

Evidence Analysis Manual:



**Steps in the Academy
Evidence Analysis Process**

Research and Strategic Business Development
Academy of Nutrition and Dietetics
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EVIDENCE ANALYSIS MANUAL: Steps in the Academy Evidence Analysis Process

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Preface

How to Use This Manual.

The *Evidence Analysis Manual* was created by the Academy of Nutrition and Dietetics (Academy) to help expert workgroup members 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.

Overview of the Manual

The manual is divided into two sections – main text and appendices:

- Main text: contains a description of each step along with examples from evidence analysis projects. These examples will help you see how the process was carried out successfully.
- Appendices: contains templates (worksheets, checklists, and other tools) of forms used in an online web-based format.

Table i on the following page presents the 5 major steps in the evidence analysis process. Each chapter in this manual corresponds to a step in this process and lists the tools used to accomplish them. They are explained in detail throughout the manual.

This manual is available in PDF format and online in the EAL > Methodology tab:
<http://www.adaevidencelibrary.com/category.cfm?cid=7&cat=0>

Table i. Steps of the Evidence Analysis Process

Steps of the Evidence Analysis Process	Brief Description	Tools
<p>Chapter 1</p> <p>Step 1 - Formulate Evidence Analysis Question</p>	<p>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).</p>	<p><i>Appendix 1: Question Formulation Template</i></p> <p><i>Appendix 2: The PICO Chart</i></p>
<p>Chapter 2</p> <p>Step 2 - Gather and Classify Evidence</p>	<p>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 secondary reports that include systematic and/or narrative review.</p> <p>(Classes are: A, B, C, D, M, R, and X.)</p>	<p><i>Appendix 3: Search Plan & Results Table</i></p> <p><i>Appendix 4: Classes of Evidence Reports</i></p> <p><i>Appendix 5: Algorithm for Classifying Research Design</i></p> <p><i>Appendix 6: Glossary of Research Design Terms</i></p>
<p>Chapter 3</p> <p>Step 3 - Critically Appraise Each Article</p>	<p>Review each article for relevance to the question and use the checklist of questions to evaluate the research design and implementation. Abstract key information from the report.</p>	<p><i>Appendix 7: Evidence Abstract Worksheet Template</i></p> <p><i>Appendix 8: Quality Criteria Checklist: Primary Research</i></p> <p><i>Appendix 9: Checklist: Primary Research Non human</i></p> <p><i>Appendix 10: Quality Criteria Checklist: Review Article</i></p> <p><i>Appendix 11: Important Considerations (from checklist) by Study Design</i></p> <p><i>Appendix 12: Tally of Primary Research Ratings</i></p> <p><i>Appendix 13: Tally Sheet Example</i></p>
<p>Chapter 4</p> <p>Step 4 - Summarize Evidence</p>	<p>Synthesize the reports into an overview table and summarize the research relevant to the question.</p>	<p><i>Appendix 14: Overview Table</i></p> <p><i>Appendix 15: Overview Table Example</i></p>
<p>Chapter 5</p> <p>Step 5 - Write and Grade the Conclusion Statement</p>	<p>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.</p> <p>(The Academy uses Grades I, II, III, IV, and V for strong, fair, weak, expert opinion only, and no evidence, respectively.)</p>	<p><i>Appendix 16: Conclusion Statement and Grade</i></p> <p><i>Appendix 17: Grade Definitions for Strength of Evidence for Conclusion</i></p> <p><i>Appendix 18: Grade Definition Table</i></p>

Step 1: Formulate Evidence Analysis Question

Analytic Framework to develop Questions for Evidence-Based Practice Guidelines

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 (Figure 1.0)

Figure 1.0 Connecting Practice Issues to Research

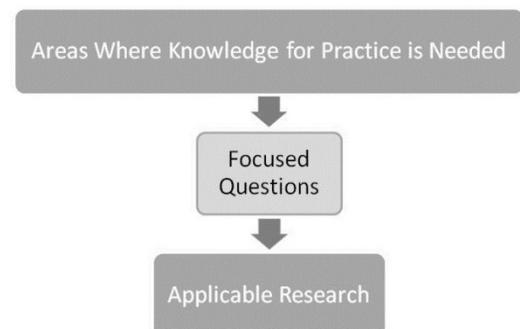


Figure 1.1 Good Questions



Ask Good Questions

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

The Academy, 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 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, consider 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 Academy House of Delegates adopted the Nutrition Care Process (NCP). This process includes four interrelated phases:

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

Figure 1.2 Nutrition Care Process

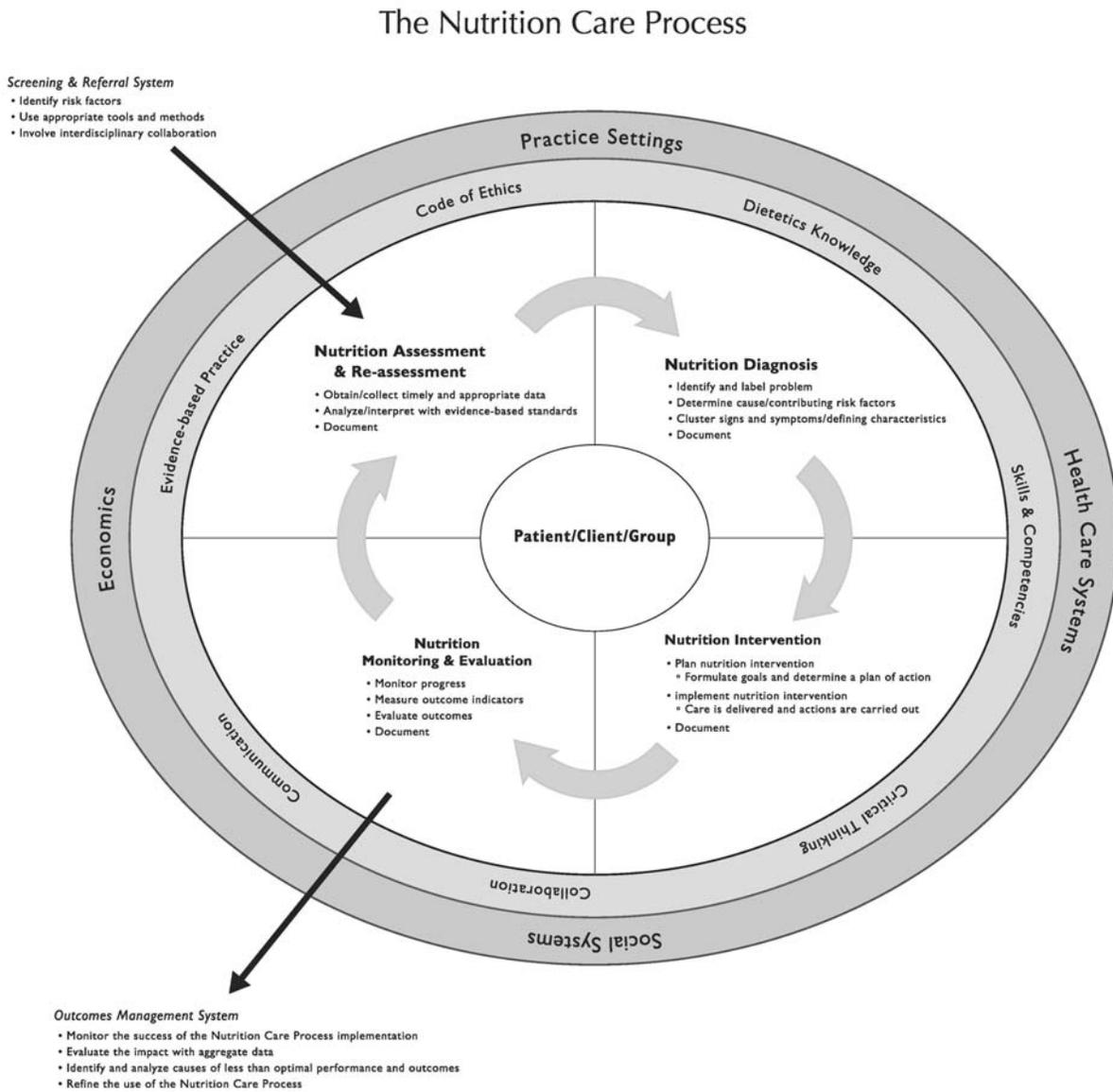


The nutrition care process can serve as the context for the way in which you formulate questions for evidence analysis. It is helpful to keep assessment factors, relevant diagnoses, range of interventions, and the intended outcomes in mind when formulating questions.

