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How evidence-based medicine biases physicians against nutrition

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ABSTRACT

Medical students in the United States are taught little about nutrition and dietetics. Worse yet, their training biases them against the studies that show the power of dietary approaches to managing disease. The current approach to evidence-based medicine encourages physicians to ignore any information that does not come from a double-blind, randomized controlled trial. Yet human beings cannot be blinded to a dietary intervention. As a result, physicians are biased toward drug treatments and against dietary interventions for the management of chronic disease.

While British surgeon Denis Parsons Burkitt was working in Africa, he noticed that many of the noninfectious chronic diseases that were common in Britain were rare among Africans who were following a traditional lifestyle. Examples included coronary artery disease, diabetes, colon cancer, appendicitis, and even varicose veins. Burkitt suggested that these "Western" diseases were largely due to a high-fat, low-fiber diet. He was eventually dubbed "the Fiber Man" for his insistence on the importance of a low-fat, high-fiber diet [1].

Western diseases are major causes of death and disability in the United States (Fig. 1) [2]. Even arthritis, the number 1 cause of disability in the United States [3], has a dietary component. Some physicians from the United States believe that osteoarthritis is due to "wear and tear" on the joints [4], yet osteoarthritis is relatively uncommon in Africa, where most of the population does most of its work by hand [5].

Burkitt argued that the Western diseases are easy to prevent but hard to cure. As he put it, if people are constantly falling off a cliff, you could place ambulances at the foot of a cliff or build a fence on the top of the cliff. He argued that we are placing too many ambulances at the foot of the cliff. Burkitt emphasized the importance of fiber in the diet and the dangers of fat: "The frying pan you should give to your enemy. Food should not be prepared in fat. Our bodies are adapted to a stone age diet of roots and vegetables" [6].

Unfortunately, medical students in the United States and perhaps some other Western industrialized nations are being trained to work the ambulances, not to build the fences. The inadequacy of the nutrition curriculum in American and British medical schools has been a matter of concern since the 1960s [7–12]. Worse yet, the training that students receive in medical school tends to bias them against the kinds of studies that show the power of diet to prevent or even cure Western diseases. The situation is actually getting worse because of the rise of evidence-based medicine. Evidence is a good thing, especially in medicine. However, the medical profession is focusing too much on one kind of evidence, to the exclusion of others [13].

Clinical trials

Medical students in the United States are taught that the double-blind, randomized controlled clinical trial (DBRCT, Table 1) is the gold standard for evaluating cause and effect and for assessing the value of treatments. The DBRCT methodology was developed to eliminate selection bias and observer bias, along with controlling for possible confounding variables.

Although the DBRCT methodology has important strengths, it also has important weaknesses (Table 2). Even the Food and Drug Administration, which requires DBRCTs to support the approval of new drugs, also relies on the results of other kinds of studies for various purposes.

Unquestionably, DBRCT methodology has important uses. Nevertheless, physicians need to understand that such methodology is not always necessary or even appropriate. Some kinds of DBRCTs can never be done. Others should never be done. Still others need never be done. Physicians need a clear understanding of when other kinds of evidence are sufficient and compelling. To clarify these points, it is helpful to understand two historical events: the Nuremberg Trials and the debates about whether cigarette smoking causes lung cancer.

Ethics and practical considerations

After World War II, Americans were shocked by the revelations of barbaric medical "experiments" that had been conducted in Nazi

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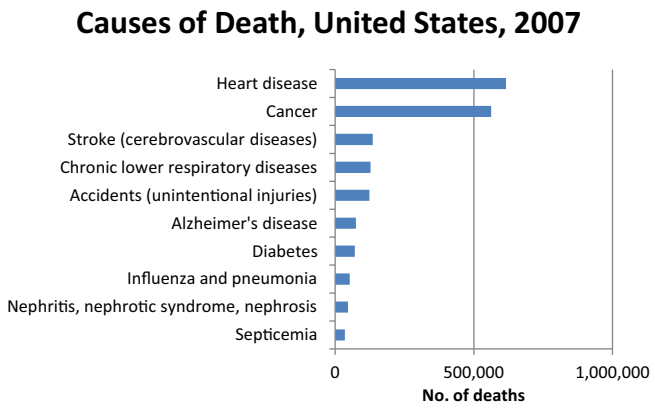

Fig. 1. Data from Jiaquan Xu, M.D.; Kenneth D.; Kochanek, M.A.; Sherry L. Murphy, B.S.; Betzaida Tejada-Vera, B.S.; Division of Vital Statistics. Deaths: Final Data for 2007. National Vital Statistics Report. 2010;58(19).

concentration camps [14]. The verdict in the Doctors' Trial at Nuremberg included legal principles that were later expanded into the World Medical Association's Declaration of Helsinki, which was first issued in 1964 and has been updated periodically [15]. Many of these principles have been incorporated into law in many countries.

