

# The Only Thing That Should Be Set in Stone Is the Ten Commandments

## Dealing With Unplanned Obsolescence in the US Dietary Guidelines

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**For more than 100 years in the United States, dietary guidance has existed to guide food choices. In the 1980s, the first formal process, by which US dietary guidance is reviewed and created, was instituted, and this process has continued to evolve, albeit slowly, up until present day. However, it is unclear if the Dietary Guidelines for Americans have kept up with the evolution of this process over the past thirty years. During this time, nutrition and medical science has evolved dramatically. Yet, despite decades of well-intentioned advice, review, updates and revisions, there has simply been an additive effect to US dietary guidance resulting in too many messages and consumer confusion. This begs the question: Does current dietary guidance consist of too many messages and some long-standing nutrition advice that may be obsolete? We present a case study that demonstrates how some old guidance may not meet the current evidentiary-based standards to establish it as a guideline today, therefore making it obsolete, and a brief overview of how the dietary guideline review and updating process have evolved over the past 40 years from one of consensus to evidentiary based. *Nutr Today*. 2010;45(4):147–153**

Most dietary guidance, whether issued by the government or by health or professional organizations, has been developed with the intent to promote overall good health (eg, Dietary Guidelines for Americans [DGA]) and/or reduce the risk

of chronic disease (eg, American Heart Association [AHA] Diet and Lifestyle Recommendations). Guidance, such as the DGA, provides the policy framework for much of the United States' national nutrition education and is the basis of many federal nutrition and feeding programs, including the Supplemental Nutrition Program for Women, Infants and Children and the National School Lunch Program. Yet, despite decades of well-intentioned advice and continued discussion, debate, reviews, updates, and revisions, there has been an additive effect to US dietary guidance resulting in too many messages and consumer confusion.<sup>1</sup> As the number of guidelines and subguidelines have grown (from 7 in 1995 to 41 in 2005),<sup>2,3</sup> a significant percentage of Americans continue to have diets too low in fruits, vegetables, fiber, and nonfat/low-fat dairy products<sup>4</sup> and are overweight or obese.<sup>5</sup>

Over time, the focus of dietary guidance has shifted from promoting foods with adequate nutrients as a means of preventing deficiencies—based on clear evidence of an association—to avoiding foods with certain nutrients to prevent chronic diseases, based on much less clear-cut associations.<sup>6</sup> Although dietary guidance issued from the government and health organizations is periodically reviewed and updated, some recommendations have not evolved in tandem with nutrition science. Despite efforts to adopt an evidence-based approach, beginning with the 2005 Dietary Guidelines,<sup>7</sup> the current process for developing guidance has demonstrated, at times, a relative inability to adapt to new scientific evidence, which in some cases would deem old recommendations outdated and obsolete. Rather than evaluate if existing advice is still relevant, a precautionary approach has been advanced in which new messages are simply added to the total.<sup>8</sup>

The amount of discussion and debate that surrounds the development and updating of dietary guidance would suggest that there is built-in flexibility to the process, that is, that substantial change will occur when warranted through scientific evidence. But substantive change rarely, if ever, takes place.

The current status of Americans' health begs the question: Does current dietary guidance consist of too many messages and some long-standing nutrition advice that may be obsolete? We put forth the argument that the answer is yes and ask an additional question: Why has the process for developing dietary guidance demonstrated a relative inability to adapt to changing research findings? We posit this is because sometimes we have to look backward, to move the health of the nation forward. To make our points, we first present a case study that focuses on one long-held standard—limit dietary cholesterol—and show how this could not meet the current evidentiary-based standards to establish it as a guideline today, making it obsolete. To address our second question, we then provide an overview of how the dietary guidelines review and updating process have evolved over the past 40 years from one of consensus to the evidentiary-based process.

### Limit Dietary Cholesterol—A Case Study of Old Advice That Would Be Obsolete Using Today's Evidence-Based Standards?

Over the years, many of the dietary guidance messages have remained remarkably similar, despite the evolution in the guidance review process. The message to reduce dietary cholesterol intake is but one example of guidance that has been widely accepted by consumers,<sup>9</sup> yet the scientific evidence both old and new is less than conclusive.

