

## An Evidence Based Approach To Interpreting Science on Food, Nutrition and Health

### Introduction

Headline: “Low-fat diet does not reduce risk of breast and colorectal cancers and heart disease in postmenopausal women” (*NIH News*, 2006). Your phone rings and you, the nutrition professional, are in the hot seat dealing with clients who reluctantly reduced their fat intake because of the benefits you cited. They want answers now! (For more information on the Women’s Health Initiative results, see *J Am Diet Assoc.* 2006; 106:785-6.)

It seems that research on dietary behaviors is making headlines more and more. But headlines or sound bites can be misleading to the consumer. In such cases, how do you respond to clients? When do you change your practice? Clients want to know what to believe when a complex dietary intervention trial does not support what nutrition professionals may have been teaching for years.

The medical profession is moving toward “evidence based medicine” (EBM). This should be a boon to nutrition practitioners because effective dietary interventions often have been overlooked in favor of medications. To use EBM, however, requires the ability to critically appraise the medical research literature. In addition, nutrition professionals need strategies for managing a huge volume of medical and consumer literature. These skills probably were not taught during your initial dietetic training (Shaughnessy et al, 1994).

This update describes some tools that can guide nutrition professionals as they view “evidence” to determine if it should be incorporated into messages to clients.

### Keeping Up With Your Clients

More than 8 million biomedical articles are published annually, although it’s estimated that only 2% of these are relevant to improved patient outcomes. A much smaller number will relate to diet, nutrition or physical activity. Information about these articles is transmitted to nutrition professionals in a variety of ways. For example, once a week, the American Dietetic Association (ADA) e-mails 25-50

journal article links to subscribers via its *Daily News*. Most nutrition professionals don’t have time to read so many articles, much less interpret the results of all the research.

In addition to scientific reports, there is the popular press’ coverage of the more “newsworthy” of the scientific press releases. ADA’s *Daily News* also contains 8 to 20 links to nutrition and health stories from the Internet, news media and popular magazines. Other medical and nutrition professional associations or services send updates to their subscribers, as well. Some provide short synopses, not scientific critiques, of key articles to keep busy professionals in touch with messages their clients might be reading.

Beyond the popular press coverage of nutrition issues and interpretation of research is the advice passed from individual to individual at the grocery store or at work. How can you expect clients to adhere to your dietary advice when you and they are inundated with information that is often conflicting?

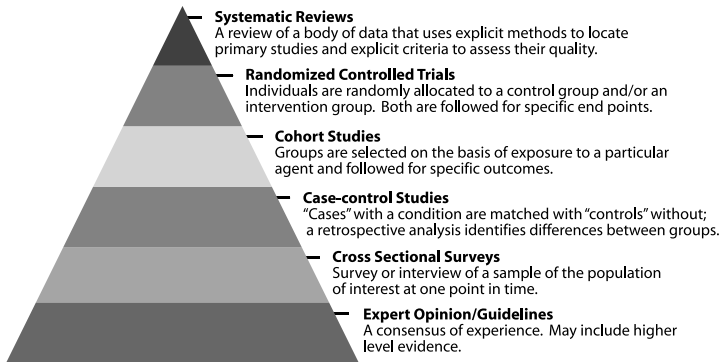
Don’t stop reading in despair; there are ways for you to determine the “weight” of the evidence.

### Systematic Reviews

How much evidence do you need before you decide to make a “new” recommendation to clients? How do you evaluate the research study to be sure it has a sound design and that the results were accurately reported based upon the evidence? The questions go on and on, and you don’t have time to review every research project in detail. That is where “systematic reviews” can help.

Systematic reviews summarize large bodies of research findings and attempt to explain differences among studies that have comparable dietary interventions. Figure 1 depicts a hierarchy of evidence. In biomedical science there is general agreement over a hierarchy: the higher a methodology is ranked, the more robust and closer to objective truth the results are thought to be.

**Figure 1. Hierarchy of Evidence (Theoretical)**



**Note:** At any point in this Hierarchy a meta-analysis may be done. A meta-analysis is a statistical analysis of the results of several independent studies considered to be comparable.

This Update will primarily focus on the systematic review. If you need a quick review of the research process, Boushey and colleagues recently published a useful review of study designs and statistical analyses in dietetic research (2006).