The Academy published the *International Dietetics & Nutrition Terminology (IDNT) Reference Manual and the IDNT Pocket Guide*, now in edition 3, to assist practitioners in implementing the Nutrition Care Process using Standardized Language for Nutrition Assessment, Nutrition Diagnosis, Nutrition Intervention and Nutrition Monitoring & Evaluation. The lists of nutrition related terminology are useful tools to review while developing evidence analysis questions. The Reference Manual is also available in an online format.

The Nutrition Care Process gives dietetics professionals a systematic structure to scientifically manage nutrition care and help patients meet health and nutrition goals. The Nutrition Care Process and Model is a visual representation that identifies factors that impact on the steps of the Nutrition Care Process. Note that screening and referral and outcomes management occur outside of the NCP model.

Figure 1.3 Nutrition Care Process and Model



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: What sorts of outcomes do we expect from nutritional care in this area of practice?

Identify Anticipated Outcomes

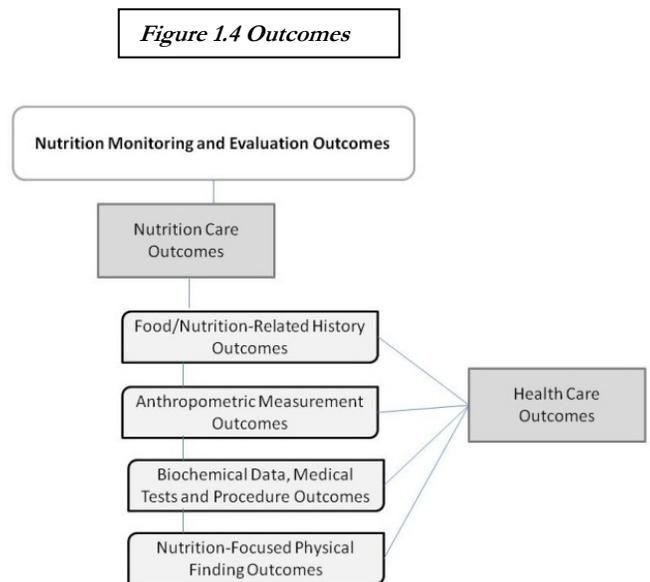
To begin the process, *start with the end in mind*. Starting with the end (the expected outcomes) will help to ensure that the focuses of the questions are related to the purpose of the guideline. There are many interesting *research* questions that might be asked, but many are not appropriate for nutritional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

This means that the question formulation process begins by looking at patient outcomes and distinguishing between nutrition care outcomes and health care outcomes (see Figure 1.4).

Monitoring and Evaluation Outcomes

Nutrition Monitoring and Evaluation Outcomes represent the dietetics practitioner’s specific contribution to care. These outcomes result directly from the Nutrition Care Process and include Food and Nutrition Related History, Anthropometric Measurements, Biochemical Data, Medical Tests and Procedures, and Nutrition Focused Physical Findings.

Nutrition Care Outcomes are often intermediate outcomes to broader health care outcomes. Adoption of the Nutrition Care Process should result in positive changes in nutrition care outcomes that in turn improve other health care outcomes. Nutrition Care Outcomes are distinguished by several characteristics.



Nutrition Care Outcomes:

- Represent results that the practitioner and/or nutrition care impacted independently
- Can be linked to nutrition intervention goals
- Are measurable with tools and resources available to the practitioner
- Occur in a reasonable time period
- Can be attributed to the nutrition care
- Are logical and biologically or psychologically plausible stepping stones to other health care outcomes (e.g., health and disease, cost, and patient outcomes)

Begin the evidence analysis question formulation process by asking: What outcomes do we anticipate from nutrition intervention in this area of practice? What changes would we expect to see in the patient/client 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.

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.

