AMERICAN DIETETIC ASSOCIATION

Scientific Affairs & Research

ADA Evidence Analysis Manual

SCIENTIFIC AFFAIRS & RESEARCH

ADA Evidence Analysis Manual

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Table of Contents

Preface

How to Use This Manual.

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

Evidence analysis is a complex process.

This manual breaks the process down into concrete parts. A distinction is made between the general *steps* of a project, and the more concrete *actions* within each step.

Table 1 presents the major Steps in the evidence analysis process. Each chapter in this manual corresponds to a step in the evidence analysis process.

Table 1. Steps of the Evidence Analysis Process

Steps of the Evidence Analysis Process	Brief Description
Step 1 Formulate Evidence Analysis Question Chapter 1	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 (PICO format). *Tool: Formulating the Question Template, Appendix 1*
Step 2 Conduct Literature Review for Each Question Chapter 2	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 are: A, B, C, D, M, R, and X.) *Tools: Classes of Evidence Reports, Appendix 2* *Search Plan & Results Tool, Appendix 3*

Step 3 Critically Appraise Each Report Chapter 3	Review each report for relevance to the question and use the checklist of questions to evaluate the research design and implementation. Abstract key information from the report. *Tools: Evidence Abstract, Appendix 4* *Quality Rating sheets, Appendix 5* *Quality Rating Criteria Checklists, Appendix 5, 6*
Step 4 Summarize Evidence Chapter 4	Synthesize the reports into an overview table and summary of the research relevant to the question. *Tools: Overview Table* *Evidence Summary*
Step 5 Develop Conclusion Statement and Assign Grade Chapter 5	Develop a concise conclusion statement (the answer to the question). 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 11*

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 based on practical needs is one of the most effective ways to identify what research 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

Ask Good Questions

Evidence analysis questions are developed by a panel of experts in a particular topic area.

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 and prioritize a list of the most important questions for practice in a given topic area.

An expert workgroup is appointed for each topic. It is the responsibility of the workgroup to formulate appropriate questions for evidence analysis. These questions give us the ability to approach the research in a focused and systematic manner. After the questions are formulated, the relevant research to answer the question is identified, abstracted and critically appraised according to widely accepted methods. The goal is to translate the best available evidence into an answer to the question 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 to 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, there are tools to help 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.

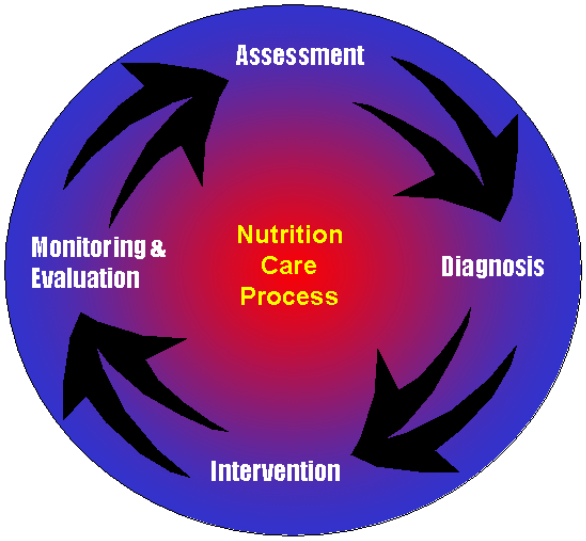
3. Formulate questions that focus on the relationship between different factors in the nutritional care process and the range of important outcomes.

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

Figure 1.0.b Nutrition Care Process



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 assessment factors, relevant diagnoses, range of interventions, and the intended outcomes 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.

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 focus 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

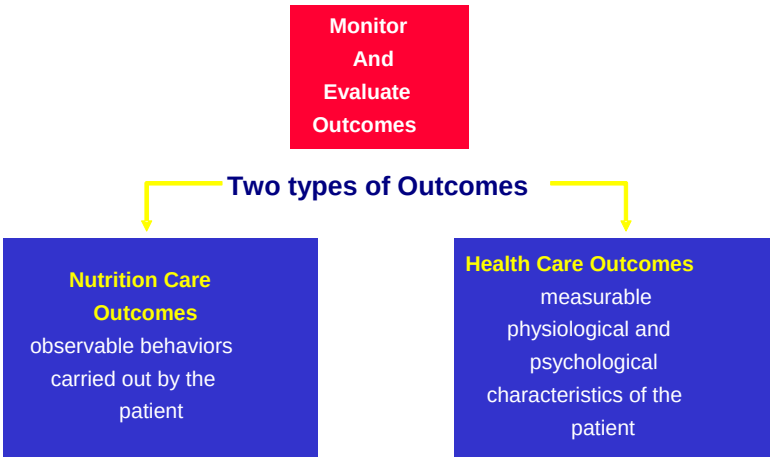
mind can help to keep the focus on practice.