The results of systematic reviews of randomized controlled trials (RCT) are considered the highest level of evidence, the "gold standard," in the research arena. In a randomized controlled trial, participants are assigned by chance to a control and/or intervention group.

The systematic review uses explicit methods to locate primary research studies that may have been discussed in other professional articles. Defined criteria are then used to assess the quality of each study reviewed.

A meta-analysis may be undertaken as part of a systematic review. This is a statistical analysis performed on the combined data from several independent primary studies that tested similar interventions. It is crucial that studies included in a meta-analysis have a sound scientific basis.

Although systematic reviews of randomized controlled trials provide the best source to judge the weight and quality of the evidence, it is important to note that there have not been a large number of randomized controlled trials conducted with nutrition interventions. RCT are costly and require interventions to occur over a long period of time. Further, compliance with dietary interventions can be difficult to monitor.

There are times when the systematic review, if restricted to RCT, doesn't give an answer about the effectiveness of a dietary intervention. For example, the Agency for Health Care Research and Quality recently commissioned a systematic review of only randomized controlled trials to evaluate interventions using

multiple vitamin/mineral supplements (Evidence-based Practice Center: Johns Hopkins, 2006). An expert panel that reviewed the report and other scientific presentations concluded that there were not enough well designed randomized controlled trials to determine if individuals did or did not benefit from multiple vitamin/mineral supplements (NIH, 2006).

The systematic review need not be limited to RCT. In such instances, however, it is important to understand and evaluate the strength of the evidence included in the review.

## Tools Within Systematic Reviews

### Quality of Evidence Ranking

Most authors of systematic reviews provide an assessment of the quality and consistency of the recommendations emanating from the review. However, currently there is no universal set of criteria. Table 1 gives several examples of systems that are used to weight the conclusions from the systematic review.

**Table 1. Sample Rating Scales for Strength of Evidence**

Systematic Review Rating System	Score or Scale	Definition
Strength of Recommendation Taxonomy (SORT) — strength of recommendation for a body of evidence (Ebell et al, 2004)	A-level	Consistent and good-quality patient-oriented evidence
	B-level	Inconsistent or limited-quality patient-oriented evidence
	C-level	Consensus, usual practice, opinion, disease-oriented evidence or case series for studies of diagnosis, treatment, prevention or screening
American Dietetic Association Evidence Library Grade Definitions * (ADA, 2006)	Grade I: Good/Strong	Good study design, unbiased, findings generally consistent across studies, one to several good quality studies, large number of subjects, size of effect is clinically meaningful, large statistical difference, generalizability to population of interest
U.S. Preventive Services Task Force (AHRQ, 2006)	A	Strongly recommends
	B	Recommends
	C	No recommendation for or against
	D	Recommends against
	I	Insufficient evidence for or against

\*Also defines Grade II: Fair, Grade III: Limited/Weak, Grade IV: Expert Opinion Only, Grade V: Not Assignable

There are more than 100 systems to rate the strength of scientific evidence (AHRQ, 2003). Note that an article given an “A” in one system may be given a “B” in another system. Criteria used to create the “score” vary greatly from system to system, and it is important to keep these criteria in mind when using the ratings to judge scientific weight.

There are times nutrition professionals will not have results of a systematic review to guide their practice. They may rely on “Guidelines” (Figure 1). Increasingly, guideline documents include grades of evidence. In these instances, Guidelines might rank higher on the Hierarchy of Evidence than is indicated in Figure 1. Some examples of Guidelines can be seen at [www.guideline.gov](http://www.guideline.gov).

### Interpreting the Numbers

When evaluating a clinical trial (intervention treatment vs. control treatment), it is necessary to know whether the measured effect is clinically important. Two ways to look at the effect are relative risk reduction (RRR) and absolute risk reduction (ARR). The relative risk reduction is the difference between the “experimental event rate and the control event rate divided by the control event rate,” usually expressed as a percentage. The absolute risk reduction is the difference between the “event rate in the intervention group and the control group.” To best understand the importance of the findings, consider both relative risk reduction and absolute risk reduction when evaluating research results.

