**Behind New Dietary Guidelines, Better Science**

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For decades, many dietary recommendations have revolved around consuming a low percentage of your [daily calories from fat](http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf#page=37). It has been widely thought that doing so would reduce your chance of having [coronary heart disease](http://health.nytimes.com/health/guides/disease/coronary-heart-disease/overview.html?inline=nyt-classifier). Most of the evidence for that recommendation has come from epidemiologic studies, which can be flawed.

Use of these types of studies happens far more often than we would like, leading to dietary guidelines that may not be based on the best available evidence. But last week, the government started to address that problem, proposing new guidelines that in some cases are more in line with evidence from randomized controlled trials, a more rigorous form of scientific research.

Sometimes we have to settle for epidemiologic or other less reliable studies because we can’t do a randomized controlled trial to prove causality. We’ll never have one for smoking and [cancer](http://health.nytimes.com/health/guides/disease/cancer/overview.html?inline=nyt-classifier), for instance, because the evidence from cohort and case-control studies, which are observational and not interventional, is so compelling that telling a random population to smoke “to see if it’s harmful” would be unethical. But there’s no reason we couldn’t randomly assign people to diets.

It turns out that we have. In fact, randomized controlled trials existed when the previous low-fat guidelines were published. It appears they were ignored.

Just recently, a [study was published in the journal Open Heart](http://openheart.bmj.com/content/2/1/e000196.full) in which researchers performed a systematic review and meta-analysis of the randomized controlled trials that were available when those guidelines were announced. They wanted to explore what evidence those creating the guidelines might have been able to consider at the time.

Before 1983, six randomized controlled trials involving 2,467 men were conducted. None were explicit studies of the recommended diet (and none involved women), but all explored the relationship between [dietary fat](http://health.nytimes.com/health/guides/nutrition/fat/overview.html?inline=nyt-classifier), [cholesterol](http://health.nytimes.com/health/guides/nutrition/cholesterol/overview.html?inline=nyt-classifier) and mortality. Five of them were secondary prevention trials — meaning that they involved only men with known problems already. Only one included healthy participants, who would be at lower risk, and therefore would be likely to have less benefit from dietary changes.

That’s a lot of participants. Moreover, many of them were at high risk. And in all of them, there was no significant difference among them in the rate of death from coronary heart disease. There were also no differences in mortality from all causes, which is the metric that matters.

The study did show that cholesterol levels went down more in the groups that ate low-fat diets. Some have used this as justification for a low-fat diet. But the difference between them was small. Mean cholesterol went down 13 percent in the intervention groups, but it went down 7 percent in the control groups. And these groups didn’t have different clinical outcomes, and that’s what we really care about.

Small changes in cholesterol levels from dietary changes also aren’t surprising to those who follow the research. About 70 percent of people are thought to be “[hyporesponders](http://www.ncbi.nlm.nih.gov/pubmed/16340654)” to dietary cholesterol. This means that after consuming three eggs a day for 30 days, they would see no increase in their plasma cholesterol ratios. Their cholesterol levels have almost no relationship to what they eat.

Don’t take my word for it. Again, there have been randomized controlled trials in this area. In 2013, researchers [published a systematic review](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3900007/) of all studies from 2003 or after. Twelve met the researchers’ criteria for inclusion in the analysis, and seven of them controlled for background diet. Most of the studies that controlled for background diet found that altering cholesterol consumption had no effect on the concentration of blood LDL (or “bad”) cholesterol. A few studies could detect differences only in small subgroups of people with certain genes or a predisposition to problems.

In other words, in most studies, all people didn’t respond. In the rest, only a minority of patients responded to changes in dietary cholesterol.

Did recommendations change when these studies were published? No, but they [got closer to changing](http://well.blogs.nytimes.com/2015/02/19/nutrition-panel-calls-for-less-sugar-and-eases-cholesterol-and-fat-restrictions/) on Thursday, when a [government committee](http://www.health.gov/dietaryguidelines/committee/) urged repeal of the guideline that Americans limit their cholesterol intake to 300 milligrams a day, saying, “[Cholesterol is not a nutrient of concern for overconsumption](http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf).” I’m sure this will come as a surprise to a vast majority of Americans, who for decades have been watching their cholesterol intake religiously. (The change won’t be official until it is approved by the Department of Health and Human Services and the Department of Agriculture, but they usually closely follow the committee’s recommendations.)