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

Health Care Outcomes:
measurable physiological and psychological patient characteristics.

Nutrition Outcomes:
observable patient behaviors.

Figure 1.1 Two Types of Medical Nutrition Therapy Outcomes



We begin the process by asking ourselves: What outcomes do we anticipate from nutrition intervention in this area of practice? Defining these, we then turn to asking the same question about health care 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 current and potential types and variations of nutrition interventions are in most need of evidence analysis. Consider:

- Common interventions that may or may not be 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 will call for different intervention methods and content. The expertise from the workgroup is needed to identify interventions to include in the evidence analysis process.

There are many different aspects of nutrition intervention. For the purposes of organizing the work 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
Intervention Focus	What is the specific content area?	▪ Altered energy needs ▪ Behavioral strategies to change intake ▪ Change caloric density of food or formula
Intervention Strategy	How is it delivered? Who is provider?	Nutrition education or counseling 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? (How long, how much?)	Frequency and duration of sessions Group versus individual sessions In-patient, community, worksite, etc.

Do 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 focus of the intervention may be relevant. In others, it may be important to examine the evidence for intervention strategies.

The expert work 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

Assessment factors identified for evidence analysis may be different for different nutrition related problems.

Ask yourself the following questions:

For the nutrition-related problem,

- Does research indicate which types of assessment methods and indicators are more relevant in the assessment process?
- Does research indicate what assessment tools are most appropriate?
- Does research indicate the appropriate range of values for relevant indicators?

Tip: When creating evidence based guides in areas where a MNT Protocol already exists, one strategy may be for the expert work group to begin with the outcome, intervention, and assessment factors identified in the protocol. Where this is not the case, the work 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 hypothesis about a relationship: What is the evidence to suggest that there is some association between an intervention or assessment method and some expected outcome?

The Question Formulation Template can help identify the critical relationships. After filling in the specific outcome, intervention, diagnosis 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 an expert panel might use the Question Formulation Template to identify the important relationships for the evidence analysis.

Figure 1.2. Example Question Formulation Template

Assessment Or Diagnosis Factors	Intervention	Nutrition Care Outcomes	Health Care Outcomes
Factor	Intervention	Outcome	Outcome
Factors	Intervention	Outcome	Outcome
Factor	Intervention	Outcome	Outcome

Three relationships are identified in Figure 1.2:

- The relationship between a particular assessment and intervention
- The relationship between the intervention and a nutrition care outcome
- The relationship between the nutrition care outcome and a healthcare outcome

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

It is 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 prioritize the most important relationships between factors in each step of the nutrition care process.

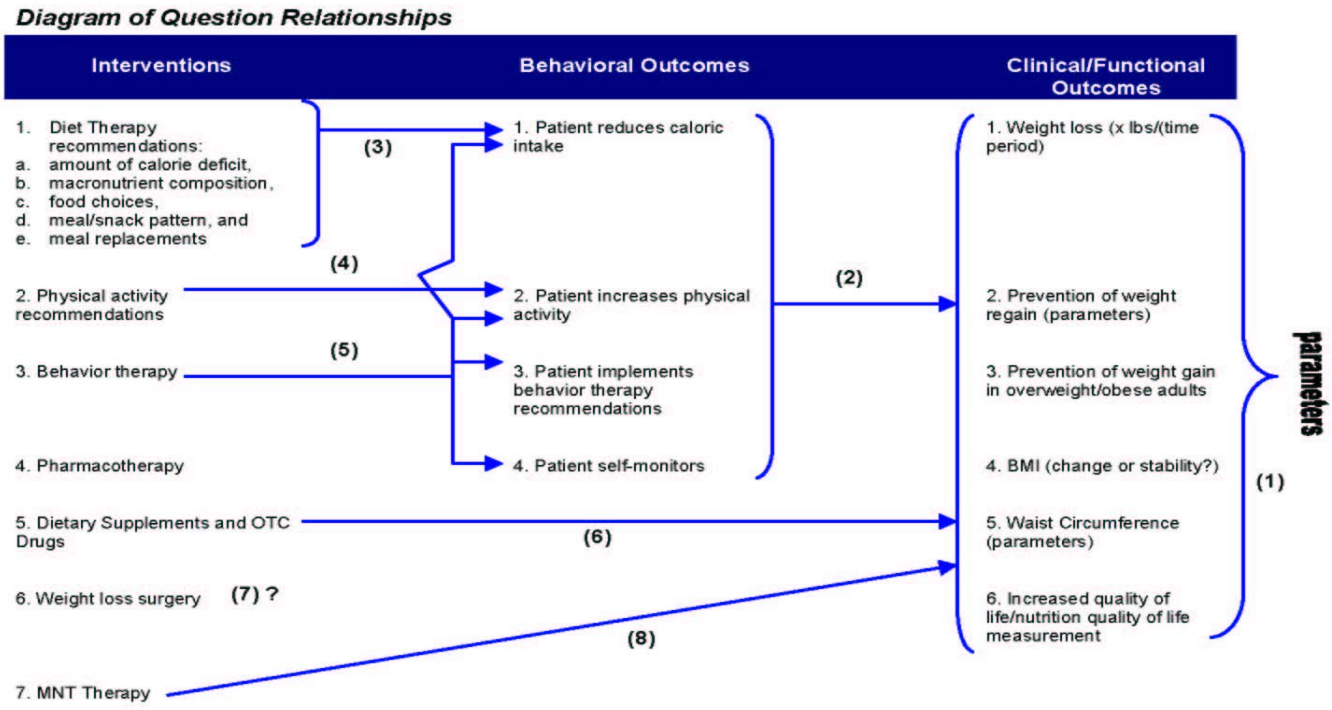
Consider:

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

Tip: The Standardized Language for the Nutrition Care Process should be referred to for ideas and recommended terminology for nutrition diagnosis, nutrition intervention and nutrition care outcomes.

Reference: International Dietetics & Nutrition Terminology (IDNT) Reference Manual. Standardized Language for the Nutrition Care Process ©2008.

Figure 1.2.a. Example of Question Factor Diagram



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

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**:**

(P) Population with a specific problem

(I) Intervention, procedure, or approach (for example, the type, amount, or timing of MNT)

(C) Comparison intervention (other approaches to care, or a "gold standard")

(O) Outcome of interest

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

Figure 1.3 Evidence Analysis Questions using PICO format

	Population (Patient or Problem)	**Intervention** (cause treatment, or prognostic factor)	**Comparison Intervention** (if necessary)	**Outcomes**
TIPS For Building	Describe group (of patients). Balance precision with brevity	What intervention are you considering? **Be specific.**	What is the main alternative to compare with the intervention. **Be Specific**	What could this intervention really affect? **Be specific**
Example:	Patients with chronic heart failure.	Daily caffeine intake	No caffeine intake	Affect blood pressure?

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:

- How effective, in terms of weight loss and maintenance, are low carbohydrate diets (defined as <35% kcals from carbohydrate)?

- What is the relationship between consuming nuts and the risk of coronary heart disease?

In the above two questions the population is not explicitly named (overweight adults, healthy adults) since the context of the question (adult weight management, disorders of lipid metabolism evidence analysis projects) provides the 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 for adults with weight issues?

- Among overweight and obese adults, what factors indicate 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 the onset of unintentional weight loss in nursing home residents?

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 most effective intervention for reducing serum LDL-C: access to US Dietary Guidelines for Americans, MNT for hyperlipidemia provided by a registered dietitian, or physician-provided dietary advice?

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

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

- Is the recommendation to increase fish consumption associated with mercury?

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 narrowed down to the most relevant and important aspect of the overall question. 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 or refocused.

Chapter 2

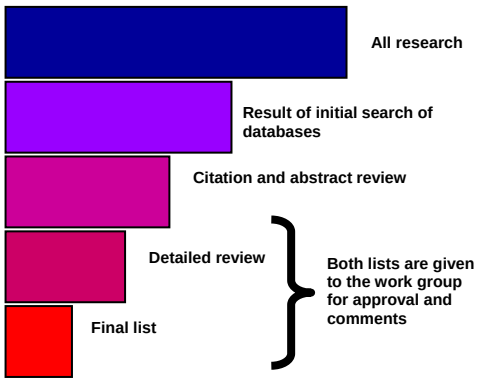
Step 2: Gathering and Classifying Evidence Reports

Finding the Best, Most Appropriate Research

After the expert work group has decided on the questions that focus the evidence analysis, the task of finding the best, most appropriate research begins. This process involves several actions:

- Develop a search plan with inclusion/exclusion criteria specified by the expert work group
- Conduct search of sources (databases, bibliographies)
- Review citation and abstracts
- Gather articles meeting criteria
- Construct a Search Plan & Results through detailed examination of included and excluded 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). The goal is to find the best available research articles that answer each question the expert panel has developed. The result will be a final list of articles to be abstracted, as well as a list of articles that were excluded following the citation and abstract review along with the reason(s) for their exclusion.

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: Identify Research that is Relevant to the Evidence Analysis Question

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?

For each specific question, determine whether there are any additional inclusion and exclusion criteria.

The following list provides an overview of the steps which 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. Write out the search strategy and document adjustments to the strategy if they occur. Allow for several iterations of searches.

    - List inclusion and exclusion criteria. The work group will define the inclusion and exclusion criteria. These criteria will be used in defining the search strategy and for filtering the identified research reports.

    - Identify search words. During the process of considering outcomes, interventions, nutrition diagnoses, and assessments, the work group may have identified a number of specific terms or factors that were important, but were not included in the actual question. These terms can be used as additional search terms to help identify relevant pieces of research. Both text word search and keyword search using MeSH definitions may be used.

