

U.S. Dietary Guidelines: An Evidence-Free Zone

Steven E. Nissen, MD

On 7 January 2016, the U.S. Department of Health and Human Services and Department of Agriculture released the Dietary Guidelines for Americans 2015–2020 (1). The preliminary report (released in February 2015) had generated considerable media attention by reversing decades of dogma with the statement that “cholesterol is not a nutrient of concern for overconsumption.” Incredibly, in the final 2015 report, this statement has been removed, instead suggesting that “individuals should eat as little dietary cholesterol as possible.” Which version should we believe? How can the same committee arrive at diametrically opposite conclusions? Now that the final report is available, it is prudent to examine how, for decades, the U.S. medical establishment has erroneously advised the population to severely limit cholesterol intake and to consider whether other conventional dietary advice will eventually prove faulty.

How strong is the scientific evidence supporting the current guidelines? The 2015 advisory committee was charged to “provide science-based advice” on nutrition and physical activity to “promote health across the lifespan and reduce the risk for major chronic diseases in the U.S. population.” Most of the recommendations are similar to prior guidelines, advising the population to limit intake of sodium, saturated fat (substituting unsaturated fats), and simple sugars and to increase consumption of fruits, vegetables, and nuts. However, a detailed review of the new guidelines confirms a disturbing reality: the nearly complete absence of high-quality randomized, controlled clinical trials (RCTs) studying meaningful clinical outcomes for dietary interventions. The report repeatedly makes recommendations based on observational studies and surrogate end points, failing to distinguish between recommendations based on expert consensus rather than high-quality RCTs. Unfortunately, the current and past U.S. dietary guidelines represent a nearly evidence-free zone.

The lack of high-quality RCTs has left dietary advice to cult-like advocates, often with opposite recommendations. One group advises virtually complete elimination of carbohydrates from the diet, whereas others promote a virtually fat-free diet. A search of online bookstores and Web sites reveals an unlimited choice of diets, all with extraordinary claims for incredible weight loss and health benefits.

The peer-reviewed medical literature also disappoints. One observational study, the Nurses' Health Study (NHS), has generated a plethora of questionable dietary claims. One NHS report claims that eating 1 ounce of nuts twice per week reduces the risk for pancreatic cancer by 35% (2) and another claims a 33% reduction in the risk for chronic obstructive pulmonary

disease for the top quintile of consumption of whole grains, polyunsaturated fatty acids, nuts, and long-chain ω -3 fats and low intakes of red processed meats, refined grains, and sugar-sweetened drinks (3). Yet another NHS report claims that daily consumption of more than 2 servings of artificially sweetened soda is independently associated with doubling the risk for a 30% or greater decline in renal function (4).

These types of poorly controlled observational studies would be difficult to publish in the peer-reviewed literature in any other field, but they are often reported with dramatic headlines by respected news organizations. Findings that suggest harm are particularly attractive to the media, such as a published study that claimed aspartame consumption doubles the risk for multiple myeloma (5). Such outrageous claims strain the credulity of thoughtful scientists but have little difficulty finding a journal that will publish them and less difficulty finding media outlets that will bring this “science” to public attention. Typically, dietary studies rely on a similar and flawed method, use of periodic dietary questionnaires to ascertain the eating patterns of participants. Recall bias and residual confounding plague such methods. There would be less interest in cult diets and poor-quality studies if nutritional research included properly designed and executed RCTs, but few exist.

How did the American medical establishment embark on a decades-long misadventure about dietary fat and cholesterol? Many observers and a popular author (6) trace the current state of confusion to the renowned Seven Countries Study directed by Ancel Keys. Begun in 1956 and funded by a grant from the U.S. Public Health Service, the study was first published in 1970 and linked intake of saturated fat and cholesterol to the risk for coronary disease (7). Before the study, Keys had already aggressively promoted the concept that dietary fat and cholesterol were closely related to the development of heart disease. He even appeared on the cover of *Time* magazine in 1961, advocating a low-fat diet as the solution to the coronary heart disease epidemic.

Critics have suggested that the Seven Countries Study was biased in favor of the hypothesis that dietary fat and cholesterol were critical factors in coronary disease (6). The study examined heart disease rates in Italy, Greece, Yugoslavia, Finland, the Netherlands, Japan, and the United States. Yet data were available for 22 countries. The researchers omitted countries, such as France, where consumption of total and saturated fat are very high but the risk for heart disease remains low. Even before the publication of the Seven Countries Study, the American Heart Association (AHA) took up the cause, recommending that Americans reduce dietary fat intake and substitute corn or soybean oil for butter. Soon, margarine (with large amounts of trans

fats) became the “heart-healthy” alternative to butter, eggs synonymous with unhealthy eating patterns, and low-fat diets the answer to the soaring rates of heart disease. The AHA continues to promote a low-fat diet. Recommendations updated on 12 August 2015 recommend “low-fat dairy products” and “if you choose to eat meat, look for the leanest cuts available” (8).

As a consequence of the widespread promotion of low-fat, low-cholesterol diets, Americans gradually reduced their consumption of these “harmful” ingredients. We reduced dietary fat but binged on carbohydrates and became increasingly obese. Type 2 diabetes grew into an epidemic that is now threatening to reverse decades of progress in reducing coronary heart disease incidence. The obsession with low-fat diets has resulted in some extraordinary and bizarre food-marketing practices. I recently observed a large bag of fat-free gummy bears sitting on a grocery store shelf with the unmistakable implication that “fat-free” equates to heart-healthy.