Nutrition Intervention consists of two interrelated components – planning and implementation. Planning involves prioritizing the nutrition diagnoses, conferring with the patient/client and/or others, reviewing practice guides and policies, and setting goals and defining specific nutrition intervention strategy. Implementation of the nutrition intervention is the action phase that includes carrying out and communicating the plan of care, continuing data collection, and revising the nutrition intervention strategy based on the patient/client response.

Nutrition Intervention is organized into four domains: Food and/or Nutrient Delivery, Nutrition Education, Nutrition Counseling and Coordination of Care. For the purposes of organizing the workgroup’s discussion for formulating evidence analysis questions, refer to each domain and identify relevant interventions (see Table 1.0).

Do not expect all domains of nutrition intervention to be relevant for evidence analysis in every nutrition related project.

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

Table 1.0 Domains of Nutritional Intervention

Nutrition Intervention Domains	Intervention Terms
Food and/or Nutrient Delivery	Meal and Snacks Enteral and Parenteral Nutrition Supplements Feeding Assistance Feeding Environment Nutrition Related Medication Management
Nutrition Education	Content Application
Nutrition Counseling	Theoretical Basis/Approach Strategies
Coordination of Nutrition Care	Coordination of other care during nutrition care Discharge and Transfer of Nutrition Care to new setting or provider

Identify Nutritional Assessment Factors

Nutrition Assessment is a systematic method for obtaining, verifying and interpreting data needed to identify nutrition related problems, their causes and significance. The five domains of nutrition assessment are: food/nutrition related history; biochemical data, medical tests and procedures; anthropometric measurements; nutrition-focused physical findings; and client history. Nutrition Assessment factors identified for evidence analysis may differ depending on the nutrition related problems.

Ask 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 which assessment tools are most appropriate?
- Does research indicate the appropriate range of values for relevant indicators?

For specific definitions and examples of nutrition assessment, nutrition intervention and nutrition outcomes, please refer to the *International Dietetics and Nutrition Terminology (IDNT) Reference Manual: Standardized Language for the Nutrition Care Process*.

Tip: When creating evidence based nutrition practice guidelines 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. If no MNT Protocol on the topic exists, then the work group will need to do some initial work to determine what factors are critical in each step of the nutrition care process.

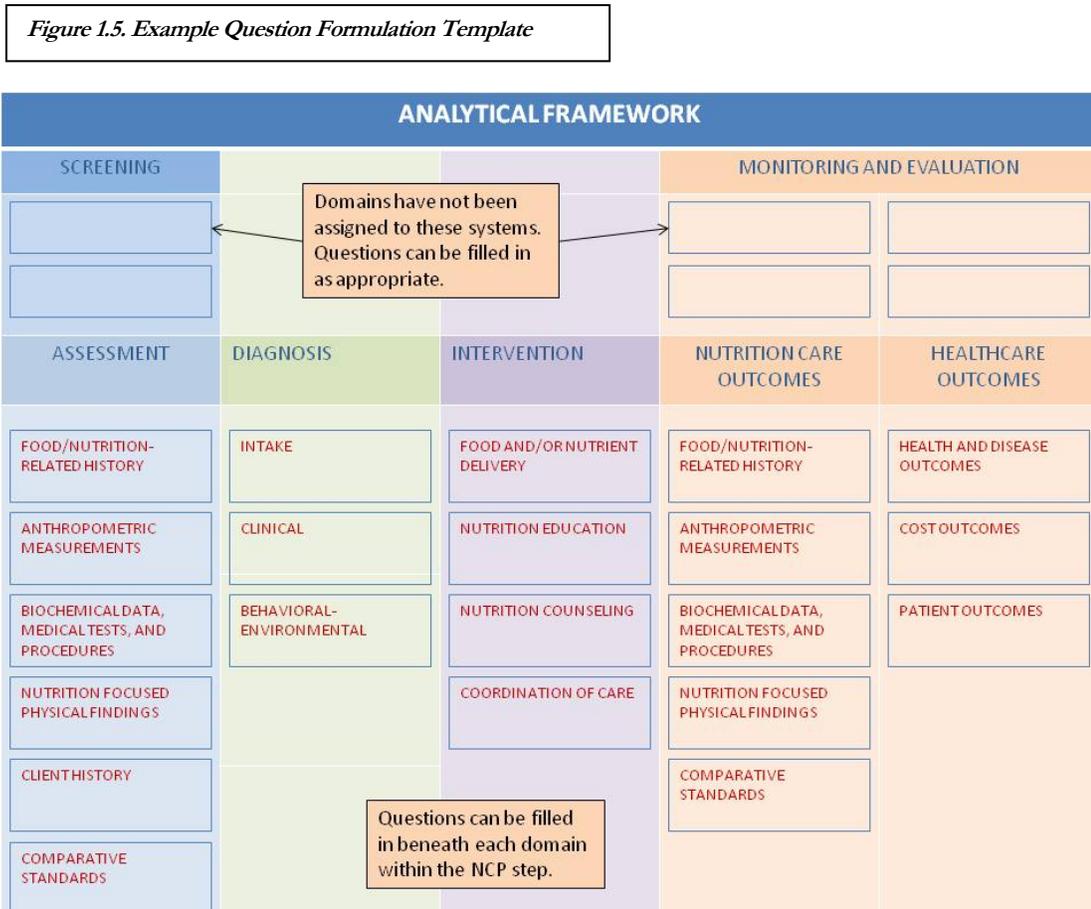
Reference: International Dietetics & Nutrition Terminology (IDNT) Reference Manual. Standardized Language for the Nutrition Care Process ©2011.