    - Identify databases to search. PubMed, Medline, CINAHL, EMBASE, Cochrane, Agricola, DARE, TRIP, AHRQ and ERIC are some common databases for clinical nutritional research. Note that search terms can vary depending on the index method used for each database.

2. Conduct the search. Depending on the number and type of sources found in 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 search plan should be recorded for future reference. Document the number of sources identified in each search.

3. Review titles and abstracts. At this point, a filtering procedure is used to determine whether a research article matches the inclusion criteria and is relevant

to the work group's questions. Typically, the lead analyst with a member of the expert work group, first reviews the citations and abstracts to filter out reports that are not applicable to the question. If a determination can not be made based on the citation and abstract, then the full text of the article is obtained for review.

4. Gather all remaining articles and reports. Gather paper or electronic copies of research articles. If there are less than eight citations, it could mean that the search was too specific to identify relevant research or that research has not been done on this topic. A broadened search should be tried. 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 strategy may be necessary.

2.2 Action 2: Document the Search Strategy

Document all steps on the Search Plan & Results tool:

- The Search Plan lists the inclusion/exclusion criteria specified by the expert work group.
- Record the search terms and databases searched in the Search Plan tool.
- The Search Plan identifies the research articles and reports to be included in the evidence analysis after the initial citation and abstract review.
- The Search Plan 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 process distinct is the rigor with which we choose the research to include in the analysis. Document the criteria 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, it 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 some research articles and not others meet our criteria strengthens the claim to have chosen the best, most appropriate research.

THE REASON FOR EXCUDING ARTICLES FROM THE EVIDENCE ANALYSIS IS DOCUMENTED IN THE SEARCH PLAN & RESULTS TEMPLATE

Constructing the Search Plan & Results

Depending on the number of the research articles and reports identified, the list of articles may be quite simple, or rather complex.

Remember, the goal is to identify the highest quality pieces of research.[1] For some questions, you may not be able to find a sufficient number of high quality articles. For other questions, you may find an abundance of good research.

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

- How well does the research answer the specific question being asked?
- 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 expert work group identified as important (e.g., stage of disease, use of measurement devices, location of study participants)?

Articles Library

Every article that is included in the evidence analysis is added to the Articles Library in the Online Portal. Abstractors or analysts are able to download a PDF file of the article to read, review and abstract. Expert work group members also have access to the full text of the articles. Articles are added to the Online Portal Articles Library according to the last name of the first author of the research study.

[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. ADA does not limit a question 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 generally 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.

Example Search Plan & Results

Table 2.0 Search Plan and Results

Question

What evidence suggests a relationship between fruit and vegetable intake and blood pressure in healthy and hypertensive adults?

Date of Literature Review for the Evidence Analysis

August 2005

Inclusion Criteria

- Age: Adults (20 years and older)
- Setting: Outpatient and ambulatory care
- Health Status: Any
- Nutrition Related Problem/Condition: Healthy and hypertensive adults without co-morbid conditions or with the following co-morbid conditions: overweight, obesity, diabetes mellitus (types 1 &2), hyperlipidemia
- Study Design Preference: 1) RCT or Clinical Controlled Studies, 2) Large randomized observational studies, 3) Cohort.
- Size of Study Groups: The sample size must equal 10 individuals for each study group. For example, this would include 10 patients in the intervention group and 10 patients in the control or comparison group.
- Study Drop Out Rate: <20%
- Year Range: 2000 – 2005
- Authorship: 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. If an author is included on more than one review or primary research article and the outcome is different, then both reviews may be accepted.
- Language: Limited to articles published in English.

Exclusion Criteria

- Age: Young adults less than 20 years of age, infants, children, and adolescents.
- Setting: Inpatient or acute care
- Health Status: Patients with poor prognosis
- Nutrition Related Problem/Condition: Critical illness and other diseases and conditions
- Study Design Preference:
- Size of study groups: <10 individuals for each study group. For example, this would include 10 patients in the intervention group and 10 patients in the control or comparison group.
- Study Drop Out Rate: >20%
- Year Range: Prior to 2000
- Authorship: Studies by same author similar in content
- Language: Articles not published in English.

Search Terms: Search Vocabulary

Health Condition:
hypertension, hypertensive, blood pressure

Intervention:
dietary fiber, insoluble fiber, fruit vegetable

Type of Study Design:
RCTs, Clinical Studies, Observational Studies, Cohort and Case-Control Studies

Electronic Databases

Database: Pubmed

Search Terms: (adults) and (hypertens* or blood pressure) and (dietary fiber or insoluble fiber or fruit or vegetable)

Hits: 194

Articles to review: 12
CENTRAL database not used.
Other databases not used.

