AMERICAN DIETETIC ASSOCIATION

Scientific Affairs & Research

ADA Evidence Analysis Manual

SCIENTIFIC AFFAIRS & RESEARCH

ADA Evidence Analysis Manual, Edition IV

120 South Riverside Plaza • Suite 2000
Chicago, IL 60606
Phone 312.899.0040 • Fax 312.899.4812
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Preface

How to Use This Manual.

The *ADA Evidence Analysis Manual* has been created to help expert panels and evidence analysts understand and carry out the process of evidence analysis adopted by the American Dietetic Association (ADA).

Evidence analysis is a complex process.

This manual breaks the process down into concrete parts. For the sake of clarity, we distinguish between general *steps* of the project, and the more concrete *actions* within each step.

Table 1 presents the major Steps in the ADA's evidence analysis process.

Table 1. Phases of the ADA's Evidence Analysis Project

Phases of the Evidence Analysis Process	Brief Description
Step 1 Formulate the Question	Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Include the patient type and special needs of the target population involved, the alternatives under consideration, and the outcomes of interest. *Tool: Formulating the Question Template, Appendix 1*
Step 2 Gather and Classify Evidence Reports	Conduct a systematic search of the literature to find evidence related to the question, gather studies and reports, and classify them by type of evidence. Classes differentiate primary reports of new data according to study design, and distinguish them from reports that are a systematic review and synthesis of primary reports. (Classes used by ADA are A, B, C, D, M, R, and X.) *Tools: Classes of Evidence Reports, Appendix 2* *Sort List Worksheet, Appendix 3*

Step 3 Critically Appraise Each Report	Review each report for relevance to the question and critique for scientific validity. Abstract key information from the report and assign a code to indicate the quality of the study. (ADA uses the symbols: +, -, 0, NA to designate positive, negative, neutral, or not assessed). *Tools: Evidence Abstract, Appendix 4* *Quality Rating sheets, Appendix 5* *Quality Rating Criteria Checklists, Appendix 5, 6*
Step 4 Summarize Evidence in a Conclusion Statement	Combine findings from all reports to arrive at a concise conclusion statement, taking into account the synthesis of all relevant studies and reports, their class, and quality ratings. *Tools: Conclusion Statement, Appendix 10* *Conclusion Grading Worksheet, Appendix 10*
Step 5 Grade the Strength of Evidence Supporting the Conclusion	Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement. (ADA uses Grades I, II, III, IV, and V for strong, fair, or weak, expert opinion only, and no evidence, respectively.) *Tools: Conclusion Statement, Appendix10* *Conclusion Grading Worksheet, Appendix 10* *Grade Definitions for Strength of Evidence for Conclusion, Appendix 10*

Each chapter in this Manual corresponds to a step in the evidence analysis process.

Overview of the Manual

The manual is set up in two main parts:

1. The main text, which provides a description of each step along with examples from other evidence analysis projects

2. Appendices, which provide reproducible masters of the templates (worksheets, checklists, and other tools). These forms are also available in electronic format.

ICON KEY

↻ Important Considerations

Template Available

Example

Within the text we provide icons to help the reader identify different kinds of content provided in the manual. The Icon Key to the left lists icons used to notify you of particularly important materials. In this manual we highlight:

- Important considerations that will help direct your thinking as you carry out the evidence analysis.
- Available templates, usually in the appendices.
- Examples from other evidence analysis projects that can help you see how the process was carried out successfully in previous projects.

Chapter

1

Step 1: Formulating the Questions

Analytic Framework for Questions for Nutrition Guides

Why Ask Questions?

The amount of research in nutrition and dietetics is massive. Practitioners need a simple, reliable way to enhance their practice with the best available scientific evidence. What is the most effective and efficient way to sort through the ocean of research in order to develop evidence-based conclusions for practice?

Ask good questions!

Asking focused questions of the research based on practical needs is one of the most effective ways to identify what is relevant. By asking the right questions, dietitians can identify research that most effectively impacts their practice.

For the evidence analysis process, asking good questions makes clear the connections between scientific research and areas where evidence-based knowledge is needed for practice. See Figure 1.0.a.

Figure 1.0.a Connecting Practice Issues to Research

How Can Dietitians "Ask Good Questions?"

That is where you come in.

The ADA, through its membership, identifies top researchers and practitioners within a field of practice. We draw on the experience of these experts to construct a list of the most important questions for practice in a given area.

These questions give us the ability to begin to approach the research in a focused and systematic manner. We take your questions, identify relevant research, and then abstract, critically appraise, and judge the quality of that research according to widely accepted methods. We then translate the best available evidence into a form that is not only easily understandable, but capable of being put into practice.

The outcome is a relevant, timely, high-quality, and understandable presentation of evidence to guide practice.

How Do We Identify "Good Questions?"

The aim is to identify issues in an area of practice where scientific evidence is needed to inform and guide practice.

Identifying good questions for evidence analysis is not easy. However, the ADA has developed a framework to help you and your colleagues generate important questions for practice in a given area of nutrition and dietetics. The purpose of this chapter is to guide you through three actions that lead to a set of good questions for evidence analysis.

Three actions will help you develop good questions:

1. Identify key factors at each step of the nutrition care process that can affect nutritional intervention outcomes.

2. Consider links between factors. In other words, how factors at one step of the nutrition care process may affect what happens later in the process.

3. Formulate questions that focus on the relationship between different factors in the nutritional care process and the range of important outcomes.

The Nutrition Care Process: A Foundation for Evidence Analysis

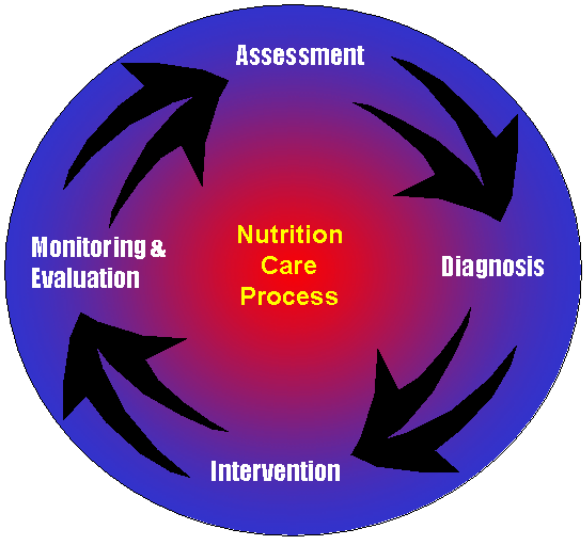
In 2002, the ADA House of Delegates adopted the nutrition care process. This process includes four interrelated phases (see Figure 1.0.b):

1. Nutrition Assessment
2. Nutrition Diagnosis
3. Nutrition Intervention
4. Nutrition Monitoring and Evaluation

The nutrition care process can serve as the context for the way in which you formulate questions for evidence analysis. It is helpful to keep these steps of the nutrition care process in mind when formulating questions.

In the evidence analysis process we identify key factors in three of the four steps: assessment, intervention, monitoring, and evaluation of outcomes.

Figure 1.0.b Nutrition Care Process



1.1 Action 1. Identify Key Factors in the Nutrition Care Process

Keep the entire nutrition care process in mind as you begin to formulate questions. Most importantly, keep the end in mind. Ask yourself: What sorts of outcomes do we expect from nutritional care in this area of practice?

Identify Anticipated Patient Outcomes

To begin the process, *start with the end in mind.*

Starting with the end (the expected outcomes) in mind will help to ensure that the focuses of the questions are related to the purpose of the guideline. There are many interesting *research* questions that might be asked, but many are not appropriate for nutritional practice. So, keeping client outcomes in

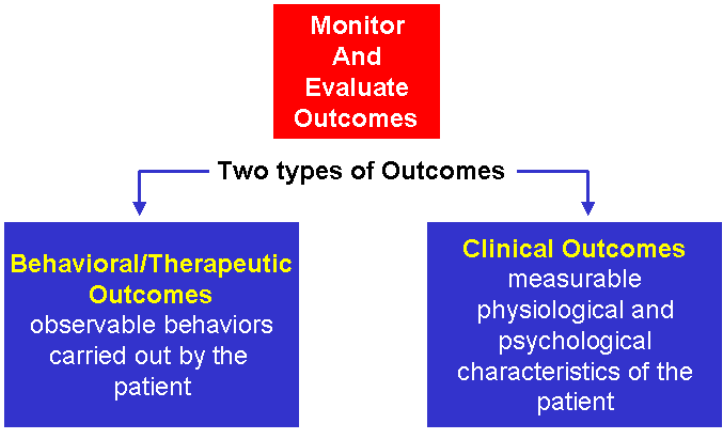
mind can help to keep the focus on practice.

This means that we begin the question formulation process by looking at patient outcomes. We distinguish between clinical and behavioral outcomes (see Figure 1.1). These two types of outcomes can be distinguished in the following way:

Clinical Outcomes: measurable physiological and psychological patient characteristics.

Behavioral Outcomes: observable patient behaviors.

Figure 1.1 Two Types of Medical Nutrition Therapy Outcomes



We begin the process by asking ourselves: What clinical outcomes do we anticipate from nutritional intervention in this area of practice? Defining these, we then turn to asking the same question about behavioral outcomes. What do we expect the patient to do after the nutritional interventions?

Identify Nutritional Intervention Factors

It is the job of the expert panel to determine what nutritional interventions stand in most need of evidence analysis.

- Common interventions that, nonetheless, have never been shown by high quality research to have proven results?
- New or innovative interventions that look promising?
- Specific aspects or characteristics of nutrition intervention such as the frequency or duration of the intervention, counseling strategies, etc.?

We anticipate that different nutrition related problems may call for different intervention methods and content. So, we need your expert advice on what interventions we need to include in the evidence analysis process.

There are many different aspects of nutrition intervention. How do you begin?

For the purposes of organizing the working group's discussion for the evidence analysis, we can identify three different aspects of nutritional intervention (see Table 1.1):

Table 1.1. Aspects of Nutritional Intervention

Aspect of Nutritional Intervention	Question It Answers	Example
Content of the Intervention	What is said, done, or provided?	Discuss with client: ▪ Micronutrients ▪ Macronutrients Provision of: ▪ Food/nutrients ▪ Education or counseling
Delivery Method or Media	How is it delivered?	Nutrition education Oral, enteral, or parenteral feeding Self management/self monitoring skill building Cognitive behavior therapy Social change theory
Context of the Intervention	What is the setting? (When, where, how long, how much?)	Frequency and duration of sessions Group versus individual sessions

Of course, we should not expect all aspects of the nutrition intervention to be relevant for evidence analysis in every nutrition related problem. For example, in some nutrition related problems only the content of the intervention may be relevant. In others, it may be important to examine the evidence for competing delivery approaches and strategies.

The working group should determine what intervention factors stand most in need of evidence analysis for the particular nutrition related problem being discussed.

Identify Nutritional Assessment Factors

As with nutritional intervention, the assessment factors identified for evidence analysis may be different for different nutrition related problems.