I wrote [here at The Upshot](http://nyti.ms/1mHuPm7) not long ago about how a growing body of epidemiologic data was pointing out that low-salt diets might actually be unhealthy. But randomized controlled trials exist there, too. A [2008 study randomly assigned patients](http://www.clinsci.org/cs/114/0221/cs1140221.htm) with [congestive heart failure](http://health.nytimes.com/health/guides/disease/heart-failure/overview.html?inline=nyt-classifier) to either normal or low-sodium diets. Those on the low-sodium diet had significantly more hospital admissions. The “[number needed to treat](http://www.nytimes.com/2015/01/27/upshot/can-this-treatment-help-me-theres-a-statistic-for-that.html)” for a normal-sodium diet above a low-sodium diet to prevent a hospital admission in this population was six — meaning that for every six people who are moved from a low-sodium diet to a normal diet, one hospital admission would be prevented. That’s a very strong finding.

Let’s not cherry-pick, though. A [systematic review of randomized controlled trials](http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009217.pub3/full) of salt intake was published last year. Eight trials involving more than 7,200 participants looked at whether advising patients to cut down on salt, or reducing sodium intake, affected outcomes. None of the trials, including ones involving people with both normal and [high blood pressure](http://health.nytimes.com/health/guides/disease/hypertension/overview.html?inline=nyt-classifier), showed a reduction in all-cause mortality.

Only one trial even showed an effect on death from cardiovascular causes, like heart attack or stroke. It was conducted on residents of an assisted-living facility who had high blood pressure — hardly representative of the population as a whole, which is what dietary guidelines are supposed to cover.

I’m pretty immersed in the medical literature, and all of this is still shocking to me. It’s hard to overestimate the effect of the dietary guidelines. Hundreds of millions of people changed their diets based on these recommendations. They consumed less fat, they avoided cholesterol and they reduced their intake of salt.

Since pretty much all calories come from fat, protein or [carbohydrates](http://health.nytimes.com/health/guides/nutrition/carbohydrates/overview.html?inline=nyt-classifier), reducing your consumption of one means that you have to increase your consumption of another. (We are not talking here about recommendations for the total amount of calories you should eat. These recommendations assume you’re eating the proper amount of calories, and seek to govern the proportion of nutrients within them.)

So, as the guidelines have recommended cutting down on meat, especially red meat, this meant that many people began to increase their consumption of carbohydrates.

Decades later, it’s not hard to find evidence that this might have been a bad move. Many now believe that excessive carbohydrate consumption may be contributing to the [obesity](http://health.nytimes.com/health/guides/symptoms/morbid-obesity/overview.html?inline=nyt-classifier) and [diabetes](http://health.nytimes.com/health/guides/disease/diabetes/overview.html?inline=nyt-classifier) epidemics. A [Cochrane Review of all randomized controlled trials](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4163969/) of reduced or modified dietary fat interventions found that replacing fat with carbohydrates does not protect even against cardiovascular problems, let alone death.

Interestingly, the new dietary recommendations may acknowledge this as well, dropping the recommendation to limit overall fat consumption in favor of a more refined recommendation to limit only saturated fat. Even that recommendation is [hotly contested by some](http://well.blogs.nytimes.com/2015/02/19/nutrition-panel-calls-for-less-sugar-and-eases-cholesterol-and-fat-restrictions/?smid=pl-share&_r=0), though. The committee is also bending a bit on salt, putting less emphasis on the 1,500-milligram daily limit on sodium for special populations, in light of the mounting evidence that too little sodium may be as bad as too much, [if not worse](http://www.nytimes.com/2014/08/26/upshot/dash-of-salt-does-no-harm-extremes-are-the-enemy.html).

It is frustrating enough when we over-read the results of epidemiologic studies and make the mistake of believing that correlation is the same as causation. It’s maddening, however, when we ignore the results of randomized controlled trials, which can prove causation, to continue down the wrong path. In reviewing the literature, it’s hard to come away with a sense that anyone knows for sure what diet should be recommended to all Americans.

I understand people’s frustration at the continuing shifts in nutrition recommendations. For decades, they’ve been told what to eat because “science says so.” Unfortunately, that doesn’t appear to be true. That’s disappointing not only because it reduces people’s faith in science as a whole, but also because it may have cost some people better health, or potentially even their lives.

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