Total articles identified to review from electronic databases: 194

Inclusion List:

List of Articles Included from Electronic Databases

Alonso A, de la Fuente C, Martin-Arnau AM, de Irala J, Martinez JA, Martinez-Gonzalez MA. Fruit and vegetable consumption is inversely associated with blood pressure in a Mediterranean population with a high vegetable-fat intake: the Seguimiento Universidad de Navarra (SUN) study. *Br J Nutr* 2004;92(2):311-319.

Beitz R, Mensink GB, Fischer B. Blood pressure and vitamin C and fruit and vegetable intake. *Ann Nutr Metab* 2003;47(5):214-220.

Broekmans WM, Klopping-Ketelaars WA, Kluft C, van den Berg H, Kok FJ, van Poppel G. Fruit and vegetables and cardiovascular risk profile: a diet controlled intervention study. *Eur J Clin Nutr* 2001;55(8):636-642.

Conlin PR, Chow D, Miller ER 3rd, Svetkey LP, Lin PH, Harsha DW, Moore TJ, Sacks FM, Appel LJ. The effect of dietary pattern on blood pressure control in hypertensive patients: results from the Dietary Approaches to Stop Hypertension (DASH) trial. *Am J Hypertens* 2000;13(9):949-955.

John JH, Ziebland S, Yudkin P, Roe LS, Neil HA, Oxford Fruit and Vegetable Study Group. Effects of fruit and vegetable consumption on plasma antioxidant concentrations and blood pressure: a randomized controlled trial. *Lancet* 2002;359(9322):1969-1974.

Miura K, Greenland P, Stamler J, Liu K, Daviglus ML, Nakagawa H. Relation of vegetable, fruit and meat intake to 7-year blood pressure change in middle-aged men: the Chicago Western Electric Study. *Am J Epidemiol* 2004;159(6):572-580.

Moore TJ, Conlin PR, Svetkey LP. DASH (Dietary Approaches to Stop Hypertension) diet is effective for stage 1 isolated systolic hypertension. *Hypertension* 2001;38(2):155-158.

Nowson CA, Worsley A, Margerison C, Jorna MK, Frame AG, Torres SJ, Godfrey SJ. Blood pressure response to dietary modifications in free-living individuals. *J Nutr* 2004;134(9):2322-2329.

Nowson CA, Worsley A, Margerison C, Jorna MK, Godfrey SJ, Booth A. Blood pressure change with weight loss is affected by diet type in men. *Am J Clin Nutr* 2005;81(5):983-989.

List of Articles Included from Handsearch or Other Means
No other articles identified.

List of Excluded Articles with Reason:

Excluded Articles	Reason for Exclusion
Hajjar I, Kotchen T. Regional variations of blood pressure in the United States are associated with regional variations in dietary intakes: the NHANES-III data. *J Nutr* 2003; 133(1):211-214.	Did not address fruits and vegetables
Streppel MT, Arends LR, van 't Veer P, Grobbee DR, Geleijnse JM. Dietary fiber and blood pressure: a meta-analysis of randomized placebo-controlled trials. *Arch Intern Med* 2005;165(2):150-156.	Did not address fruits and vegetables
Whelton SP, Hyre AD, Pedersen B, Yi Y, Whelton PK, He J. Effect of dietary fiber intake on blood pressure: a meta-analysis of randomized, controlled, clinical trials. *J Hypertens* 2005; 23(3):475-481.	Did not address fruits and vegetables

Summary of Articles Identified to Review:

Number of Primary Articles Identified: 9

Number of Review Articles Identified: 0

Total Number of Articles Identified: 9

Number of Articles Reviewed but Excluded: 3

The next step is the work of analyzing the research articles.

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

Document the type of research design for each included article.

In some situations the eligibility of a research report depends on the research design used. For example, in questions about the effectiveness of a treatment or intervention, a randomized controlled trial is the preferred research design; however, questions about etiology, causation or harm are best answered with cohort or case control research designs; diagnosis and screening questions can be answered with cross-sectional designs; and natural history and prognosis questions use cohort designs. There might not be much research available for new and emerging areas of practice or for practices that historically have been accepted as usual practice. In these situations, which are common in dietetics, all research designs are included but greater weight is given to results from studies using designs at the top of the hierarchy.

First, divide the studies and reports listed on the Search Plan and Results template into two categories: primary research (original studies) and secondary research, (review, meta-analysis and/or 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 shows the classification system used by ADA. A more comprehensive presentation of the different elements in the classification system as well as a glossary of research terms are presented in Appendix 3. The type of research design is determined during the critical appraisal step and recorded on the quality checklist template.