Ask yourself the following questions:

- Does research indicate some types of assessment methods or indicators are more relevant in the assessment process of a given nutrition related problem?
- Does research indicate what assessment tools are most appropriate for a given nutrition related problem?

Tip: When creating evidence based guides in areas where a MNT Protocol already exists, one strategy may be for the working group to begin with the outcome, intervention, and assessment factors identified in the protocol. Where this is not the case, the working group may need to do some initial work to decide what factors are critical in each step of the nutrition care process.

1.2 Action 2: Consider Linkages among Factors

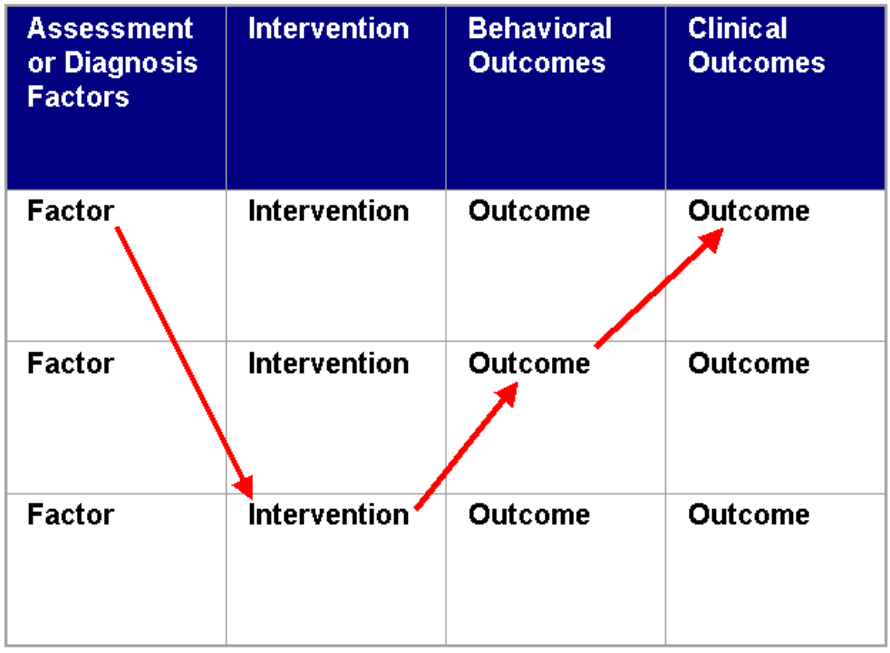
Fundamentally, questions are ways of posing a relationship: What is the evidence to suggest that there is some association between an intervention or assessment method and some expected outcome?

It is logically possible to link every factor in a list of assessment methods or intervention strategies to every expected outcome of the nutrition care process. However, researching every possible relationship is practically impossible. Evidence analysis draws on the expertise and knowledge of the expert panel to specify the most important relationships between factors in each step of the nutrition care process.

The Question Formulation Template can help identify the critical relationships. After filling in the specific outcome, intervention, and assessment factors, the template allows the expert panel to visualize the relationships among the different factors.

Figure 1.2 presents an example of how a expert panel might use the Question Formulation Template to identify the important relationships for the evidence analysis.

Figure 1.2. Example Question Formulation Template



Three relationships are identified in Figure 1.2:

- The relationship between a particular assessment and intervention
- The relationship between the intervention and a behavioral outcome
- The relationship between the behavioral outcome and a clinical outcome

Once the expert panel has filled in the relationships in the Question Formulation Template, they can translate the "arrows" into questions.

1.3 Action 3: Formulate Questions that Link Earlier Factors to Outcomes

Once the important relationships have been identified these relationships need to be expressed as focused questions. Focused questions in the evidence analysis process generally include the following elements**:**

1. Population with a specific problem
2. Intervention, procedure, or approach (for example, the type, amount, or timing of MNT)
3. Comparison intervention (other approaches to care, or a "gold standard")
4. Outcome of interest

Incorporating these four elements is referred to as the "PICO" format.

Questions should be specific enough to focus our search for applicable research, but broad enough to not overly limit the scope of the literature search. For instance:

Poor questions:

- Is a one-shot motivational interviewing session effective for reducing after-school soda consumption among teens? (too specific)
- Is Medical Nutrition Therapy effective? (too broad)

Good questions:

- What is the evidence to support the relationship between dietary recommendations, such as macronutrient composition (high or low protein, high or low carb, high or low fat) and reduced caloric intake?
- What is the evidence regarding the difference in effectiveness for weight loss of Internet-based nutritional interventions and face-to-face interventions?

In the above two questions the population is not explicitly named (obese subjects) since the context of the question (evidence analysis for adult weight management) provides scope of the population of interest.

Different Purposes Call for Different Types of Questions

In evidence appraisal, four types of questions are used.

1. Diagnosis and Screening: How to determine if a nutrition related problem or condition is present? When to treat?

- Is there a validated questionnaire that can be used to determine readiness for nutrition intervention and behavior change?
- Who should be screened for metabolic syndrome?

2. Natural History and Prognosis: What is the progression of the nutrition related problem prior to and after diagnosis?

- What risk factors have been associated with onset of unintentional weight loss?

3. Therapy, Prevention and Control, Performance Improvement [Treatment/Intervention]: What action is effective in a given situation?

- For a patient with Gestational Diabetes Mellitus, what distribution of carbohydrate maintains normoglucose throughout the day? Should lower carbohydrate be recommended at breakfast?
- For asymptomatic adults with elevated low-density lipoprotein cholesterol (LDL-C), what is the preferred intervention for reducing serum LDL-C and mortality: access to US Dietary Guidelines for Americans, MNT for hyperlipidemia provided by a registered dietitian, or physician-provided dietary advice?
- What evidence is there of a proven protective effect of onions and garlic against any type of cancer?

4. Etiology, Causation, Harm: What is the potential for positive and/or negative consequences of a specific aspect of nutritional care (or its absence)?

- What is the probability of cardiac decompensation for heart failure patients with and without sodium restricted diets?

Question Formulation is an Iterative Process

Questions should not be too specific, and not too broad, but "just right." Of course, as the evidence analysis proceeds, the expert panel and evidence analysts may find that a question is answered by an unmanageable amount of research and needs to be made more specific. Alternatively, the evidence analysis team may find that there is simply not enough research to answer a particular question and so the question may need to be broadened.

Chapter

2

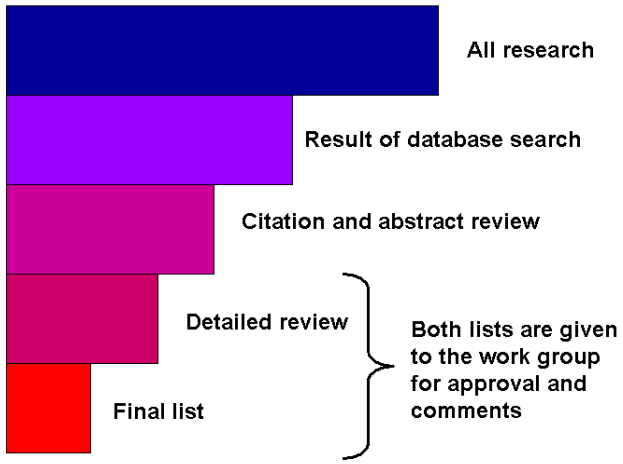
Step 2: Gathering and Classifying Evidence Reports

Finding the Best, Most Appropriate Research

Once the working group has decided on the questions that focus the evidence analysis, we begin the task of finding the best, most appropriate research. This process involves several actions:

- Create an inclusion/exclusion criteria list
- Conduct search of sources (databases, bibliographies)
- Review citation and abstracts
- Construct a *Sort List* through detailed examination of articles.

Figure 2.0. Steps in Identifying the Best Available, Most Relevant Research



Through this process the identification of evidence becomes increasingly detailed and precise (see Figure 2.0). The goal is to find the top six to ten high-quality research articles that answer each question the expert panel has posed. The result will be a *Sort List* that identifies not only the final list of articles to be analyzed, but a short list of articles that were excluded (along with the reasons for their exclusion).

While the expert panel is not involved in every step of the search process, it is important for all members of the evidence analysis team to have a clear understanding of the rigor of the search process.

2.1 Action 1: Determine the General Inclusion and Exclusion Criteria

Consider the following questions:

- What are the general inclusion and exclusion criteria for the literature search?
- What are the general search terms for each question?

Then determine whether there are any additional inclusion and exclusion criteria for each specific question.

Example Inclusion Criteria for Original Research

Below are inclusion and exclusion criteria for the development of an adult weight management evidence based guide.

1. The sample size must be 10 or more for each study group. This means at least 10 patients in the intervention group and at least 10 patients in the control or comparison group.
2. Specific descriptors about the patient population that will be included in the evaluation are overweight and obesity, advanced age, ethnicity, nationality, gender, and dropouts.
3. Specific descriptors about the patient population that will be excluded are extreme conditions, for example, cancer and HIV/AIDS, patients who have had procedures that have an adverse impact on weight, (e.g. transplantation), patients on nutrition support, and individuals under the age of 20 years.
4. If the dropout rate in a study is 20% or greater, the study will be rejected. (A Cochrane Systematic Review requirement).
5. If an author is included on more than one review article or primary research article that is similar in content, the most recent review or article will be accepted and earlier versions will be rejected.
6. If an author is included on more than one Review Article and the content is different, then both reviews may be accepted.

Example Inclusion Criteria for Review Articles

Table 2.1. Example of Inclusion/Exclusion Criteria for Review Articles

Inclusion Criteria	Exclusion Criteria	Rationale
Patient Population		
Age	Young adults less	Comparability with other

Adults (20 years and older)	than 20 years of age to include infants, children, and adolescents.	MNT Guides for Practice.
Setting Outpatient and Ambulatory Care	Inpatient or Acute Care	
Health Status	Patients with a poor prognosis	Patients with poor prognosis are excluded because weight reduction is generally not appropriate for these patients.
Nutrition Related Problem/Condition Overweight and obesity without co-morbid conditions or with the following co-morbid conditions: Diabetes mellitus, types 1 & 2 and gestational Hyperlipidemia Hypertension Back pain, hip replacement, knee replacement	Oncology Treatment/ Rehabilitation HIV/InfectionAIDS Critical illness (including acute illnesses of burns, ventilator dependent, trauma, sepsis, parenteral and enteral nutrition support) Patients who have undergone transplantation Patients on dialysis All other diseases/conditions .	Diseases/conditions chosen were based on timing of MNT protocol development, likelihood of having an impact on protocol/guideline and budgetary constraints.
Search Criteria		
Study Design Preferences: RCT or Clinical Controlled Studies Large nonrandomized observational studies Cohort, case-control studies		
Year Range July, 1998 -- 2003	Prior to June, 1998	The Clinical Guidelines for Overweight included an extensive analysis of the evidence in this area through June 1998, including quality rating of articles reviewed, and grading of recommendations made.
Limited to articles in English	Articles not in English	
Data Bases:		

2.2 Action 2: Conduct a Thorough Search for Evidence Relevant to the Questions

The following list provides an overview of the steps the ADA evidence analysis team goes through to identify research through database searches.