Because the ARR and RRR can be confusing at times, another numerical index, the Number Needed to Treat (NNT), is being used more often to help determine whether new research findings warrant a change in patient treatment. The NNT is the number of people you would need to treat with a stated treatment to prevent one additional outcome. The lower the number, the fewer people you would need to treat or counsel on a specific dietary intervention before the positive outcome would be seen in one of them. There is no magic number, and other factors such as cost, safety or side effects should be considered.

Let’s look at how the three methods might be applied. A RRR is stated as: If you take 2 grams of plant sterols/stanols daily for 12 weeks, you will reduce your serum LDL cholesterol by 15% as compared to the control group. An ARR statement would be that 36% of the participants taking 2 grams of plant sterols/stanols daily reduced their serum LDL cholesterol by 15% compared to 0.00% of the control group. Which sounds more impressive to your patient? Probably the RRR statement.

The Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Cholesterol in Adults introduced the recommendation to add 2 grams of plant sterols/stanols a day as a therapeutic option for lowering LDL cholesterol (NHLBI, 2002). A study by Craig and coworkers (2005) reported an NNT of 2.8. At the end of the 12-week study, five of the 14 (36%) clients in the intervention group achieved a 15% drop in total cholesterol compared with none of the 11 in the control group.

The NNT = 1/ARR  
 ARR = Experimental Event Rate – Control Event Rate

Using the percentages in the ARR statement above, the calculation would be:  
 ARR = 0.36 - 0.00 = .36  
 NNT = 1/.36 = 2.8 (round up to 3)

The authors sum up the results as: “Using the Number Needed to Treat index, for each 2.8 patients counseled with routine prescription of plant sterols/stanols, one additional patient would obtain a reduction in cholesterol by 15% compared with conventional management. This was achieved without any detrimental effects on the dietary fatty acid profile.”

Although the NNT is not seen in many nutrition-related research projects, it can often be calculated from available data (see [www.cebm.utoronto.ca/glossary/nnts.htm](http://www.cebm.utoronto.ca/glossary/nnts.htm)).

### Some Online Options

Table 2 includes sources (some at no charge; others by subscription or membership) for systematic reviews that may include evidence for nutrition interventions. A health science librarian can be helpful in accessing reviews.

**Table 2. Selected Evidence Based Medicine Resources That May Include Evidence to Answer Nutrition Questions**

“No Charge” Access Sources	
Bandolier	<a href="http://www.jr2.ox.ac.uk/bandolier">www.jr2.ox.ac.uk/bandolier</a>
Canadian Task Force on Preventive Health Care	<a href="http://www.ctfphc.org/">http://www.ctfphc.org/</a>
Database of Abstracts of Reviews of Effects (DARE)	<a href="http://www.york.ac.uk/inst/crd/crddatabases.htm">http://www.york.ac.uk/inst/crd/crddatabases.htm</a>
Effective Health Care	<a href="http://www.york.ac.uk/inst/crd/ehcb.htm">http://www.york.ac.uk/inst/crd/ehcb.htm</a>
Institute for Clinical Systems Improvement (ICSI)	<a href="http://www.icsi.org">www.icsi.org</a>
National Guideline Clearinghouse (NGC)	<a href="http://www.guideline.gov">www.guideline.gov</a>
U.S. Preventive Services Task Force (USPSTF)	<a href="http://www.ahcpr.gov/Clinic/uspstfix.htm">http://www.ahcpr.gov/Clinic/uspstfix.htm</a>

**Table 2. Selected Evidence Based Medicine Resources That May Include Evidence to Answer Nutrition Questions**

Subscription or Membership Sources	
American Dietetic Association Evidence Analysis Library	<a href="http://www.adaevidencelibrary.org">www.adaevidencelibrary.org</a>
Clinical Evidence—British Medical Journal Publishing	<a href="http://www.clinicalevidence.com/ceweb/conditions/index.jsp">http://www.clinicalevidence.com/ceweb/conditions/index.jsp</a>
Cochrane Database of Systematic Reviews	<a href="http://www.cochrane.org">www.cochrane.org</a>
Consumer Magazines DIGEST	<a href="http://www.mcnuttwbsite.com">www.mcnuttwbsite.com</a>
DynaMed	<a href="http://www.dynamicmedical.com">http://www.dynamicmedical.com</a>
EBM Online/Evidence Based Medicine	<a href="http://ebm.bmjournals.com/">http://ebm.bmjournals.com/</a>
Family Practice Inquiries Network	<a href="http://www.fpin.org">http://www.fpin.org</a>
InfoRetriever	<a href="http://www.infopoems.com/">http://www.infopoems.com/</a>
Physicians' Information and Education Resources (PIER)	<a href="http://pier.acponline.org/index.html?hp">http://pier.acponline.org/index.html?hp</a>