Table 2.3. Hierarchy and Classification of Studies[2]

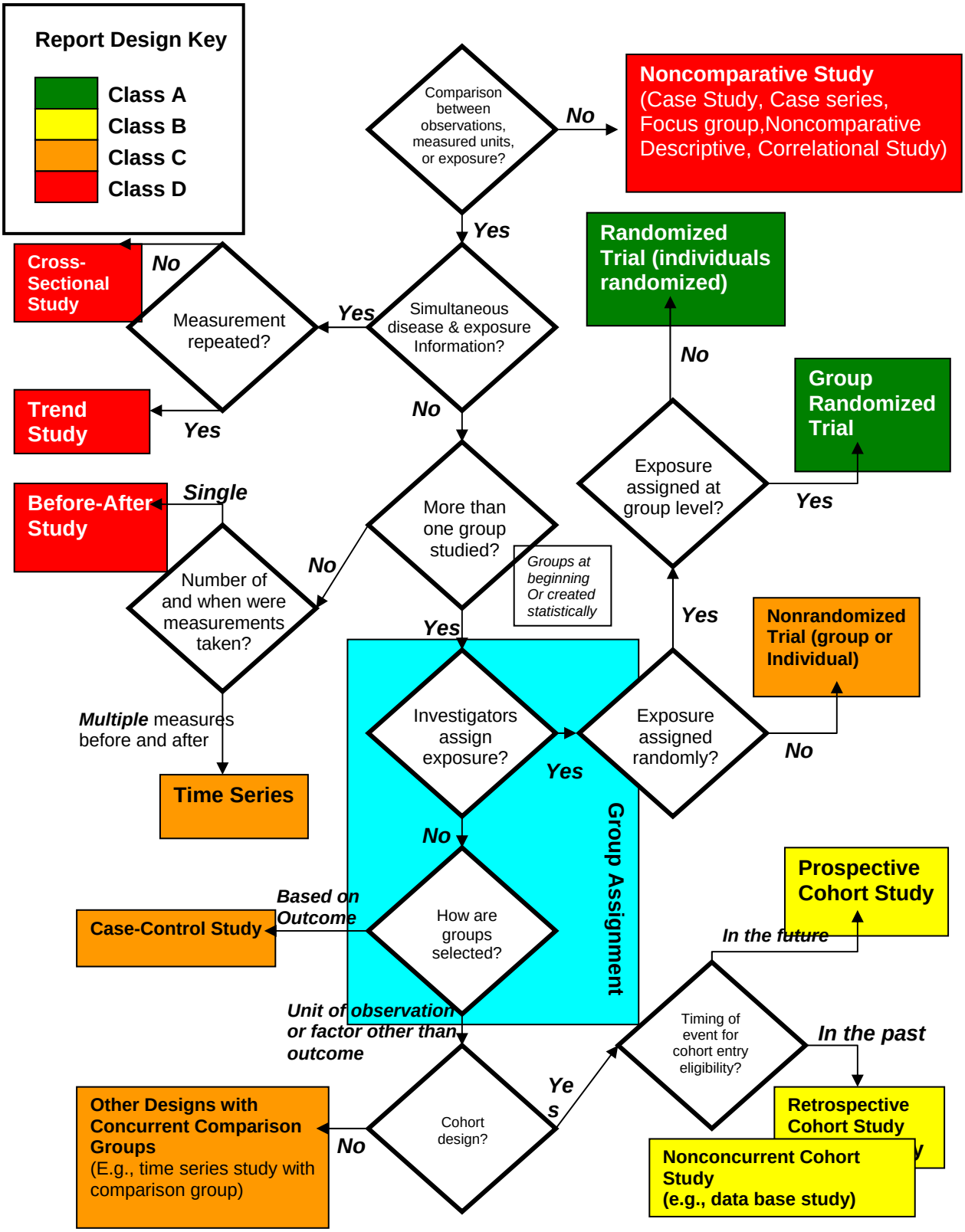
Primary Reports		Secondary Reports	
A	Randomized controlled trial (RCT)	M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Cohort study		
C	Nonrandomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Time series	R	Narrative review (Review article) Consensus statement Consensus report
D	Cross-sectional study Trend 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 Algorithm for classifying the research designs of primary studies. This is done when the article is reviewed and appraised.

Classifying 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.

[2] Adapted from © Joint Commission Resources: "A Practical Approach to Evidence Grading". Joint Commission Journal on Quality Improvement 2000:Volume 26(12):707

Figure 2.3. Algorithm for Classifying the Research Design of Primary Studies



Chapter 3

Step 3: Critically Appraise Each Report

Instructions for Abstracting an article onto the Evidence Worksheet

An abstractor or analyst is responsible for critically reviewing each research article 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 (answer to the question) and grade the strength of the evidence. The information from all worksheets becomes part of the Evidence Overview 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.a and Table 3.1.b.
- *Quality Criteria Checklists*: checklists of questions to help you determine the relevance and validity of primary and review articles—found in Table 3.2.b and in the Appendices section
- Study Design Table: a table that indicates which 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 included article on the *Search Plan & Results*.