1. Plan the search strategy to identify the "current best evidence" relevant to the question. The plan for identification and inclusion of articles and reports should be systematic and reproducible, not haphazard. Allow for several iterations of searches. Write out the original search strategy and document adjustments to the strategy if they occur.

2. List inclusion and exclusion criteria. The working group has already defined the inclusion and exclusion criteria. However, these criteria may be refined after an early look at the available studies. These specifications will now be used in limiting the number of articles examined during the search process.

3. Identify search words. During the process of identifying outcomes, interventions, and assessments, the working group may have identified a number of specific terms that were not included in the more general formulation of the question. These terms can be used as search terms to help identify relevant pieces of research. Both text word search and MeSH definitions may be used.

4. Identify databases to search. Medline, CINAHL, EMBASE, Cochrane, DARE, TRIP, AHRQ are some common databases for nutritional research. Search terms can vary depending on the database.

5. Conduct the search. Depending on the results of the initial search, adjustments might have to be made in the search strategy and to inclusion/exclusion criteria, and additional searches run. Changes to the plan should be recorded for future reference. Document the number of sources identified in each search.

6. Review titles and abstracts. At this point, a more fine-grained filtering procedure is needed to determine whether a piece of research is appropriate for answering the working group's questions. The evidence analysts review the citation lists and abstracts and filter out titles that are not applicable to the question.

7. Gather all remaining articles and reports. The list of research studies identified at this point makes up the *Sort List* (though, we still have to decide which research will be included and which will be excluded). Ideally, this list should be somewhere between eight and twenty citations. Fewer than eight citations may mean that the search was too specific to identify appropriate research, and should be broadened. A long list of citations could include articles and reports that are tangential to the question or address the question in a general way. In this case a more focused search is needed.

2.3 Action 3: Classify the Articles and Reports by Type of Research Design

In order to create the *Sort List* we need to begin the process of classifying the research articles and reports by research design.

First, divide the studies and reports on the *Sort List*s into two categories: primary research (original studies) and secondary, interpretive, or review syntheses of previously reported studies.

Second, classify the studies or reports according to the type of research, that is, by study design. Study designs are organized into a hierarchy based on the ability of the design to test causal relationships. Table 2.3, below, shows the classification system used by ADA. A more comprehensive presentation of the different elements in the ADA's classification system as well as a glossary of research terms are presented in the Appendix.

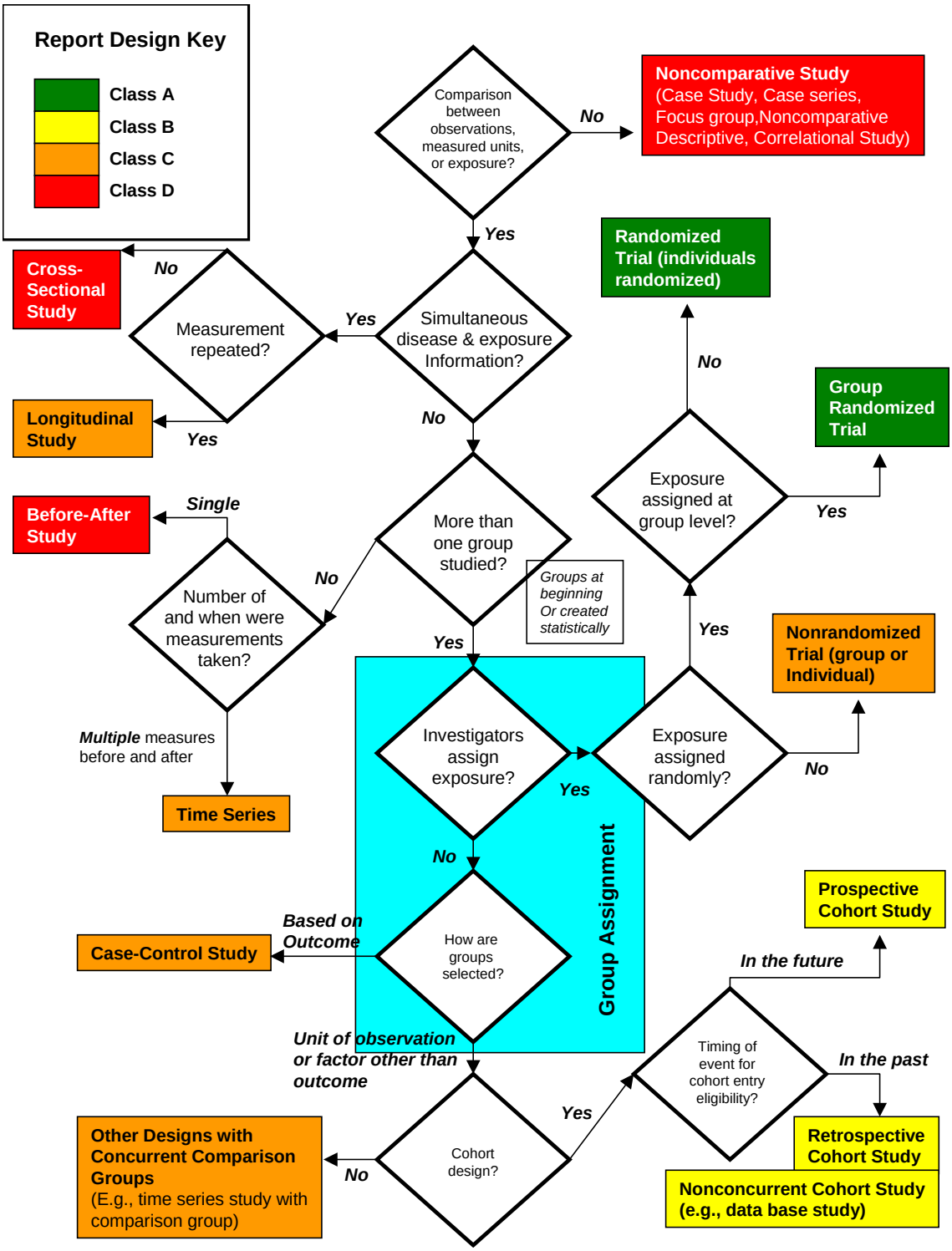
Table 2.3. Classes of Evidence Reports

Primary Reports of New Data Collection (Research Report)		Reports That Synthesize or Reflect on Collections of Primary Reports	
A	Randomized controlled trial (RCT)	M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Cohort study		
C	Nonrandomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study Time series	R	Narrative review (Review article) Consensus statement Consensus report
D	Cross-sectional study Case series Case report Before and after study	X	Medical opinion

The ADA uses a study design algorithm to help you identify the study design. Refer to Figure 2.3 Study Design Algorithm for help differentiating research design. In some cases this will be done while the article is read and appraised.

Sorting studies and reports gives an initial picture of the type of studies and level of evidence available. It also helps organize the reports for the next step of critical appraisal.

Figure 2.3. Algorithm for Classifying Primary Study Research Design



2.4 Action 4: Create the *Sort List*

The *Sort List* is a crucial part of the evidence-based guide. It has a dual function:

- The *Sort List* identifies the research articles and reports to be included in the evidence analysis.

- The *Sort List* keeps track of research articles and reports that were identified in the search but excluded from the analysis because of applicability or inclusion/exclusion criteria.

Why Include a List of Excluded Articles?

Part of what makes the ADA's evidence analysis procedure distinct is the rigor with which we choose the research to include in the analysis. This means that we must be very careful about our procedure for including *and excluding* research. By providing the reader with a list of articles that we considered, but which we did not use in the evidence analysis, answers the question, "Why didn't you use this article?"

Sometimes we are faced with a plethora of high quality research—being very thoughtful and explicit about why we choose some research pieces and not others strengthens our claim to have chosen the best, most appropriate research.

INCLUDING ARTICLES NOT USED IN THE EVIDENCE ANALYSIS WITH A REASON ANSWERS THE QUESTION, "WHY DIDN'T YOU USE THIS ARTICLE?"

Constructing the *Sort List*

Depending on the number of the research articles and reports identified, constructing the *Sort List* may be quite simple, or rather complex.

Remember, the goal is to identify six to ten of the highest quality pieces of research.[1] For some questions, you may not be able to find this number of high quality pieces. For other questions, you may find many more than ten good research pieces.

In order to choose which pieces of research to include, take into consideration the following questions:

- How well does the research answer the question being asked?

[1] The evidence analysis method developed by the Institute for Clinical Systems Improvement (ICSI) (on which the ADA's evidence analysis process is modeled) prescribes identifying "up to six important research reports" that speak to the question. We do not limit ourselves to six studies as existing studies are not always of sufficient design or power to be able to provide adequate evidence. The point of the ICSI protocol, however, is that a relatively small number of highly powered, focused, well designed studies that agree in findings are sufficient to answer the question. See Institute for Clinical Systems Improvement. 2002. "Evidence Grading System. Accessed from the ICSI website, http://www.icsi.org/knowledge/detail.asp?catID=113&itemID=619, January 9, 2004.

- Does the piece of research meet the expert panel's inclusion and exclusion criteria?
- What demographic subgroups does the research take into account (e.g., race, obese versus non-obese, nationality, etc.)?
- What other factors or characteristics have the working group identified as important (e.g., stage of disease, use of measurement devices, location of study participants)?

Your finished Sort List will be a table that lists the selected and excluded articles. For excluded articles, you will need a column that explains the reason for the article's exclusion. See the example Sort List in Table 2.4.

Table 2.4. Example Sort List

QUESTION # 1: MEDICATION-RELATED ARTICLES	
Bross R, Hoffer LJ. Fluoxetine increases resting energy expenditure and basal body temperature in humans. *Am J Clin Nutr*. 1995;61(5):1020-1025. (n=20 obese patients) [Canada]	
Bruder N, Raynal M, Pellissier D, Courtinat C, Francois G. Influence of body temperature, with or without sedation, on energy expenditure in severe head-injured patients. *Crit Care Med*. 1998;26(3):568-572. (n=24)	
Chiolero RL, Breitenstein E, Thorin D, Christin L, de Tribolet N, Freeman J, Jequier E, Schutz Y. Effects of propranolol on resting metabolic rate after severe head injury. *Crit Care Med*. 1989;17(4):328-334.	
EXCLUDED ARTICLES WITH REASON	
Al-Adsani H, Hoffer LJ, Silva JE. Resting energy expenditure is sensitive to small dose changes in patients on chronic thyroid hormone replacement. *J Clin Endocrinol Metab*. 82(4):1118-1125.	NR-IA Sample size n=9 does not meet study criteria; although answers question re: small changes in thyroid medication
Amoroso P, Wilson SR, Moxham J, Ponte J. Acute effects of inhaled salbutamol on the metabolic rate of normal subjects. *Thorax*; 48(9):882-885.	NR-design/methods; sample size of n=10 meets criteria; however, had n=3 drop-outs; May reconsider using if no other studies with larger sample sizes available.
Bettany GE, Camacho-Hubner C, Obeid O, Halliday D, Powell-Tuck J. Metabolic effects of adjuvant recombinant human growth hormone in patients with continuing sepsis receiving parenteral nutrition. *JPEN J Parenter Enteral Nutr*. 1998;22(4):199-205.	NR-design/methods; sample size of n= 8 patients doesn't meet criteria.