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.

The figure below presents an example of how an expert panel might use the Question Formulation Template to identify the important relationships for the evidence analysis.



The three relationships identified in the table are:

- The relationship between a particular assessment factor and an intervention
- The relationship between the intervention and a nutrition care outcome
- The relationship between the nutrition care outcome and a health care outcome

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

While it may be possible to link every factor in a list of assessment methods or intervention strategies to every expected outcome of the nutrition care process, 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.

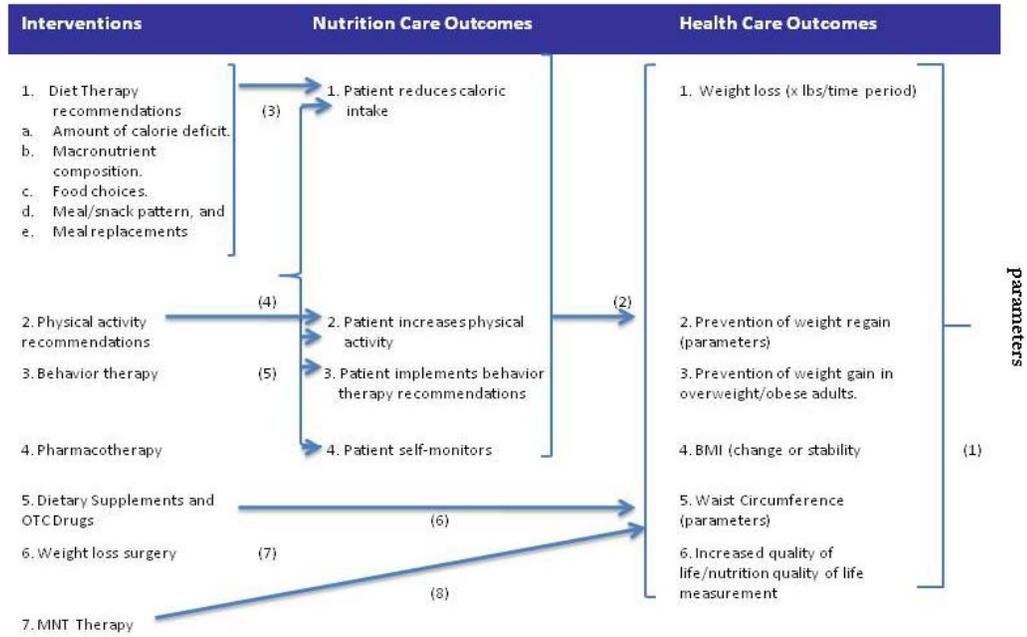
Consider the following factors:

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

Tip: The *International Dietetics & Nutrition Terminology Reference Manual* should be referred to for ideas and recommended terminology for nutrition assessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation outcomes.