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

Before you attempt to abstract details about the study into the worksheet, you will need to read carefully the article. 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 limitations 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 report to determine the 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 constructs and domains indentified in the AHRQ report on *Systems to Rate the Strength of Scientific Evidence.*

Review Articles

Most review articles are organized in the same way as primary research reports. The difference is that in reviews, published research studies are the "subjects" in the study. Look

in 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 validity 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.

[3]Table 3.1.a. What to Abstract from Primary Research Report

Citation:	List the complete bibliographical citation
Study Design:	Name of the study design. Refer to algorithm
Class:	(A, B, C, D) Based on classes of evidence reports (Table 2.3)
Quality Rating:	(+, Ø, -) Based on quality criteria checklist
Research Purpose:	Research question being investigated in study
Inclusion Criteria:	Requirement for study eligibility
Exclusion Criteria:	Items that disqualify an individual from participation in study.
Description of 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 Summary:	Outcome(s) and other indicators Important variables and methods of measurement Was blinding use?
Description of Actual Data Sample:	Relevant descriptors of sample and comparison of groups at baseline Note loss of subjects (withdrawals, dropout, response rate, etc.)

Summary of Results:	Abstract results including quantitative data and statistics. Be specific. Often tables are created in this section. (Include statistical significance – P values, confidence intervals, relative risk, odds ratios, likelihood ratio, number needed to treat, if available)
Author Conclusion:	As stated by the author in body of report
Reviewer Comments:	*Note strengths and limitations of the study. Identify concerns that affect study validity and generalizability (Always italicize)*

Table 3.1.b. What to Abstract from Review Article

Citation:	List the complete bibliographical citation
Study Design:	Type of review (systematic, narrative, meta-analysis)
Class:	(M, R, X) Based on classes of evidence reports
Quality Rating:	(+, Ø, -) Based on quality criteria checklist
Research Purpose:	Question being addressed in the research
Inclusion Criteria:	Criteria for article inclusion
Exclusion Criteria:	Why articles were excluded from review.
Description of Study Protocol:	Search procedures Was study quality assessed? Type of interventions and outcomes investigated, populations included
Data Collection Summary:	What type of information was abstracted from articles? How was it combined? What analytic methods were used, if any?
Description of Actual Data Sample:	# of articles included # of articles identified Number and type of studies reviewed Sample size of studies, and characteristics of the study participants
Summary of Results:	What are the main results of the review? Be specific. Abstract results including quantitative data and statistics, especially effect sizes Tables that summarize results can be useful.
Author Conclusion:	As stated by the author in body of report
Reviewer Comments:	*Note strengths and limitations of the review. Identify concerns that affect the validity of the review. How generalizable are the findings? (Always italicize)*

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 criteria are written in the form of yes/no questions to help the abstractor or analyst examine the report for important details about the design of the study and its execution. Finally, the reviewer uses the *Checklist* to assign an overall rating to the study. A symbol indicating positive (+), neutral (∅), or negative (-) is selected from the dropdown tool on the *Evidence Worksheet* to assign the 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 abstractor or analyst becomes more familiar with the research area and the use of the *Evidence Worksheet* and the *Checklist*.[1]

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 rating of primary research and review articles
- To support inter-rater agreement among reviewers/abstractors

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 practice, and ten validity questions that address scientific soundness. The relevance questions and validity questions make up the criteria. These detailed checklists should guide the abstractor or analyst and help him/her to recognize various threats that may undermine sound research and can lead to invalid conclusions.

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It is assumed that users of the *Quality Criteria Checklists* will have a graduate degree, an understanding of research and statistics, and will have completed training in ADA's Evidence Library Training Workshop.

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 procedures (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?**	Yes No
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 selection of study subjects/patients free from bias?**	Yes No
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 study groups comparable?**	Yes No
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")?	
4.	**Was method of handling <u>withdrawals</u> described?**	Yes No
4.1	Were follow-up methods described and th 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 funding or sponsorship unlikely?**	Yes No
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

The *Quality Criteria Checklist: Review Articles* has ten validity questions that incorporate the AHRQ 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	Yes	No

	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?	
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 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. Recent systematic reviews published in the peer reviewed literature can earn a positive (+) rating.

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 abstractors or analysts (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" indicates that the 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 Questions* (found in Table 3.2.c and in the Appendices section) identifies sub-questions that are the most important consideration for each type of study. A well-planned and well-executed study would address these points, plus others, in the report.

Occasionally, a major question is not applicable (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 designation (minus -, neutral ∅, or plus +). The final determination is 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 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 Display all Checklists Relevant to a Particular Question in a Single Table

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 information into an easy to use format. All checklists are connected to worksheets linked to the same evidence analysis question are compiled into a table electronically. The table is automatically linked to the evidence summary. See Table 3.3.