In areas where a large amount of research has been done the number of potential articles for inclusion may be too large for the scope of the project. ADA has developed the online Sort List Tool (See Appendix 2) to assist the analyst with this process. The tool also serves to document the selection of research articles, thereby maintaining transparency.

The next step is the work of analyzing the reports.

Chapter 3

Step 3: Critically Appraise Each Report

Instructions for Using the Evidence Worksheet

A reviewer is responsible for critically reviewing each report and abstracting key information on to the *Evidence Worksheet*. The abstracted information on the *Evidence Worksheet* is used later by the expert panel to write the conclusion statement and grade the strength of the evidence. The information from all worksheets becomes part of the Evidence Table that supports the conclusion statement.

There are several documents that will help you to complete the *Evidence Worksheet*:

- "Tips" worksheets: primary and review article worksheets that include tips for how to fill out the worksheets—found in Table 3.1 and Table 3.1.b.
- *Quality Criteria Checklists*: checklists of questions to help you determine the relevance and quality of primary and review articles—found in Table 3.2.a and Table 3.2.b and in the Appendices section
- Study Design Quality Questions Table: a table that indicates which quality questions are most relevant for different study designs—found in Table 3.2.c and in the Appendices section

This chapter will describe how to use all these tools to accurately complete the *Evidence Worksheet* for each article on the *Sort List*.

3.1 Action 1: Abstracting Key Information from the Research Report into the *Evidence Worksheet*

Before you attempt to assess the quality of a piece of research, you will need to read carefully the article and then abstract details about the study into the worksheet. While abstracting the article, pay close attention to the study design and execution elements that affect the scientific validity of the work.

WHY IS THE WORKSHEET SO IMPORTANT?

Purpose of the Worksheet

The worksheets provide an organized way to:

- Abstract key information for future reference.
- Identify study details that allow determination of study quality.
- Summarize major findings including the magnitude of effect and the statistical significance and/or confidence interval.
- Record author's conclusion.
- Note reviewer's comments about the study quality and applicability.

Instructions for Filling out the Evidence Analysis Worksheets

Below is a brief description of how to begin taking key information from the research article and transferring it into the worksheet. The process is somewhat different for primary research articles versus review articles.

Primary Research Reports

Read the Abstract and Introduction of the report to determine purpose and population studied. Look for details about study design, criteria for study eligibility, the practice studied, study protocol, and the variables measured in the Method section. Find results in the text and tables of the Results section. See how the author interprets the findings and describes any limitations of the study in the Discussion section. Usually the author closes the report with a concise conclusion of the study. Transfer relevant information onto the *Evidence Worksheet*. (Refer to Table 3.1 for Primary Research Abstracting Tips noted on an *Evidence Worksheet*.)

Just after (or during) the abstracting, use the *Quality Criteria Checklist* for primary research to assess the quality of the study.

Review Articles

Most review articles are organized the same as primary research reports. The difference is that in reviews, published research studies are the "subjects" in the study. Look in the introduction of the report to find the purpose, population studied, and context for the review. Details about the search plan, criteria for study eligibility, the interventions, procedure and/or factors and outcomes of interest, methods for assessing quality of articles and abstracting data should be in the method section. These are described in a systematic review or meta-analysis, but generally have been less structured in narrative reviews. Find results in the text and tables of the results section. See how the author interprets the findings and describes any limitations of the study in the discussion section. Usually the author closes the report with a concise conclusion of the study. Transfer relevant information onto the *Evidence Worksheet*. (Review Article Abstracting Tips are noted on an *Evidence Worksheet* in Table 3.1.b.)

Just after (or during) the abstracting, use the *Quality Criteria Checklist* for review articles to assess the quality of the study.

Tips for Completing Primary Research and Review Article *Evidence Worksheet*s

Below, we provide two *Evidence Worksheets*—one for primary research and the other for review articles—that include tips for filling in the appropriate information. You can find these in Table 3.1.a and Table 3.1.b.

A blank copy of the *Evidence Worksheet* is included in the Appendix.

Table 3.1.a. What to Abstract from Primary Research Report

Question		
Date of review	Reviewer	
Author/Year: Complete Reference:		
Design Type: Name of the study design	Class: (A, B, C, D)	Quality: (+, 0, --)
Purpose/Population Studied/Practice Studied	Sample, Primary Outcome(s) /Results & Significance	Authors' Conclusions *Reviewer and Expert panel Comments (italicized)*
Purpose: Research question being investigated in study Inclusion Criteria: Requirement for study eligibility Exclusion Criteria: Study Protocol: What happened in the study Describe interventions, regimens, risk factors, or procedures studied; when outcomes were measured; how intervening factors were managed Data Collection: Outcome(s) and other indicators Important variables and methods of measurement Was blinding used?	Actual Sample: Relevant descriptors of sample and comparison of groups at baseline Note loss of subjects (withdrawals, drop out, response rate, etc) Results: Abstract results including quantitative data and statistics (Include statistical significance—P values, confidence intervals, relative risk, odds ratios, likelihood ratio, number needed to treat, if available)	Author's Conclusions: As stated by the author in body of report *Reviewer's Comments:* *Note strengths and limitations of the study. Identify concerns that affect study validity and generalizability*

Table 3.1.b. What to Abstract from Review Article

Question		
Date of review	Reviewer	
Author/Year: Complete Reference:		
Design Type: Type of review	Class: (M, R, X)	Quality: (+, 0, --)
Purpose/Population Studied/Practice Studied	Primary Outcome(s) /Results & Significance	Authors' Conclusions *Reviewer and Expert panel Comments (italicized)*
Purpose: Question being addressed in the research Inclusion Criteria: Criteria for article inclusion Exclusion Criteria: Study Protocol: Search procedures Was study quality assessed? Types of interventions and outcomes investigated, populations included Data Collection: Outcome(s) and other measures Why type of information was abstracted from articles? How was it combined? What analytic methods were used, if any?	Actual Sample: # articles included # of articles identified Number and type of studies reviewed Sample size of studies, and characteristics of the study participants Results: What are the main results of the review? Abstract results including quantitative data and statistics, especially effect sizes	Author's Conclusions: As stated by the author in body of report ***Reviewer's Comments:*** *Note strengths and limitations of the review. Identify concerns that affect the validity of the review. How generalizable are the findings?*

3.2 Action 2: Completing Worksheets and Determining a Quality Rating

As the report is being examined, refer to the appropriate *Quality Criteria Checklist* to be reminded of the criteria for sound scientific research. The quality criteria are written in the form of yes/no questions to help the reviewer examine the report for important details about the design of the study and its execution. Finally, the reviewer uses the *Quality Criteria Checklist* to assign a quality rating to the study. A symbol indicating positive (+), neutral (∅), or negative (-) quality is entered on the top right corner of the *Evidence Worksheet* to assign the quality rating.

The task of critically appraising a research report is complex and requires time and concentration. At first, the process takes about 2 hours per article. Time is reduced as the reviewer becomes more familiar with the research area and the use of the *Evidence Worksheet* and the *Quality Criteria Checklist*.

Using a computer facilitates the processes of abstracting articles and maintaining files.

Purpose of the *Quality Criteria Checklists*

WHAT IS THE PURPOSE OF THE *QUALITY CRITERIA CHECKLISTS*?

- To identify the concepts that are widely accepted as elements of sound scientific investigation
- To provide a tool to enable systematic, objective quality rating of primary research and review articles
- To support inter-rater agreement among reviewers

Background of the Checklists for Primary Research and Review Articles

The content of the *Quality Criteria Checklists* is based on the quality constructs and domains identified in the Agency for Healthcare Research and Quality (AHRQ) report on *Systems to Rate the Strength of Scientific Evidence* (2002).

Both checklists include four relevance questions that address applicability to dietetic practice, and ten validity questions that address scientific soundness. The relevance questions and validity questions make up the criteria for rating study quality.

These detailed checklists should guide the analyst and help him/her recognize various threats that undermine sound research and can lead to invalid conclusions.

It is assumed that users of the *Quality Criteria Checklists* will have at least a basic understanding of research and statistics, and will have training in ADA's process through the training module, workshop, or other method.

When used by knowledgeable persons, the checklists should yield consistent results across raters. It is recommended that inter-rater agreement be examined and verified before embarking on a project.

Quality Criteria Checklist: Primary Research

The *Quality Criteria Checklist: Primary Research* includes ten Validity Questions based on the AHRQ domains for research studies. Sub-questions are listed under each validity question that identify important aspects of sound study design and execution relevant to each domain. Some sub-questions also identify how the domain applies in specific research designs. The *Quality Criteria Checklist: Primary Research* is presented in Table 3.2.a as well as in the Appendices section.

Table 3.2.a. Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS	
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes No
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes No
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No
4. Is the intervention or procedure feasible? (NA for some Epidemiological studies)	Yes No
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.	
VALIDITY QUESTIONS	
1. Was the research question clearly stated? 1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified? 1.2 Was the outcome(s) (dependent variable(s)) clearly indicated? 1.3 Were the target population and setting specified?	Yes No
2. Was the selection of study subjects/patients free from bias? 2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? 2.2 Were criteria applied equally to all study groups? 2.3 Were health, demographics, and other characteristics of subjects described? 2.4 Were the subjects/patients a representative sample of the relevant population?	Yes No
3. Were study groups comparable? 3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if Randomized Controlled Trial (RCT)) 3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? 3.3 Were concurrent controls used? (Concurrent preferred over historical controls.) 3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? 3.5 If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) 3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	Yes No

		Yes No
4.	**Was method of handling withdrawals described?**	
4.1	Were follow-up methods described and the same for all groups?	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate), and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was blinding used to prevent introduction of bias?**	Yes No
5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	
5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**	Yes No
6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
6.2	In observational study, were interventions, study settings, and clinicians/provider described?	
6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
6.6	Were extra or unplanned treatments described?	
6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes No
7.1	Were primary and secondary endpoints described and relevant to the question?	
7.2	Were nutrition measures appropriate to question and outcomes of concern?	
7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
7.5	Was the measurement of effect at an appropriate level of precision?	
7.6	Were other factors accounted for (measured) that could affect outcomes?	
7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes No
8.1	Were statistical analyses adequately described the results reported appropriately?	
8.2	Were correct statistical tests used and assumptions of test not violated?	
8.3	Were statistics reported with levels of significance and/or confidence intervals?	
8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
8.6	Was clinical significance as well as statistical significance reported?	
8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**re conclusions supported by results with biases and limitations taken into consideration?**	Yes No
9.1	Is there a discussion of findings?	
9.2	Are biases and study limitations identified and discussed?	