#### The Recommendation

Dietary recommendations since 1968 have admonished everyone to limit dietary cholesterol intake, despite the accumulation of convincing evidence that dietary cholesterol has little or no impact on cardiovascular disease risk. In 1968, the AHA Nutrition Committee first recommended limiting daily dietary cholesterol intake to no more than 300 mg/d for patients with high total blood cholesterol levels.<sup>10</sup> This intake value was based on small clinical studies conducted with men diagnosed with hypercholesterolemia and set by simply cutting the 1968 consumption data value of 600 mg/d in half.<sup>11</sup> This dietary intake recommendation was established despite the AHA's own referencing of large

epidemiological studies that found no relationship between dietary cholesterol intake, serum cholesterol, and coronary heart disease (CHD) in the general healthy population.<sup>10</sup> This arbitrary value was never intended for the generally healthy public, yet it was further extended to the US population through the 1977 Dietary Goals. The AHA and the 2005 DGA continue to recommend limiting cholesterol intake to no more than 300 mg/d,<sup>3</sup> and the National Cholesterol Education Program Adult Treatment Panel III Guidelines recommend no more than 200 mg/d, even for individuals at low risk.<sup>11</sup> All of these authoritative guidelines are intended to be broad-based recommendations directed to the general public; however, there was no broad-based scientific evidence in 1968, nor is there now, that reducing dietary cholesterol to 300 mg/d for the average healthy American will reduce cardiovascular disease risk. Despite the lack of scientific evidence, this guidance message continues to be perpetuated.

#### Scientific Evolution

Early studies focused on serum total cholesterol as the primary marker for risk, and dietary cholesterol was, at the time, believed to have a direct effect on this marker. Most recently, the focus has turned to cholesterol and lipoprotein ratios, including the low-density lipoprotein/high-density lipoprotein (LDL/HDL) ratio, as being more accurate predictors of risk. Clinical feeding studies demonstrate that, on average, the LDL/HDL cholesterol ratio is predicted to increase 0.01 U per 100-mg/d increase in dietary cholesterol, an amount unlikely to significantly affect cardiovascular disease risk.<sup>12</sup>

Perhaps even more important than the use of clinical studies when creating population-directed guidance is the relevance of large population-based studies that should be examined and heavily weighed. Two of the world's largest cohort studies reported no significant relationship between dietary cholesterol intake and increased CHD risk factors or events.<sup>13,14</sup> Furthermore, the 2005 Dietary Guidelines Advisory Committee (DGAC) outlined in their review process that in establishing population level dietary guidance, observational studies should be given top priority, only supplemented by well-designed clinical intervention with widely accepted health outcomes.<sup>3</sup> Yet, despite the lack of findings, dietary guidance continues to repeat and reinforce the recommendation to limit cholesterol intake to 300 mg/d. The guidance review process needs to be updated such that old recommendations, and the science upon which they were based, are reviewed. There is nothing in the current dietary guidance revision process that allows for this seemingly important provision of new widely accepted end-points of LDL cholesterol, HDL cholesterol, and

LDL/HDL cholesterol values, which would likely result in the elimination of early studies as evidence.

### Impact of an Old Message on Current Dietary Intake

Lowering cholesterol from 600 to 300 mg/d cannot be done without severely limiting or eliminating essential foods and food groups from the diet. Reductions in the intake of eggs, meat, dairy, and seafood based on messages to reduce intake of dietary cholesterol could be negatively impacting high-quality protein and essential nutrient intakes. There are 5 food groups for a reason, as each group is a major contributor of at least 1 nutrient and provides substantial contributions for many other nutrients. As such, significant reductions in intakes of certain foods because of broad sweeping dietary guidance can lead to significant reductions in intakes of essential nutrients.<sup>15</sup> Because this guidance has been internalized by the vast majority of Americans, it would appear that these dietary guidelines have led to inadvertently limiting or eliminating eggs, a nutrient-rich food, from the diets of most people, while experts are at the same time calling for Americans to eat more nutrient-dense foods.<sup>3,16</sup>

A recent risk model analysis of dietary cholesterol and CHD questions the wisdom of current recommendations to minimize cholesterol intake.<sup>17</sup> The study found that for 80% to 85% of the population, dietary cholesterol from eggs contributes less than 1% to the incidence of CHD. Studies have found that including as many as 3 eggs per day (about 640 mg of cholesterol) had no significant effect on the LDL/HDL cholesterol ratio.<sup>18</sup> Moreover, studies show that when LDL increases as a result of eating eggs, the LDL cholesterol is generally large and less atherogenic, even among individuals classified as cholesterol hyperresponders.<sup>19,20</sup> When egg intake was examined in 2 large epidemiological cohort studies, one with men and the other with women, consuming up to 1 egg a day did not increase heart disease risk in healthy individuals.<sup>13,14</sup>

