MMWR Morb Mortal Wkly Rpt.* 1997;48:74-77.

223. Centers for Disease Control and Prevention. Missed opportunities in preventive counseling for cardiovascular disease. *MMWR Morb Mortal Wkly Rep.* 1998;47:91-95.

224. Neighbor WEJ, Scott CS, Schaad DC, Macdonald SC, Van Citters R. Assessment and counseling of coronary risk factors by family practice residents. *J Fam Pract.* 1991;32:273-281.

225. Ross EM, Rosenberg IH, Dawson-Hughes B, Col NF, Wong JB. Fitting nutrition into the medical model: the role of decision analytic cost-effectiveness techniques. *Eur J Clin Nutr.* 1999;53 Suppl 2:S25-S28.

226. Curry S, Kristal A, Bowen D. An application of the stage model of behavior change to dietary fat reduction. *Health Educ Res.* 1992;7:97-105.

GLOSSARY for Tables 1 Through 12

Alt	Alternative
Avg	Average
BRFSS	Behavioral Risk Factor Surveillance Survey
C	Combined
Cal	Calorie
CAD	Coronary artery disease
CHD	Coronary heart disease
Chol	Cholesterol
Cnslg	Counseling
Cont	Control group
Crit	Criterion
CSI	Cholesterol/saturated fat index
CVD	Cardiovascular disease
D-gm SFA	Dietary grams of saturated fatty acids
DINE	Dietary Instrument for Nutrition Education
F	Female
F & V	Fruits and vegetables
F/U	Follow-up
g	Gram(s)
G/d	Grams per day
HMO	Health Maintenance Organization
Hr	Hour(s)
Hx/o	History of
Intv	Intervention group
M	Male
MD	Medical doctor
Mo	Months
Modif	Modification
MPH	Master of Public Health

GLOSSARY, continued

Msg	Message
NA	Not available
NCEP	National Cholesterol Education Panel
NP	Nurse practitioner
NR	Not reported
Poly	Polyunsaturated
Poly fat	Polyunsaturated fat
Pts	Patients
q	every
RD	Registered Dietician
RN	Registered Nurse
ROS	Review of systems
RR	Relative Risk
RRR	Relative Risk Reduction
Sat fat	Saturated fat
Trans	Trans-saturated fat
Unsat	Unsaturated
vs.	versus
w/	With
Wkly	Weekly
Wk(s)	Week(s)
Yr(s)	Year(s)