10. Is bias due to study's <u>funding or sponsorship</u> unlikely? 10.1 Were sources of funding and investigators' affiliations described? 10.2 Was there no apparent conflict of interest?	Yes No
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Quality Worksheet.*	
NEUTRAL (∅) *If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Quality Worksheet.*	
PLUS/POSITIVE (+) *If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.*	

Quality Criteria Checklist: Review Articles

The *Quality Criteria Checklist: Review Articles* has ten validity questions that incorporate the AHRQ quality domains for systematic reviews. These questions identify the systematic process for drawing valid inferences from a body of literature. The *Quality Criteria Checklist: Review Articles* can be found in Table 3.2.b and in the Appendices section.

Table 3.2.b. Quality Criteria Checklist: Review Articles

RELEVANCE QUESTIONS		
1. Will the findings of the review, if true, have a direct bearing on the health of patients?	Yes	No
2. Is the outcome or topic something that patients/clients/population groups would care about?	Yes	No
3. Is the problem addressed in the review one that is relevant to dietetics practice?	Yes	No
4. Will the information, if true, require a change in practice?	Yes	No
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1. Was the research question clearly focused and appropriate?	Yes	No
2. Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	Yes	No
3. Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	No
4. Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	No
5. Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes	No
6. Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	No
7. Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issues considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes	No
8. Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	No
9. Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes	No

10. Was bias due to the review's funding or sponsorship unlikely?	Yes No
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the review should be designated with a minus (-) symbol on the Evidence Quality Worksheet.*	
NEUTRAL (∅) *If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a neutral (∅) symbol on the Evidence Quality Worksheet.*	
PLUS/POSITIVE (+) *If most of the answers to the above validity questions are "Yes" (must include criteria 1, 2, 3, and 4), the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.*	

When these quality criteria for review articles are applied to "traditional" narrative reviews and practice guidelines from past years, it is practically impossible to get a positive rating. This is because authors seldom report their search strategy and did not give explicit attention to the scientific quality of included research.

Instructions for Using the Quality Checklist

During or after reading the research report and abstracting the key information onto the *Evidence Worksheet*, each of the relevance and validity questions on the *Quality Checklist* is considered and a "yes" or "no" answer is given. A record of the answers to each question is useful for checking work and verifying consistency among reviewers (i.e., inter-rater reliability).

Sub-questions on the *Quality Criteria Checklist: Primary Research* identify points to consider when answering each Validity Question. Not all sub-questions are meant to apply in every study; and the yes/no determination is not based on adding up answers to sub-questions. A "yes" reflects the reviewer's judgment that the quality criterion was adequately addressed in the report.

While all questions on the checklists are important to sound research, some criteria take on added importance in specific research designs. The *Study Design, Distinguishing Characteristics, and Important Quality Questions* (found in Table 3.2.c and in the Appendices section) identifies sub-questions that are most important quality consideration for each type of study. A well-planned and well-executed study would have these points, plus others, addressed in the report.

Occasionally, a major question is not relevant (NA) to the specific study. Use of NA is indicated in relevance questions 1 and 4 and validity question 3 of the *Primary Research Checklist*.

Checklists include directions for assigning the final quality rating (minus -, neutral ∅, or plus +).

The final quality rating determination is written on the *Evidence Worksheet*. Weakness in the study or review should be noted in the Reviewer's Comments section of the *Evidence Worksheet*.

Table 3.2.c. Study Design, Distinguishing Characteristics, and Important Quality Considerations

Study design type	Distinguishing characteristics of design	Most important quality considerations (from checklist)*
EXPERIMENTAL & QUASI-EXPERIMENTAL STUDIES	**(Investigator manipulated independent variable, and a control group always used)**	
Randomized controlled trial (Preferred for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable) randomization to groups	3.1, 3.2, 4.3 2.1, 2.3, 5.1, 5.2, 6.1, 6.3 – 6.7, 7.4
Nonrandomized trial (Frequently used for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable)	2.1 – 2.3, 3.1 – 3.3, 4.3 5.1, 5.2, 6.1, 6.3 – 6.7, 7.1 – 7.7
OBSERVATIONAL STUDIES	**(Comparisons made)**	
Comparison of 2 or more groups (also called prospective cohort) (Preferred for etiology, causation, or harm questions)	comparison of existing "convenient" groups getting different interventions or exposures	2.1, 2.2, 4.3, 4.4, 7.1, 7.3, 7.4, 7.6, 7.7, 8.5 2.3, 3.2, 3.3, 5.2, 5.3, 6.2 – 6.7
Single group before-after or time series	subject serves as own control	2.1, 2.3, 2.4, 6.2, 7.4, 7.6 4.3, 5.1, 5.2, 6.3 – 6.7, 7.1 – 7.3, 7.5 3 - NA**
Sensitivity & specificity of diagnostic test (Preferred for diagnosis questions)	dichotomous (yes/no) outcome comparison with "gold standard"	3.7, 4.5, 5.5 2.4, 6.8, 7.6
EPIDEMIOLOGICAL ANALYTIC STUDIES	**(Comparisons constructed analytically, groups created post hoc)**	
Cohort study (Preferred for natural history and prognosis questions)	membership based on defining characteristic or factor	2.1, 4.3, 7.1, 7.3, 7.4, 7.7, 8.5 2.3, 3.4, 5.3, 6.3,
Case-control study (Preferred for etiology, causation, or harm questions)	"cases" with outcome identified then "matched" with non-cases (controls) from same population look back for exposure	2.1, 3.5, 4.3, 7.3, 7.4, 7.6, 7.7 2.3, 5.4, 6.3, 6.4
Cross-sectional study (Preferred for diagnosis questions) (Used for etiologic, causation, or harm questions)	outcome (dependent variable) and exposure (independent variable) measured at same time	4.3, 7.4, 7.7 2.1, 2.3, 2.4, 3.4, 5.3, 6.8, 7.2, 7.4 – 7.6 3 - NA, if comparison groups are not constructed

DESCRIPTIVE STUDIES	(No comparison)	
Case series	describe process and outcomes prospectively, "natural history" with no intervention	2.1, 4.3, 6.5, 6.6, 7.1, 7.4, 7.6 2.3, 2.4, 5.2, 5.3, 7.2, 7.3 3 - NA

*See: *Quality Criteria Checklist*: Primary Research. Bolded items are most important for that study design. The other (not bold) items are also common threats to validity in study type.

**NA = not applicable

3.3 Action 3: Recording Assessments on the *Tally Sheet of Quality Ratings*

Because we are interested in the findings of many pieces of research as they relate to a particular question, we need a way to pull together the quality rating information into an easy to use format. This is the function of the *Tally Sheet of Quality Ratings* (shown below and in the Appendices section.

Table 3.3. Example Tally Sheet of Quality Ratings

Author				
Year				
Relevance Questions				
1				
2				
3				
4				
Validity Questions				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
Quality Rating (+, 0, -)				
Magnitude of effect				
Sample size				
Relevance to target population				

The analyst records the yes/no answers to each of the relevance and validity questions on the *Tally Sheet of Quality Ratings*. The Expert Panel will use this Tally Sheet when they determine the overall grade of the body of evidence as it relates to a particular question in Step 5 of the evidence analysis process.

At the end of Step 3 the following materials are available on the Online Forum for the expert panel to review:

- *Sort List*
- *Evidence Worksheest*
- Copies of all articles
- *Quality Ratings/Quality Checklists*

Chapter

4

Step 4: Writing the Evidence Summary

Instructions for Summarizing the Body of Evidence

Now the evidence analyst team is ready to pull it all together.

Creating an evidence summary involves combining relevant and scientifically valid information into a brief, coherent, and easy-to-read summary.

Writing an evidence summary can be a challenge. We have divided into a series of actions and offer some tips to help you do this.

4.1 Action 1: Organize the Studies

Not all studies will carry the same weight in your evidence summaries. Some studies provide direct answers to your question while others may provide insight in a more indirect manner.

How should you organize your studies?

We have created the *Overview Table Template* to give you the ability to quickly assess which studies are going to be the most important for answering your question. (See the example overview table and the overview table template in the Appendices section.). The overview table is an extension of the *Quality Rating Tally Sheet* in that it adds factors that the working group or the research indicates are important considerations when comparing and synthesizing research findings.

In most instances, the studies that have the highest quality designs and largest numbers of participants will be more important for writing the evidence summary than smaller samples and weaker studies.

Overview tables are handy tools for you to be able to see, at a glance, how the different studies compare. The same comparisons are not important for every question in every

evidence analysis. So, you will need to decide for yourself (or, with others in your team if you are doing the evidence analysis as a team effort) what the critical comparison factors are for your topic and question.

For instance, differences in the race of the participants matter for some nutritionally relevant procedures or disease states. In others, race does not matter. So, while the race of the sample populations would be a part of some overview tables, it would not have an important place on others. The research should give you a sense of the important comparison factors. Ask yourself, what comparison factors do researchers most often take into account?

YOU MAY NOT NEED TO USE AN OVERVIEW TABLE IF YOU ARE WORKING WITH A RELATIVELY SMALL NUMBER OF RESEARCH ARTICLES.

Filling out the overview table should not be an arduous task. Almost all the information for the overview table can be transferred from the *Evidence Worksheet*s.

Once you've filled out an overview table for the articles you've analyzed, you are ready to begin writing!

4.2 Action 2: Write a Brief Statement of the Relevant Findings of Each Study

Summarize the findings of each study (as they related to the question you are trying to answer) in one to three sentences. These study-specific summaries will be included in the final evidence summary under "Specific Findings."

When writing the specific findings for each study you will want to capture the following information:

- author(s) and publication year
- outcomes (and measurements) of interest
- important sample characteristics and comparison factors (e.g., sex, age, weight, nationality, etc.)
- implications for practice (if stated in the article)
- limitations of findings (e.g., Were there confusing or problematic measurements that make interpretation problematic?)

Some Examples

Keep the question you are trying to answer in mind. This will help you focus on the relevant outcomes.

Below are some examples taken from an evidence analysis of measurements of resting metabolic rate (RMR). In some examples, we mark the different pieces of information.

Question to be answered: What is the difference between indirect calorimetry-identified energy requirements as compared to the most-often used predictive formulas (Owen equations)?