One of the basic principles expressed in the Declaration of Helsinki is that "the well-being of the individual research subject must take precedence over all other interests" [15]. In other words, medical researchers cannot deliberately expose people to harm, just to see how sick they get. That is why no one has done a DBRCT to prove that HIV causes AIDS in humans. DBRCTs are rarely if ever done to establish the cause of disease in human beings. Fortunately, other kinds of evidence can be used to establish causality.

The DBRCT methodology is simply impractical for studying some other kinds of problems. For example, one cannot run a DBRCT to prove that cigarette smoking causes lung cancer. Not only would it be impossible and unethical to assign some people to smoke cigarettes, the study would have to last for at least 20 years, long enough for the lung tumors to arise. Nevertheless, by the 1950s, epidemiologic studies had provided solid evidence that cigarette smoking was the major cause of lung cancer. In response, the tobacco industry and its defenders fought hard to muddy the waters.

One of the most effective of the tobacco industry's supporters was Sir Ronald Aylmer Fisher, a British statistician whose mathematical achievements and promotion of statistical methods in scientific research had revolutionized 20th century science [16]. Fisher's clever rebuttals of the epidemiologic studies of lung cancer all boiled down to basically the same complaint: that no one had done any DBRCTs, and in the absence of DBRCTS, one could not draw any reliable conclusions [12].

Epidemiologic methods

Fortunately, another prominent British statistician saw through Fisher's smokescreen. Sir Austin Bradford Hill had pioneered the use of DBRCTs in medicine, but he was wise enough to recognize their limitations. Hill came up with a set of considerations (Table 3) to guide inquiry about causality when no DBRCTs can or should be done [17].

Although DBRCTs are useful for evaluating the short-term use of a drug therapy, they are simply impractical for evaluating dietary interventions, for the following reasons:

- People do not necessarily eat what they are told to eat, especially not for any length of time.
- Subjects cannot be blinded to what they are eating.
- To study a rare outcome, such as type 1 diabetes, the study would have to enroll an enormous number of people.
- To study a disease that takes years to develop, the trial would have to last for years.

If people are asked to follow a particular diet for the purposes of an experiment, some of them will, and some of them will not. In the end, the people who stick to their assigned diet will be, to some

Table 1
What is a double-blind, randomized, placebo-controlled clinical trial?

Term	What it means
Double-blind trial	Neither the subject nor the person who is evaluating the subject knows what treatment the subject receives
Randomized trial	Neither the doctor nor the subject chooses what treatment any individual subject gets. Instead, subjects are randomly assigned to one of two or more groups, each of which receives a different kind of treatment
Placebo	A placebo is a fake treatment that looks like the real thing. A study of a pill might use a lookalike pill as a placebo. A placebo is sometimes called a sugar pill, even though it might not contain sugar. An injection of plain salt water is sometimes used as a placebo in trials of injectable medication. Sham surgery is occasionally used as a control for clinical trials of surgical procedures
Controlled trial	One group of subjects receives one kind of treatment and another, identical group (controls) receives a different kind of treatment or no treatment at all
Clinical trial	The experimental subjects are human beings, as opposed to laboratory animals or cell cultures

Table 2
Weaknesses of randomized, double-blind, placebo-controlled drug trials.

Potential weakness	Explanation
Size	Clinical trials are designed to be large enough to show differences in how well the drug works, but they are too small to tell us much about rare side effects. That is why regulators rely so much on adverse event reporting for drugs that are already on the market
Duration	Clinical trials typically involve only a short period of treatment. Thus, they tell us nothing about the risks and benefits of long-term use
Patient population	Many clinical trials have systematically excluded people who were elderly or sick or were taking other medications. This may make the drug look safer than it really is
Relevance of the endpoints	To get useful results within a reasonable amount of time and with a reasonable number of subjects, the clinical trial may use some sort of alternative endpoint. For example, a clinical trial may measure how the drug affects the patient's cholesterol levels, when the real question is whether it saves lives
Relevance of the comparison	Many clinical trials compare a drug to an inactive treatment (placebo). They do not necessarily compare the drug to the best available alternative, whether it is a different drug or a change in diet
Context of the study	Given what we already know about this disease, is it even reasonable to do this study? Is this study evaluating treatments for the symptoms of a disease that could easily be cured by other means?