What do we really know about low-fat diets and limitation of saturated fat as a coronary disease prevention strategy? In reality, we do not know very much. However, the best available evidence does not clearly support the widely held belief that Americans should limit saturated fat and cholesterol in the diet. A 2014 systematic review and meta-analysis examined 32 observational studies involving more than 500 000 participants (9). Comparing the top and bottom thirds of baseline dietary fat intake, the relative risk for coronary heart disease was 1.03 (95% CI, 0.98 to 1.07) for saturated fats, 1.00 (CI, 0.91 to 1.10) for monounsaturated fats, 0.87 (0.78 to 0.97) for long-chain ω -3 polyunsaturated fats, 0.98 (CI, 0.90 to 1.06) for ω -6 polyunsaturated fats, and 1.16 (CI, 1.06 to 1.27) for trans fats. Of course, this analysis shares the same limitations of the observational research it summarizes.

Fortunately, a large (7447 participants) high-quality RCT was finally published in 2013, the PREDIMED (Prevenición con Dieta Mediterránea) study, conducted in Spain, comparing the Mediterranean diet with the conventional AHA-style, low-fat diet in participants at risk for coronary disease (10). The multivariable-adjusted hazard ratios for coronary disease were 0.70 (CI, 0.54 to 0.92) for the group assigned to a diet enriched with extra-virgin olive oil and 0.72 (CI, 0.54 to 0.96) for the group assigned to a diet enriched with nuts, both compared with the low-fat diet.

How do we proceed in the pursuit of scientific understanding about the relationship between diet and coronary disease? It is time for careful RCTs testing various dietary interventions—studies unlikely to be industry-funded. Federal agencies, such as the National Institutes of Health and Centers for Disease Control and Prevention, must fund and help conduct such trials. The successful completion of the PREDIMED Study, funded by the Spanish government, proves that such studies are feasible. Properly performed studies may demon-

strate that saturated fat and cholesterol are indeed nutrients of concern, but the opposite conclusion is also possible. It is time to transition from the current evidence-free zone to an era where dietary recommendations are based on the same quality evidence that we demand in other fields of medicine.

From The Cleveland Clinic, Cleveland, Ohio.

Disclosures: The author has disclosed no conflicts of interest. Form can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M16-0035.

Requests for Single Reprints: Steven E. Nissen, MD, Department of Cardiovascular Medicine, The Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195; e-mail, nissens@ccf.org.

Author contributions are available at www.annals.org.

Ann Intern Med. 2016;164:558-559. doi:10.7326/M16-0035

References

1. U.S. Department of Health and Human Services, U.S. Department of Agriculture. Dietary Guidelines for Americans 2015–2020. 8th Edition. December 2015. Accessed at <http://health.gov/dietaryguidelines/2015/guidelines> on 8 January 2016.
2. Bao Y, Hu FB, Giovannucci EL, Wolpin BM, Stampfer MJ, Willett WC, et al. Nut consumption and risk of pancreatic cancer in women. *Br J Cancer.* 2013;109:2911-6. [PMID: 24149179] doi:10.1038/bjc.2013.665
3. Varraso R, Chiuve SE, Fung TT, Barr RG, Hu FB, Willett WC, et al. Alternate Healthy Eating Index 2010 and risk of chronic obstructive pulmonary disease among US women and men: prospective study. *BMJ.* 2015;350:h286. [PMID: 25649042] doi:10.1136/bmj.h286
4. Lin J, Curhan GC. Associations of sugar and artificially sweetened soda with albuminuria and kidney function decline in women. *Clin J Am Soc Nephrol.* 2011;6:160-6. [PMID: 20884773] doi:10.2215/CJN.03260410
5. Schernhammer ES, Bertrand KA, Birmann BM, Sampson L, Willett WC, Feskanih D. Consumption of artificial sweetener- and sugar-containing soda and risk of lymphoma and leukemia in men and women. *Am J Clin Nutr.* 2012;96:1419-28. [PMID: 23097267] doi:10.3945/ajcn.111.030833
6. Teicholz N. *The Big Fat Surprise: Why Butter, Meat & Cheese Belong in a Healthy Diet.* New York: Simon & Schuster; 2014.
7. Coronary heart disease in seven countries. Summary. *Circulation.* 1970;41:1186-95. [PMID: 5442782]
8. The American Heart Association's Diet and Lifestyle Recommendations. Accessed at www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyEating/The-American-Heart-Associations-Diet-and-Lifestyle-Recommendations_UCM_305855_Article.jsp# on 7 January 2016.
9. Chowdhury R, Warnakula S, Kunutsor S, Crowe F, Ward HA, Johnson L, et al. Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis. *Ann Intern Med.* 2014;160:398-406. [PMID: 24723079] doi:10.7326/M13-1788
10. Estruch R, Ros E, Salas-Salvadó J, Covas MI, Corella D, Arós F, et al; PREDIMED Study Investigators. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med.* 2013;368:1279-90. [PMID: 23432189] doi:10.1056/NEJMoa1200303

Annals of Internal Medicine

Author Contributions: Conception and design: S.E. Nissen.
Drafting of the article: S.E. Nissen.
Critical revision for important intellectual content: S.E. Nissen.
Final approval of the article: S.E. Nissen.