- Arciero [author] found that the Owen equations under predicted ($p<0.05$) by 5% (within group) with a range of –27% to 15% on an individual basis **[outcome of interest].** There was a significant underestimation in RMR with onset of menopause **[comparison factor],** suggesting a possible need to develop separate equations for older men and women (based on large variations in kcal intake and leisure activities) **[implications for practice].**

- Frankenfield found that in non-obese men and women **[comparison factor]**, the Owen equation predicted RMR to within 10% of measured in 73% of subjects. Errors tended to be underestimates (21% of all subjects versus 6% who were over estimated) **[outcome of interest].**

- In a Fredrix study of 40 male and female healthy individuals (51-82 years) **[comparison factor]** found the Owen equation under predicted the measured RMR value by 4%. **[outcome of interest].**

- The Clark study found that in 29 young, healthy men (age 24 ±3.3 years) measured RMR was 1% greater than the Owen equation prediction, but this finding was not statistically significant **[limitation of findings].**

- Garrell et al studied 67 (39 male, 28 female) normal weight, healthy individuals to compare measured versus predicted RMR. They found that the Owen formula predicted measured RMR within 10% of the measured value in 80% of the subjects. However, standard errors reported are unclear and lead to confusing conclusions (Table 3 appears to provide impossible SE on a mean percent.) **[limitation of findings]**

4.3 Action 3: Examine the Overview Table for "Themes"

Now that you have summarized the gist of each article as it relates to your question, you need to begin to consider how the different articles relate to each other. For instance:

- Are there any patterns of agreement or disagreement among the articles with respect to your question? In the indirect calorimetry example, what articles found that the Owen equation overestimated RMR? What articles found that the Owen equation underestimated RMR?

- What comparisons are commonly made in the research? For example, do many pieces of research control for age or sex? Is overweight a common comparison factor?

- Are there sets of articles that focus on a specific stage of a disease (e.g., acute, recovery, chronic)?

This is what we mean by looking for "themes."

Use your overview table to help you identify common patterns in the research.

4.4 Action 4: Write the Evidence Summary

Now you are ready to pull it all together. Keep all your resources handy (articles, worksheets, overview tables, and specific summaries) as you will probably need to refer back to them.

What goes into the evidence summary depends heavily on the topic and question. There are several critical pieces of information that should be present. These pieces of information might correspond, roughly to paragraphs in the evidence summary.

Important Components for Evidence Summaries

1. Overall summary statement. This should be a fairly brief statement that focuses on any general agreement among the studies. What, in general, did the studies find relative to your question? Were there studies that disagreed?

2. Comparison factors statements. You may need a couple of paragraphs depending on the topic and the important comparison factors. For instance, you may need a paragraph that presents findings differentiating for sex, for age, and for disease stage (e.g., acute, recovery, chronic). Your comparison factors will have been defined in your overview template. Again, was there agreement among articles? What, if any, lines of disagreement were there?

3. Methodological statements. Give the reader a sense of the types of research designs used. Perhaps your analysis revealed two studies with strong research

designs and three with weaker designs. How large were the study samples? Were there any recurrent problems in the studies or study designs?

4. Outcome impact statements. Are there any interventions, research procedures, or intervening factors that may affect outcomes? For instance, one study may have found that study participants who had lost weight prior to the study had different outcomes. If this factor was not taken into account in other studies you should mention it because it could affect the interpretation of other studies.

5. Definitions. In some circumstances, you may need to offer your reader brief definitions of key terms. You may also need to give your reader some information on what criteria were used to make a judgment on the quality or usefulness of a study for your purpose. Note the example of the criteria used to determine research study quality for an evidence analysis of indirect calorimetry.

Below is an example of a definition drawn from the indirect Calorimetry evidence analysis project. Because the quality of the study depended heavily on the correct use of the calorimeter, and because many dietitians may not be familiar with this tool, the working group believed it was important to clarify how they defined "high quality."

Definition of High Quality Study from Indirect Calorimetry Project:

Studies identified as "high quality" or "strong design" (i.e., a "plus" quality rating) had to identify or discuss individual characteristics and covariance factors associated with weight, age, and diseases allowed or excluded. In addition they had to address indirect calorimeter protocol adherence in the following areas:

1. machine calibration

2. 20-30 minute rest before measurement if traveling to a measurement center or to discuss procedures prior to single measurements (e.g., machine acclimation measurements,

3. steady state (e.g., pre-determined group mean covariance, elimination of erratic measurements and/or ongoing acceptable monitoring)

4. measurement length

5. exercise restrictions in healthy adults the day prior to measurements or identifying/monitoring movement restrictions/restlessness in critically ill patients

6. fasting (ideally, specifying fasting length) with an exception for studies including patients on IV, parenteral or enteral feedings.

4.5 Action 5: Write a Preliminary Conclusion Statement

Now you need to pull all the information together into a "bottom line" conclusion statement. What, overall, does the evidence tell us?

Usually, the analyst drafts a preliminary conclusion statement that goes to the expert panel for consideration. Remember, you are writing this for practitioners. Your conclusion needs to be clear, simple, and to the point.

Look over your specific finding statements. What do they tell you?

Where the evidence on a question agrees, writing a conclusion statement may be fairly simple. In cases where the evidence disagrees or reaches no clear consensus you will have to take that into account in your summary.

Below are some examples of conclusion statements for different nutritional problems taken from prior evidence analysis projects.

Spinal Cord Injury Example

Question: What are the caloric and protein needs during the acute and rehabilitation phases following spinal cord injury?

Preliminary Conclusion:

Calories: Caloric needs of spinal cord injured patients during the acute and rehabilitation phases should be based on measured energy expenditure (serial indirect calorimetry measurements). If indirect calorimetry is not available, needs can be estimated using 22.7 kcal/kg body weight for individuals with quadriplegia and 27.9 kcal/kg for those with paraplegia.

Protein: Protein intakes of 0.8 to 2.4 grams/kg have been used without untoward effects in the acute phase of SCI. A level of 2 gm/kg is a prudent guideline for estimating protein and nitrogen needs during this phase.

4.6 Action 6: Filling in the Evidence Summary Sheet

Once you have written the evidence summary and conclusion statement you are ready to bring everything together into the Conclusion Grading Worksheet.

The Conclusion Grading Worksheet is the primary working tool for the working group. It brings all the critical information together so that the working group can offer their assessment of the evidence.

The Conclusion Grading Worksheet has the following format.

Table 2. Conclusion Statement and Conclusion Grading Worksheet

Purpose of the Evidence Appraisal Process (List the original question)
Conclusion Statement: (Write conclusion after considering the quality, quantity, and consistency of all available evidence, as well as the of findings and their likely clinical impact.)
Evidence Summary: (Concisely summarize key findings that justify the conclusion.)
Conclusion Grade: (Assign an overall grade for the strength of the evidence supporting the conclusion statement. Refer to table of grades on the following page.) (Grade levels: I—good/strong, II—fair, III—limited/weak, IV—expert opinion only or V-not assignable)
Evidence Sources and Evidence Table*: (Include all relevant, current sources identified and appraised. Each listed reference can be linked to a completed Evidence Abstract and Quality Rating Worksheet.) List: Complete Reference, Report Class (A, B, C, D, M, R, or X), and Quality Rating (+, O, -, or NA)

When collated together, the Evidence Abstract and Quality Rating Worksheets for all reviewed articles and reports make up the Evidence Table.

You can find a template for the Conclusion Grading Worksheet in the Appendices section.

4.7 Action 7: Preparing the Evidence Summary and Conclusion for the Working Group

In order to facilitate the evidence grading, the expert panel will need a packet of materials from the evidence analysts and the time to meet to discuss the conclusion statement and evidence.

There are several completed documents that the working group will need in order to grade the conclusion statement and evidence:

1. The *Conclusion Statement Worksheet*
2. The *Tally Sheet of Quality Ratings*
3. The *Sort List*
4. The *Evidence Worksheets* for all research sources

THE EVIDENCE ANALYST IS A CRITICAL RESOURCE FOR THE WORKING GROUP

There is one more resource that the working group will need in the grading session: the evidence analyst.

Because the evidence analyst has been the one to analyze each piece of research in fine detail, they are often called upon by the working group members to answer questions about a particular piece of research. In cases where multiple analysts worked on the research for a question, the lead evidence analyst should be available to answer questions during the working group's grading session.

Chapter

5

Step 5: Grading the Conclusion Statement

How Strong is the Evidence?

The final step in the evidence analysis process is the expert panel's grading of the body of evidence available to support the conclusion statement.

This step is characterized by discussion and deliberation and so may take some time. Even with all the prior work done by evidence analysts, it takes time and careful thought from the expert panel to craft the conclusion statement and assign a grade.

5.1 Grading the Evidence Statement

In the final step the expert panel reviews all the documents produced during the evidence analysis and comes to a consensus on the strength of the evidence supporting the conclusion statement.

Before the expert panel grading session, expert panel members should review the Conclusion Statement and Evidence Summary as well as the Tally Sheet of Quality Rating and the individual *Evidence Worksheet*s. In some cases, where a working group member may have a question regarding a particular piece of research, they may want to review the original article.

Some expert panels have found it useful to designate one or two of its members to read each of the research articles on the *Sort List* for a particular question. In this case, the expert panel members who have read the articles may take the lead in discussions of the working group concerning those questions.

During the grading session, expert panel members should ask the following questions:

- Does the Evidence Summary accurately capture all the key information contained in the *Evidence Worksheet*s regarding the question?
- Does the Conclusion Statement accurately and clearly sum up the evidence as it pertains to dietetic practice?

Once the expert panel is satisfied with the Evidence Summary and Conclusion Statement, they need to assign a grade. The expert panel should review the ADA's evidence grading scheme to make sure they understand the criteria for the different grades. Additionally, we have created a *Conclusion Grading Table* to help the working group come to consensus regarding the strength of the evidence.

A copy of the Conclusion Grading Table can be found in Table and in the Appendices.

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Table 5.1 Grading the Strength of the Evidence for a Conclusion Statement or Recommendation
Conclusion Grading Table

Strength of Evidence Elements	**Grades**				
	I **Good/Strong**	**II** **Fair**	**III** **Limited/Weak**	**IV** **Expert Opinion Only**	V **Grade Not Assignable**
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns, OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design, OR Consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published research studies	Relevant studies have not been done

Strength of Evidence Elements (continued)	I Good/Strong	II Fair	III Limited/Weak	IV Expert Opinion Only	V Grade Not Assignable
Clinical impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of the effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

Adopted by The American Dietetic Association from Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. *Jt Comm J Qual Improv*. 2000;26:700-712

Appendices

Table 1.2 Question Formulation Template

Nutrition Care Area: _____ Target Population: _____ Usual Setting: _____

Identify Factors

First, list factors that are important and drive practice decisions in the area of nutrition care population of interest.