## Do-It-Yourself Analyses

If you can't wait for a published systematic review of headline nutrition topics, you can critically appraise the news-making nutrition research report yourself. Let's go back to the headline that had clients ready to disregard your advice about lowering fat: "Low-fat diet does not reduce risk of breast and colorectal cancers and heart disease in postmenopausal women." You want to know if the results of that study apply to your patient.

The first step is to go to the published literature to find the evidence that most closely applies to your patient. Writing a PICO Question is a technique that can help clarify the evidence you are seeking. The clinical question usually includes: Population, Intervention, Clinical Outcome (sometimes C also stands for Comparison). Remember to consider the dietary approach your patient is following and what type of outcome is expected. The PICO for your patient might be: For postmenopausal women (P), what type of diet (I) is most effective for lowering weight and reducing cardiac risk factors (CO)? A search of MEDLINE, accessible without charge through PubMed (<http://www.nlm.nih.gov/>), could lead you to the following article

as the best evidence: "Comparison of the Atkins, Ornish, Weight Watchers and Zone diets for weight loss and heart disease risk reduction" (Dansinger et al, 2005). After collecting evidence, you need to ask some critical questions (Table 3). Then decide if you are going to change the advice you give your patient or wait for further research.

**Table 3. Questions to ask to critically appraise a research article.\***

<p><b>Is the study relevant to your patient?</b></p> <ul style="list-style-type: none"> <li>• Would implementing the studied intervention result in improved patient outcomes?</li> <li>• Is the population studied appropriate?</li> <li>• Is the intervention feasible?</li> </ul> <p><b>Is the study valid?</b></p> <ul style="list-style-type: none"> <li>• Was the research study's purpose and design clearly stated?</li> <li>• Was selection of study participants unbiased?</li> <li>• Were study groups comparable?</li> <li>• Was the method of handling dropouts described?</li> <li>• Were all involved in the study blinded to treatment group?</li> <li>• Were interventions described in detail?</li> <li>• Were outcomes clearly defined and measurements valid and reliable?</li> <li>• Were statistical analyses appropriate?</li> <li>• Were conclusions supported by results?</li> <li>• Was bias due to funding source unlikely?</li> </ul>
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\* Adapted from ADA Evidence Analysis Manual, edition 4. [www.adaevidencelibrary.org](http://www.adaevidencelibrary.org)

## Bottom Line

Taking an evidence based approach to nutrition practice gives a framework for knowing when to adopt new nutrition messages, discard old dogma and look for answers to nutrition questions asked by consumers and patients. Because every study has strengths and weaknesses, carefully consider the weight and relevance of scientific evidence before changing a practice. Practice decisions must be based on sound science using the best available evidence. Evidence Based Medicine tools can help you find answers to consumer and clinical questions, although, at times, the answer may be that research has not yet identified a clear answer.

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- Evidence-based Practice Center: Johns Hopkins University. Multivitamin/Mineral Supplements and Prevention of Chronic Disease Evidence Report (Publication No. 06-E012), 2006. Accessed June 3, 2006. [www.ahrq.gov/clinics/tp/multivittp.htm](http://www.ahrq.gov/clinics/tp/multivittp.htm)
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- News from the Women's Health Initiative: Reducing total fat intake may have small effect on risk of breast cancer, no effect on risk of colorectal cancer, heart disease, or stroke. *NIH News.* February 7, 2006. Accessed June 3, 2006. [www.nih.gov/news](http://www.nih.gov/news)
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- Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. *JAMA.* 2002; 288:321-33.

### Additional Resources

- Medical Research: Finding the Best Information (Patient Page). Brian Pace, Richard M. Glass. *JAMA.* 2000; 284:1336.
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