Eggs are one of the primary sources of cholesterol in the American diet. Yet more importantly, they are low in calories (78 for 1 large egg), naturally low in sodium, an excellent source of selenium, and a good source of high-quality protein, riboflavin, and choline, as well as providing lutein and zeaxanthin, 2 potent antioxidants that may play a role in decreasing the susceptibility of the LDL cholesterol particles to oxidation and in reducing the risk of cataracts and macular degeneration.<sup>21</sup> Eggs also provide vitamin B<sub>12</sub>, folate, vitamin A, vitamin D, vitamin B<sub>6</sub>, vitamin E, phosphorous, iron, and zinc, many of the nutrients for which large portions of the population are deficient.<sup>22,23</sup> The mere fact that there may be potentially significant negative effects associated with limiting foods and food groups known to have a

positive impact on health, particularly in light of the lack of evidence that would prove otherwise needs to be questioned when updating and reviewing dietary guidance.

### Unintended Consequences of Obsolete Guidance

In recent years, it has become increasingly evident that reductions in intakes of eggs, because of messages to reduce dietary intake of cholesterol, could be having a negative impact on adequate choline intake. Eggs are among the richest and most frequently consumed sources of choline in the US diet. Choline is needed for neurotransmitter synthesis, cell membrane signaling, lipid transport, and methyl-group metabolism.<sup>24</sup> It is especially important for women who are pregnant or of childbearing age as low intakes of dietary choline increase the risk for having a child with neural tube defects.<sup>25</sup> An analysis of data from the National Health and Nutrition Examination Survey 2003–2004 found that for older children, men, women, and pregnant women, mean choline intakes were far below the adequate intake. Ten percent or fewer had usual choline intakes at or above the adequate intake.<sup>26</sup> Another study found that a lack of beneficial nutrients, such as vitamins B<sub>6</sub>, folate, and fiber, has a greater impact on heart disease risk than the presence of nutrients to limit, such as cholesterol.<sup>27</sup>

As both the AHA recommendations and DGA have been communicated as broad-based recommendations intended for the general public, it would appear that this guidance might inadvertently result in limiting or eliminating eggs (Figure), a nutrient-dense food, from the diets of most Americans. At the same time, this contradicts what many health professionals are communicating to Americans—eat more nutrient-dense foods.

### How Does US Guidance Compare With the Rest of the World?

In contrast to the US guidance to limit cholesterol to no more than 300 mg/d, Australia, New Zealand, Canada, and the United Kingdom have rescinded their former cholesterol restrictive advice and do not make such specific recommendations for cholesterol intake.<sup>28</sup> These countries instead focus on limiting saturated and *trans*-fat intake and other dietary modifications known to achieve desirable blood cholesterol levels and reduce CHD risk. Interestingly, Canada, like the United States, uses the same Institute of Medicine Dietary Reference Intakes report to create dietary guidance; however, despite this, Health Canada did not include a cholesterol guideline in their 1992 food guide, did not mandate that cholesterol have a daily reference value included on food nutrition facts panel, and left cholesterol off the list of dietary guidelines issued in 2007. Similarly in 2005, the US Department of Agriculture (USDA) eliminated