Assessment or Diagnosis Factors	Interventions	Behavioral Outcomes	Clinical Outcomes

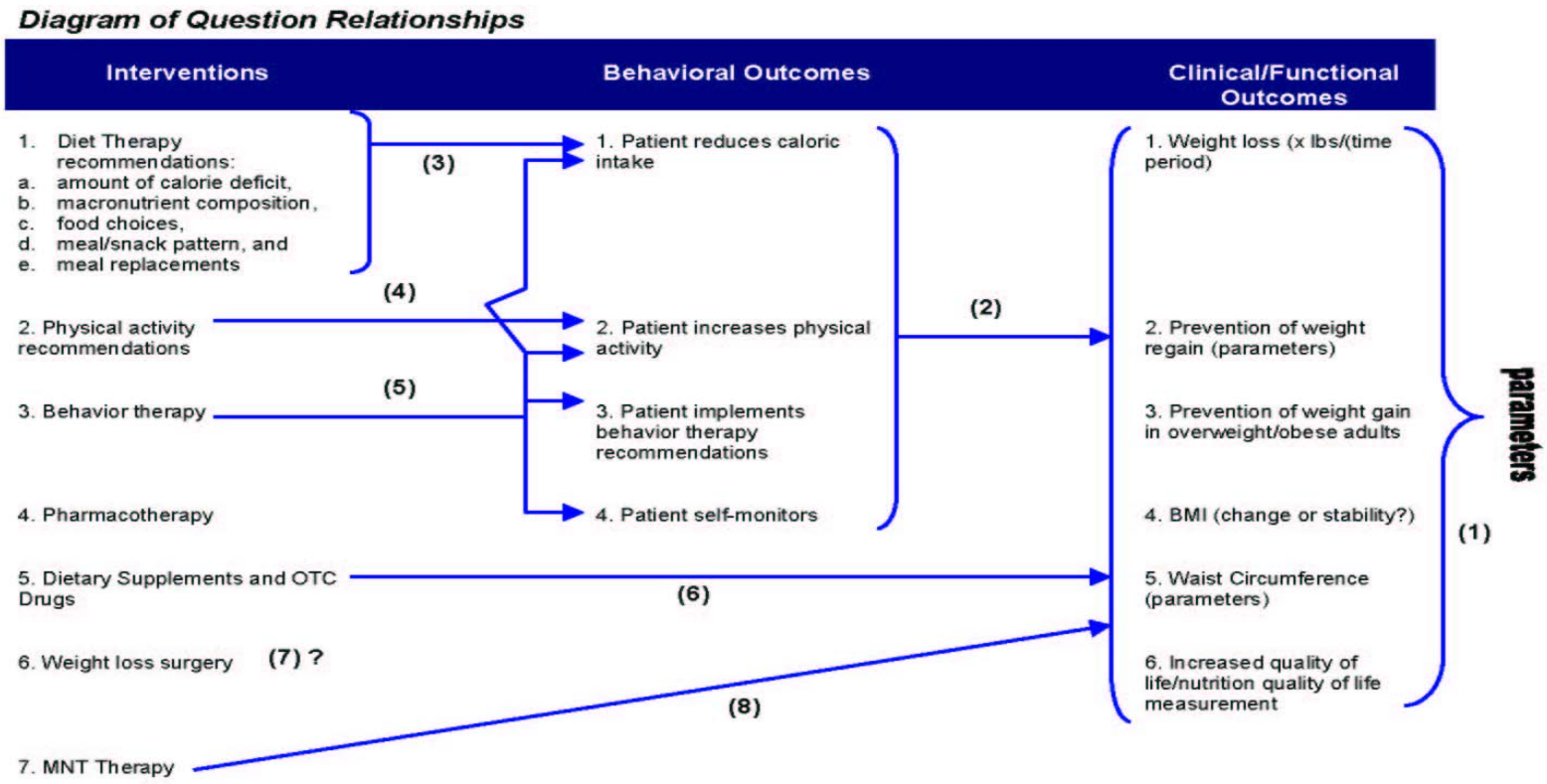
Linkages between Factors

Second, what questions do you have about the relationships or linkages of the listed factors?
Consider:

- Areas of uncertainty
- Assumption to be verified with scientific evidence
- Variations in practice

Figure 1.2.a presents an example of factors and linkages among factors.

Figure 1.2.a. Example of Question Factor Diagram



Third, specify question for evidence analysis using "PICO"
Specify **P**opulation, **I**ntervention, **C**omparison, desired **O**utcome.

Questions linking Assessment or Diagnosis Factors to Intervention Factors:

Questions linking Assessment or Diagnosis Factors to Behavioral or Clinical Outcomes:

Questions linking Intervention Factors to Behavioral or Clinical Outcomes:

Sort List Worksheet

Use a *Sort List* worksheet to help you organize your decision. The *Sort List Worksheet* is a simple table that lists the research articles in rows and presents the critical information you need to select the appropriate articles in the columns.

Table presents an excerpt of a *Sort List* worksheet used on one evidence analysis project.

Note that in this example relevance and quality ratings are both presented using a plus (+), neutral (Ø), and minus (-) rating. Even though the formal evidence analysis has not yet been completed, a review of the methods section of the articles will allow you to make a provisional estimate of the quality rating (the formal, detailed quality rating will come later). Obviously, high relevance, high quality articles will be the first choice for the *Sort List*. However, depending on the question, you may also want to take into account other factors like population, country, etc.

Table 2.1. Sample Sort List Tool

PRIMARY ARTICLES								
Article Available	**Author**	**Year**	**Study Sample**	**Chemical**	**Statistical Analysis**	**Relevance (plus, neutral, minus)**	**Quality Rating (plus, neutral, minus)**	**Country**
Y	Bross	1995	20 mod obese F	Fluoxetine	2-class repeat meas ANOVA;2 sample-2 tail Test	+	+	Canada
Y	Bruder	1998	24 trauma pt	4 grp: Fentanyl '+Midazolam; Fentanyl, Midazolam, '+ curarization; Thiopental; No sedation	Analysis of variance w/ Fisther's posterior least significant difference test; Linear regression for EE	+	Ø	France
REVIEW ARTICLES								
Y	Damask MC	1987		drug categories		+	Ø	USA
Y	Lamont LS	1995		beta-blockers		+	+	USA

You may find that not all the column heads are relevant for your project. Change the heads to categories that apply to your topical area or question.

PRIMARY ARTICLES								
Article Available	Author	Year	Population	Chemical	Statistical Analysis	Study Design		Country
REVIEW ARTICLES								

Glossary of Terms Related to Research Design

Case-control study

A study which involves identifying patients who have the outcome of interest (cases) and matching with individuals who have similar characteristics, but patients without the same outcome (controls), and looking back to see if they had the exposure of interest.

Case Series

A descriptive study of a series of patients, defined by eligibility criteria, and where the natural history is an unfolding course of events (disease progression, therapies, outcomes, etc.). The study investigators do not manipulate interventions

Cohort Study

A study that involves the identification of a group (cohort) of individuals or subjects with specific characteristics in common and following this cohort forward to observe the development of the outcome of interest. Groups can be defined at the beginning or created later using data from the study (i.e. age group, smokers/non-smokers, frequency of consumption of specific food group).

Cost-benefit analysis

Assesses whether the cost of an intervention is worth the benefit by measuring inputs (treatments) and outcomes and converting both into monetary units (dollars).

Crossover study design

A study where the administration of two or more experimental therapies one after the other in a specified or random order to the same group of patients. The group of individuals serves as its own control. This is a special type of randomized or non-randomized trial.

Cross-sectional study

A study based where exposures and outcomes are observed or measured simultaneously in a population, usually by survey or interview. In this design, a researcher examines the association of the factors, but cannot infer cause and effect.

Intention to treat analysis

A method of analysis for randomized trials in which all patients randomly assigned to one of the treatments are analyzed together, regardless of whether or not they completed or received that treatment.

Meta-analysis

A systematic review of the literature that uses quantitative methods to merge the results of valid studies.

Nonrandomized Trial

A study where patients or subjects have been assigned to the treatment, procedure, or intervention alternatives by a method that is not random. The investigator does define and manage the alternatives.

Randomized clinical trial (RCT)

Patients or individuals meeting eligibility requirements are randomized into an experimental group or a control group. The experimental treatment and its alternative are clearly defined and the protocols for implementation are tightly managed by the researcher.

Time Series

A study collecting data at a series of points in time on the same population to observe trends in a defined construct of interest or related constructs of interest..

Systematic review

A summary of the medical literature that uses explicit methods to conduct a thorough literature search, critically appraise individual studies, and report the findings.

Table 3.0 Evidence Abstract and Quality Rating Worksheet

Question		
Cite Topic		
Date of review		
Reviewer		
Author/Year: Complete Reference:		
Design Type: Class: Quality Rating:		
Pub Med ID:		
Purpose/Population Studied/Practice Studied	Primary Outcome(s) /Results & Significance	Authors' Conclusions/ *Reviewer and Expert Panel Comments (italicized)*
Purpose: Inclusion Criteria: Exclusion Criteria: Study Protocol: Data Collection Summary:	Actual Sample: Results: (Table format available)	Author's Conclusions: *Reviewer's Comments:*

Classes of Evidence Reports

Primary Reports of New Data Collection (Research Report)		Reports That Synthesize or Reflect on Collections of Primary Reports	
A	Randomized controlled trial (RCT)	M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Cohort study		
C	Nonrandomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study Time series	R	Narrative review (Review article) Consensus statement Consensus report
D	Cross-sectional study Case series Case report Before and after study	X	Medical opinion

Quality Rating Criteria Checklists: Primary Research and Review Article

Symbols Used to Designate the Quality of Evidence Reports

+ Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- Indicates that these issues have not been adequately addressed.

∅ Indicates that the report is neither exceptionally strong nor exceptionally weak.

NA Indicates that the report is not a primary reference and therefore the quality has not been assessed.

Quality Criteria Checklists

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes No Unclear N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes No Unclear N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1.	**Was the <u>research question</u> clearly stated?**	Yes No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?	
1.3	Were the target population and setting specified?	
2.	**Was the <u>selection</u> of study subjects/patients free from bias?**	Yes No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	
2.2	Were criteria applied equally to all study groups?	
2.3	Were health, demographics, and other characteristics of subjects described?	
2.4	Were the subjects/patients a representative sample of the relevant population?	
3.	**Were <u>study groups comparable</u>?**	Yes No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)	
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	
4.	**Was method of handling <u>withdrawals</u> described?**	Yes No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was <u>blinding</u> used to prevent introduction of bias?**	Yes No Unclear N/A
5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	
5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk	

		factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.		**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**	Yes No Unclear N/A
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6d, 6e, and 6f assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.		**Were outcomes clearly defined and the measurements valid and reliable?**	Yes No Unclear N/A
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.		**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes No Unclear N/A
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.		**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes No Unclear N/A
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.		**Is bias due to study's funding or sponsorship unlikely?**	Yes No Unclear N/A
	10.1	Were sources of funding and investigators' affiliations described?	
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Quality Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Quality Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.