Members of the expert workgroup can quickly view the answers to the questions in the Quality Criteria Checklist in a side-by-side comparison for each research study that is relevant to a particular question. This information will assist them when they make a determination about the grade or strength of the evidence available to answer the question. Likewise, users of the evidence library can also view this information in the tabular format. The side-by-side comparison of quality constructs and domains for each research article may assist the user's understanding of the rationale for the overall grade assigned by the expert workgroup. Publishing this table online is another example of ADA's commitment to transparency.

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 abstractor or analyst records the yes/no answers to each of the relevance and validity questions. The Expert Panel will use this table 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 / Search Plan & Results*
- *Abstracted Worksheets for each article*
- *Full text of each article*
- Quality Ratings/Quality Checklists

Chapter 4

Step 4: Creating the Overview Table and Writing the Evidence Summary

Summarizing the Body of Evidence

The Evidence Summary consists of two parts: the Overview Table and the narrative synthesis.

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

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 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 adds factors that the work group or the research indicates are important considerations when comparing and synthesizing research findings.

In most instances, the studies that have good research designs or large numbers of participants will be more important for writing the evidence summary than smaller samples and weaker studies.

Overview tables are handy tools for everyone 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, the team will need to decide what the critical comparison factors (the headings for the columns in the table) are for your topic and question.

AN OVERVIEW TABLE IF YOU ARE WORKING WITH A RELATIVELY SMALL NUMBER OF RESEARCH ARTICLES.

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?

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

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: 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.

4.6 Action 6: Preparing the Evidence Summary for the Work 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 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 expert work 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 work group's grading session.

Chapter 5

Step 5: Writing and Grading the Conclusion Statement

How Strong is the Evidence?

The final step in the evidence analysis process is the expert panel's writing and 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 Action 1: Draft a Preliminary Conclusion Statement

Now all the information is pulled together into a "bottom line" conclusion statement. What, overall, does the evidence tell us? What is the answer to the evidence analysis question?

Usually, the lead analyst drafts a preliminary conclusion statement that goes to the expert panel for consideration. Conclusion statements are written with practitioners in mind. The 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.

5.2 Grading the Strength of the Evidence Supporting the Conclusion 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

Error! Reference source not found. presents an example of factors and linkages among factors.

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 Nutrition Care Outcomes:

Questions linking Intervention Factors to Health Care Outcomes:

Sort List Table

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 Worksheet

<table>
<tr><td>Citation:</td><td></td></tr>
<tr><td>Study Design:</td><td></td></tr>
<tr><td>Class:</td><td>Based on classes of evidence reports (Table 2.3)</td></tr>
<tr><td>Quality Rating:</td><td>+, Ø , - Based on quality criteria checklist</td></tr>
<tr><td>Research Purpose:</td><td></td></tr>
<tr><td>Inclusion Criteria:</td><td></td></tr>
<tr><td>Exclusion Criteria:</td><td></td></tr>
<tr><td>Description of Study Protocol:</td><td>Recruitment
Design
Blinding used (if applicable)
Intervention (if applicable)
Statistical Analysis
(These prompts assist you in determining which information to abstract from research article.)</td></tr>
<tr><td>Data Collection Summary:</td><td>Timing of Measurements
Dependent Variables
• Variable 1: brief description (how measured?)
• Variable 2: brief description (how measured?)
• etc.
Independent Variables
Control Variables</td></tr>
<tr><td>Description of Actual Data Sample:</td><td>Initial N: (e.g., 731 (298 males, 433 females))
Attrition (final N):
Age:
Ethnicity:
Other relevant demographics:
Anthropometrics (e.g., were groups same or different on important measures)
Location:</td></tr>
<tr><td>Summary of Results:</td><td>
<table>
<tr><th>Variables</th><th>Treatment Group Measures and confidence intervals</th><th>Control group Measures and confidence intervals</th><th>Statistical Significance of Group Difference</th></tr>
<tr><td>Dep var 1</td><td>Mean, CI.
e.g., 4.5±2.2</td><td>Mean, CI.
e.g., 1.5±2.0</td><td>Stat signif difference between groups
e.g., p=.002</td></tr>
<tr><td>Dep var 2</td><td></td><td></td><td></td></tr>
<tr><td>Etc.</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Other Findings</td></tr>
</table>
</td></tr>
<tr><td>Author Conclusion:</td><td></td></tr>
<tr><td>Review Comments:</td><td>Italicize reviewer and expert panel comments.</td></tr>
</table>

Classes of Evidence Reports

Primary Reports		Secondary 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 Trend Study Case series Case report Before and after study	X	Medical opinion

Quality Rating Criteria Checklists: Primary Research and Review Article

Symbols Used

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

-- **Negative:** Indicates that these issues have not been adequately addressed.

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

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 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 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 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

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

Article	Classification	Quality Rating	Study Design	Sample	Intervention	Outcomes	Limitations

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 the addition of Grade V: Not Assignable in September 2004. As the work was accomplished by the Work 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.