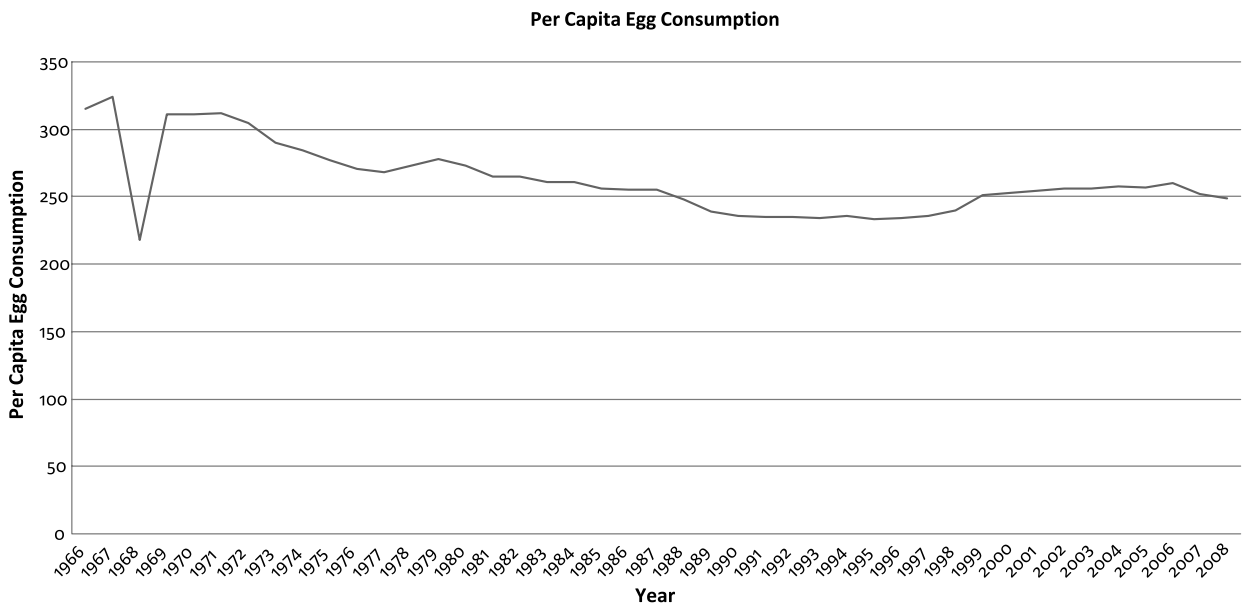


Figure. Per-capita egg historical consumption trend. Sources: Livestock, Dairy and Poultry Situation and Outlook, July 2006, USDA ERS; Egg and Egg Products: Supply and Disappearance. August 2009. USDA ERS. <http://www.ers.usda.gov/publications/ldp/LDPTables.htm>; <http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1367>.

the cholesterol component from their diet quality measurement tool, the Healthy Eating Index. Is this advice obsolete? The actions of many countries around the world, and even those of the USDA, would indicate yes. As new scientific evidence has evolved, and old evidence reviewed in light of new findings, a fundamental shift occurred that removed dietary cholesterol, and the associated foods, out of the spotlight.

### A Century Of Dietary Guidance—From Consensus to Evidence

Some form of government-promulgated dietary guidance has informed consumer food choices in the United States for more than 100 years. In 1917, the USDA released its first guidance, “How to Select Foods,”<sup>29</sup> emphasizing vitamin, mineral, and food group intake. Although a number of subsequent documents, brochures, and guidance recommendations were released over the next 60 years, it was not until 1977 that the first formal guidance was established as Dietary Goals for the United States by the Senate Select Committee on Nutrition and Human Needs (eg, the McGovern Report) and finalized as the 1980 DGA.<sup>30</sup>

#### Eat More, Eat Less—A Controversial Revolution Begins

Beginning in 1977, the scientific underpinnings by which the first Dietary Goals were established, and have been

cemented as status quo, have been met with controversy and skepticism. Based largely on key testimonies to the Senate Committee by Dr Ancel Keys who supported the novel hypothesis that all fats were bad for health,<sup>31</sup> and written by former journalist Nick Mottern, the American Medical Association reviewed the disease-diet relationships outlined in the resultant Dietary Goals and called the evidence “tenuous, fragmentary, and conflicting.”<sup>32</sup> In 1979, the “Healthy People: The Surgeon General’s Report on Healthy Promotion and Disease Prevention” was issued, based on the findings from an American Society of Clinical Nutrition expert panel review investigating the association between diet and health outcomes. Following the release of this report and a year of meetings, the Department of Health and Human Services (HHS) and USDA jointly issued the first DGA (1980). The 1980 DGA was based on the standard of “best scientific consensus and opinion,” but many would assert not clear scientific evidence, as our case study demonstrates, which is considered to be the current standard for dietary guidance.

#### PL 101-445—The Mandate

Fifteen years later, the first statutorily mandated DGA report was published in 1995, following the National Nutrition Monitoring and Related Research Act of 1990 (PL 101-445) passage. This requires that the USDA and HHS secretaries jointly publish the report every 5 years

“based on the preponderance of scientific and medical knowledge current at the time of publication.”<sup>33</sup> This also marked the first time that an external DGAC was appointed by the secretaries of the USDA and HHS to review new science and provide evidence-based recommendations to the agencies. Although the 1995 Committee was the first step toward a science-based process, and away from the opinion-based McGovern report, it would take another decade for a systematic, evidentiary-based review process to be implemented.