Quality Criteria Checklist: Review Articles

RELEVANCE QUESTIONS				
1. Will the answer if true, have a direct bearing on the health of patients?	Yes	No	Unclear	N/A
2. Is the outcome or topic something that patients/clients/population groups would care about?	Yes	No	Unclear	N/A
3. Is the problem addressed in the review one that is relevant to dietetics practice?	Yes	No	Unclear	N/A
4. Will the information, if true, require a change in practice?	Yes	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.				
VALIDITY QUESTIONS				
1. Was the question for the review clearly focused and appropriate?	Yes	No	Unclear	N/A
2. Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	Yes	No	Unclear	N/A
3. Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	No	Unclear	N/A
4. Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	No	Unclear	N/A
5. Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes	No	Unclear	N/A
6. Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	No	Unclear	N/A
7. Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes	No	Unclear	N/A
8. Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	No	Unclear	N/A
9. Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes	No	Unclear	N/A
10. Was bias due to the review's funding or sponsorship unlikely?	Yes	No	Unclear	N/A
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the review should be designated with a minus (-) symbol on the Evidence Quality Worksheet.*				
NEUTRAL (∅) *If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a neutral (∅) symbol on the Evidence Quality Worksheet.*				
PLUS/POSITIVE (+) *If most of the answers to the above validity questions are "Yes" (must include criteria 1, 2, 3, and 4), the report should be designated with a plus symbol (+) on the Evidence Quality Worksheet.*				

Study Design, Distinguishing Characteristics and Important Quality Considerations

Study design type	Distinguishing characteristics of design	Most important quality considerations (from checklist)*
EXPERIMENTAL & QUASI-EXPERIMENTAL STUDIES	**(Investigator manipulated independent variable always control group)**	
Randomized controlled trial (Preferred for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable) randomization to groups	3.1, 3.2, 4.3 2.1, 2.3, 5.1, 5.2, 6.1, 6.3 – 6.7, 7.4
Nonrandomized trial (Frequently used for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable)	2.1, 2.3, 3.1-3.3, 4.3 5.1, 5.2, 6.1, 6.3 – 6.7, 7.1 – 7.7
OBSERVATIONAL STUDIES	**(Comparisons made)**	
Comparison of 2 or more groups (also called prospective cohort) (Preferred for etiology, causation, or harm questions)	comparison of existing "convenient" groups getting different interventions or exposures	2.1, 2.2, 4.3, 4.4, 7.1, 7.3, 7.4, 7.6, 7.7, 8.5 2.3, 3.2, 3.3, 5.2, 5.3, 6.2 – 6.7
Single group before-after or time series	subject serves as own control	2.1, 2.3, 2.4, 6.2, 7.4, 7.6 4.3, 5.1, 5.2, 6.3 – 6.7, 7.1 – 7.3, 7.5 3 - NA**
Sensitivity & specificity of diagnostic test (Preferred for diagnosis questions)	dichotomous (yes/no) outcome comparison with "gold standard"	3g, 4e, 5e 2.4, 6.8, 7.6
EPIDEMIOLOGICAL ANALYTIC STUDIES	**(Comparisons constructed analytically, groups created post hoc)**	
Cohort study (Preferred for natural history and prognosis questions)	membership based on defining characteristic or factor	2.1, 4.3, 7.1, 7.3, 7.4, 7.6, 8.5 2.3, 3.4, 5.3, 6.3
Case-control study (Preferred for etiology, causation, or harm questions)	"cases" with outcome identified then "matched" with non-cases (controls) from same population look back for exposure	2.1, 3.5, 4.3, 7.3, 7.4 7.6, 7.7 2.3, 5.4, 6.3, 6.4
Cross-sectional study (Preferred for diagnosis questions) (Used for etiologic, causation, or harm questions)	outcome (dependent variable) and exposure (independent variable) measured at same time	4.3, 7.4, 7.6 2.1, 2.3, 2.4, 3.4, 5.3, 6.8, 7.2, 7.4 – 7.6 3 - NA, if comparison groups are not constructed
DESCRIPTIVE STUDIES	**(No comparison)**	
Case series	describe process and outcomes prospectively, "natural history" with no intervention	2.1, 4.3, 6.5, 6.6, 7.1, 7.4, 7.6 2.3, 2.4, 5.2, 5.3, 7.2, 7.3 3 - NA

*See: *Quality Criteria Checklist*: Primary Research. Bolded items are most important for study design. The other (not bold) items are also common threats to validity in study type.

**NA = not applicable

Tally Sheet of Quality Ratings

Instructions: This sheet can be used to record quality rating for each criterion (yes/no/NA) and the final quality determination (+, 0, -) as each article is appraised. Recording answers for each criterion provides a record for future reference and facilitates a check of intra- and inter-rater reliability. Rows across the bottom can be used for notes. In this example the space is used to note specific information that would be relevant to the Expert Group responsible for formulating the Conclusion Statement and its grade.

Author								
Year								
Relevance Questions								
1								
2								
3								
4								
Validity Questions								
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
Quality Rating (+,0,-)								
Magnitude of effect								
Sample size								
Relevance to target population								

Overview Table Template

Authors		GENDER		ETHNICITY				AGE RANGE								Topic Relevant Comparators													
	Sample size	Male	Female	Multiethnic (incl Black)	Asian/Chinese	Caucasian	Setting*	18-20	21-30	31-40	41-50	51-60	61-70	71-80	81-90														OVERALL RATING(+,0,-)

Conclusion Statement and Conclusion Grading Worksheet

Purpose of the Evidence Appraisal Process

(List the original question.)

Conclusion Statement:

(Write a brief conclusion after considering the quality, quantity, and consistency of all available evidence, as well as the of findings and their likely clinical impact.)

Evidence Summary:

(Concisely summarize key findings that justify the conclusion.)

Conclusion Grade:

(Assign an overall grade for the strength of the evidence supporting the conclusion statement and subpoints within the statement. Refer to table of grades on the following page.)

(Grade levels: I—good/strong, II—fair, III—limited/weak, IV—expert opinion only or V—not assignable)

Evidence Sources & Evidence Table:

(Include all relevant, current sources identified and appraised. Each listed reference can be linked to a completed Evidence Abstract and Quality Rating Worksheet.)

List: Complete Reference, Report Class (A, B, C, D, M, R, or X), and Quality Rating (+, O, -, or NA)

Attach:

- *Sort List*
- *Evidence Worksheet*s for every article

Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation

Grade I: Good—The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power.

Grade II: Fair—The evidence consists of results from studies of strong design answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: Limited—The evidence consists of results from a limited number of studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because the studies that have been done are inconclusive due to lack of generalizability, bias, design flaws, or inadequate sample sizes.

Grade IV: Expert Opinion Only—The support of the conclusion consists solely of the statement of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

Grade V: Not Assignable*— There is no evidence available that directly supports or refutes the conclusion.

Adapted by the American Dietetic Association from: Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712.

*ADA approved addition, September 2004. As the work was accomplished by the Working Groups and the trained Evidence Analysts, several situations occurred where none of the original four grades were applicable resulting in the designation of "not assignable." Of note, ICSI also reviewed and modified their grading system and in November 2003 they adopted a "not assignable" grade.

Grading the Strength of the Evidence for a Conclusion Statement

Instructions: Compile *Evidence Worksheets* of all studies and reports relevant to each key question addressed by the clinical recommendation, practice guideline or position statement. The expert panel makes a considered judgment to formulate each conclusion statement using its knowledge of the evidence and methods used to generate it. Then a grade is assigned to indicate the strength of the evidence supporting the conclusion statement.

Table 5.1 Grading the Strength of the Evidence for a Conclusion Statement or Recommendation
Conclusion Grading Table

Strength of Evidence Elements	**Grades**				
	I Good/Strong	**II Fair**	**III Limited/Weak**	**IV Expert Opinion Only**	V **Grade Not Assignable**
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns, OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design, OR Consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published research studies	Relevant studies have not been done

Strength of Evidence Elements (continued)	I Good/Strong	II Fair	III Limited/Weak	IV Expert Opinion Only	V Grade Not Assignable
Clinical impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of the effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

Adopted by The American Dietetic Association from Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. *Jt Comm J Qual Improv.* 2000;26:700-712.
Revised by ADA September 2004.

APPENDIX 11: STUDY DESIGN TABLE

Study Design Characteristics

	Distinguishing Features	Questions Answered	Generalizability	Internal Validity	Result	Typical Statistics
Randomized Controlled Trial (RCT)	• Random assignment to groups • Investigator manages exposure to the casual agent • Prospective • Can establish cause and effect	• Efficacy--can it work? • What is the magnitude of effect? • What proportion benefit? • Which approach is better?	• sample representative of reference population	• randomization process • adherence to protocol • attrition/withdrawal • blinding – patient – provider – data collector	• quantitative measure of outcomes – adjusted for confounders • yes/no for outcome • % experimental / % control	• mean, standard deviation – t-test – analysis of variance – multivariate analysis • Chi square, logistic regression • RR relative risk
Non-randomized Trial	• Natural groups or allocation with nonrandom procedure • Investigator manages exposure to the causal agent • Prospective • Confounders-other factors could affect intervention and/or outcome	• Effectiveness--does it work? • What is the magnitude of effect? • What proportion benefit? • Which approach is better?	• sample representative of reference population	• selectivity bias within groups, baseline differences • details of intervention • attrition/follow up • blinding – patient – provider – data collector	•quantitative measure of outcomes – adjusted for confounders and covariates • yes/no for outcome •% experimental / % control	• mean, standard deviation – t-test – analysis of variance – multivariate analysis • Chi square, logistic regression • RR relative risk
Cohort Study	• Group, identified with common characteristic, followed forward in time • No investigator manipulation, analytical • Prospective • "Exposure" data collected before outcome • Can establish temporal sequence	• Does "exposure" lead to "outcome"? • What proportion develops the outcome? • Is there a dose response? • What are the "protective" and the "risk" factors?	• sample representative of reference population	• large enough sample to pick up outcome events • period between exposure and onset • Confounders assessed • Follow up (80%)	• yes/no for outcome • % with outcome in each group • stratified by subgroups • adjusted for confounders	• logistic regression • RR relative risk • Chi square • multivariate analysis
Case-control Study	• People with disease (cases) matched with people without (controls) • Look back in time for past exposure to factor • No investigator manipulation, analytical • Retrospective, survey or record review • Association only	• Is outcome associated with presence of factor? • What are risk factors? • What are protective factors? • Is there a dose response?	• sample representative of reference population	• good match between cases and controls/bias • recall bias • ability to find exposure data • blinded data collectors	• proportion (%) with exposure to factor in each group • stratified by subgroups • adjusted for confounders	• OR odds ratio • multivariate analysis • multivariate analysis
Cross-sectional Study	• Group identified by some characteristic (outcome) • Look once, exposure and outcome collected at same time • No investigator manipulation • Association only	• Is outcome associated with presence of factor? • What factors are correlated? • Are there clues to suggested a more rigorous study is indicated?	• sample representative of reference population • biologically plausible	• recall bias • blinded data collectors	• % with factor in each group • stratified by subgroups • adjusted for confounders	• OR odds ratio • multivariate analysis • multivariate analysis
Case Series	• Patients defined by diagnosis or treatment • Followed prospectively • Observational study, no investigator manipulation	• What is the experience of a set of patients with a disease in common? • What are the details of care provided?	• not representative of reference population	• all cases in time period • inclusion/exclusion criteria • consistent measurement • investigator bias	• data for each subject shown on table • quantitative • qualitative/subjective	• simple descriptive statistics • means, std deviation • range • frequency • percent