### **2005—A New Scientific Evidentiary-Based Approach**

In 2005, the 13-member-appointed DGAC was charged to adopt a systematic evidence-based review process. The goal of this new process was 2-fold: to create necessary changes to old guidance and establish new guidance based on newly emerged science.<sup>3</sup> As a result of this new charge, the DGAC created working subgroups to review topical diet-related health issues. To create the systematic review process, the DGAC outlined priority literature (eg, human studies, largely adults), agreed that the greatest emphasis would be on observational studies and clinical trials with well-accepted clinical end points, created specific literature search strategies (eg, vitamin E review limited to publication dates 1995–2004), critically reviewed all selected studies for rigor and relevance to the question at hand, and utilized a prototype table to be used by all subcommittees for summarizing the literature. This systematic process resulted in 124 pages of tables detailing each study considered and weighed as evidence in the updating and revision of the existing guidance. This laborious effort by the DGAC is to be applauded; however, it is perplexing that given the state of US dietary intake and chronic disease prevalence, no substantial changes to the existing guidance have yet to come about. To answer our second question, first, “Why has the process for developing dietary guidance demonstrated a relative inability to adapt to changing research findings?” We suggest that, in addition to examining emergent science and “cutting-edge nutrition issues,” the process needs to apply the 2005 rigorous systematic evidence-based approach to allow for the comprehensive reevaluation of old guidance and its associated scientific evidence.

As demonstrated with the case study, the dietary cholesterol intake recommendation and the accompanying message to “limit” intake began its history steeped in controversy. Despite the accumulation of convincing evidence that dietary cholesterol and the associated foods have little or no impact on CHD risk, the perceived association has been perpetuated for more than 40 years through the DGA with no reconsideration.<sup>3</sup> While we

have focused on the dietary cholesterol guidance, it is but one example of a guideline that needs to be reexamined. Other guidance that warrants potential review and revision as recommendations have not kept pace with our current scientific knowledge includes total fat as current scientific evidence suggests that fat quality, such as the intake of good fats omega-3 and omega-6, DHA (docosahexaenoic acid), and EPA (eicosapentaenoic acid), is perhaps more important to health promotion than limiting total fat intake<sup>34</sup>; numerous recent studies have found no conclusive cause-and-effect relationship between saturated fat intake and increased heart disease risk,<sup>35</sup> and although fiber has been shown to be conclusively, positively associated with reduced disease risk, the scientific evidence for whole grains is suggestive, but not conclusive.<sup>36</sup> We presented the brief case study to highlight how current scientific research challenges generally accepted nutrition tenets and confronts old guard thinking, albeit unsuccessfully thus far. Not only is change slow to take place, there also appears to be a lack of accountability when dietary guidance does not work or is associated with unintended, but potentially harmful effects.

### **The Time Has Come to Reexamine Old Guidance Using New Standards**

Although there is a mandatory review process every 5 years of the research supporting the Dietary Guidelines, the evaluation process has not evolved as quickly as the science. Rather than reevaluate the relevance of existing advice or the need to revise dietary recommendations based on new research, the DGA has taken a more precautionary approach that simply adds new messages to the total, making it difficult for health professionals to educate consumers and for consumers to activate the guidelines in their daily lives. There seems to be a resistance to reevaluating dietary advice that is entrenched in conventional nutrition thinking, even if it is based on outdated evidence. Perhaps the validity of the mostly precautionary, nutrient-based approach currently used needs to be reevaluated, and the guidelines prioritized and consolidated based on the most current research findings, rather than simply adding more dietary guidance messages to address all possible dietary concerns. The 2005 Dietary Guidelines provided fledgling efforts in that direction by recommending Food Groups to Encourage.<sup>3</sup> The question posed now is: Do we continue along the same track, perpetuating old guidance with minor changes that are virtually imperceptible to consumers, and therefore, ultimately meaningless, or do we take a fresh look and critically examine, reevaluate, and, based on new evidence, recast dietary guidance that has been promulgated thus far? We

suggest that those involved in the process of developing nutrition guidance should be called upon to reevaluate what the science, old and new, states and determine how best to translate that into meaningful guidance for consumers. The time has now come to heed the call for new, inventive approaches for developing and prioritizing meaningful and actionable dietary guidance based on the latest research findings so that substantive gains in public health can be realized in the future, and obsolete guidance can be admonished to where it belongs, in the past.

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*Readers will be pleased to note that some but not all of the concerns about recommendations have been addressed in the 2010 DGAC Report. [www.dietaryguidelines2010.gov](http://www.dietaryguidelines2010.gov).*

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