Figure 1.6 Example of Question Factor Diagram

Diagram of Question Relationships



Formulate Questions: 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 Medical Nutrition Therapy)
- (C) Comparison intervention (other approaches to care)
- (O) Outcome of interest

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

Table 1.1 Evidence Analysis Question 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) in healthy adults?
- What is the relationship between consuming nuts and the risk of coronary heart disease in patients with hyperlipidemia?

Always explicitly include the population of interest in the question.

Different Purposes Call for Different Types of Questions

In evidence appraisal, four types of questions are used.

1. Diagnosis and Screening: Is a nutrition related problem or condition present? How do you determine when and how the problem is treated?

- 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 normogluucose 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 for healthy adults 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.

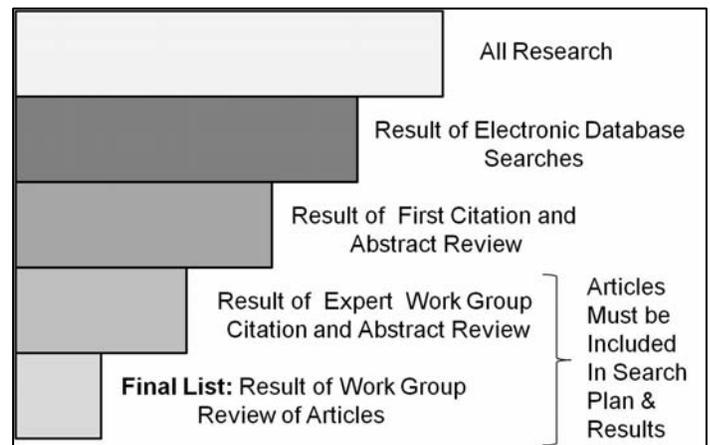
Step 2: Gather and Classify Evidence

Finding the Best, Most Appropriate Research

After the expert workgroup 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 using various sources (databases, bibliographies)
- Review citations 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. 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 any 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.

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 Academy 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 workgroup will define the inclusion and exclusion criteria. These criteria will be used in defining the search strategy and for filtering the identified research reports. The Academy uses only peer-reviewed research; that is, articles accepted for evidence analysis must be peer-reviewed and published in a juried publication. Additionally, the Academy does not include animal studies in its evidence analysis.
 - 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 to 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 workgroup's questions. Typically, the lead analyst with a member of the expert workgroup, first reviews the citations and abstracts to filter out reports that are not applicable to the question. If a determination cannot 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. Obtain paper or electronic copies of all research articles that remain on the list following the citation and abstract review. If there are less than six 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. When there is a long list of citations, ascertain whether it includes articles that are tangential to the question or address the question in only a general way. In this case a more focused search strategy may be necessary.

Document the Search Strategy

Document all steps on the Search Plan & Results tool:

- **Question:** Record the evidence analysis question on the Search Plan and Results Tool (see Table 2.0)
- **Date of Literature Review:** List the month and year of the last date included in the search. For example, if you search for articles published from January 2000 through August 2008, list August 2008. This allows users of the library to know that any articles published after August 2008 are not part of this review.
- **Inclusion Criteria:** Prior to the search, the inclusion criteria for age, setting, sample size, dropout rate, language, year range and other factors is determined by the expert work group. Only research that meets the criteria will be accepted for evidence analysis.

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

Why Include a List of Excluded Articles?

Part of what makes the Academy's evidence analysis process distinct is the rigor with which we choose the research to include in the analysis. Project managers document the criteria for including *and excluding* research. By providing the reader with a list of articles that were identified in the initial search, *but excluded* when it was determined that the article did not meet specific inclusion criteria (e.g., sample size too small), 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.

Articles Library on Academy Portal

Every article that is included in the evidence analysis project is added to the Articles Library in the Online Portal. Analysts 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.

Construct 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)?

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 of 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, Kluit 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, Daviglius 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. <i>J Nutr</i> 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	Did not address fruits and vegetables

<p>trials. <i>Arch Intern Med</i> 2005;165(2):150-156.</p>	
<p>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. <i>J Hypertens</i> 2005; 23(3):475-481.</p>	<p>Did not address fruits and vegetables</p>

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.

Classify the Articles by Type of Research Design

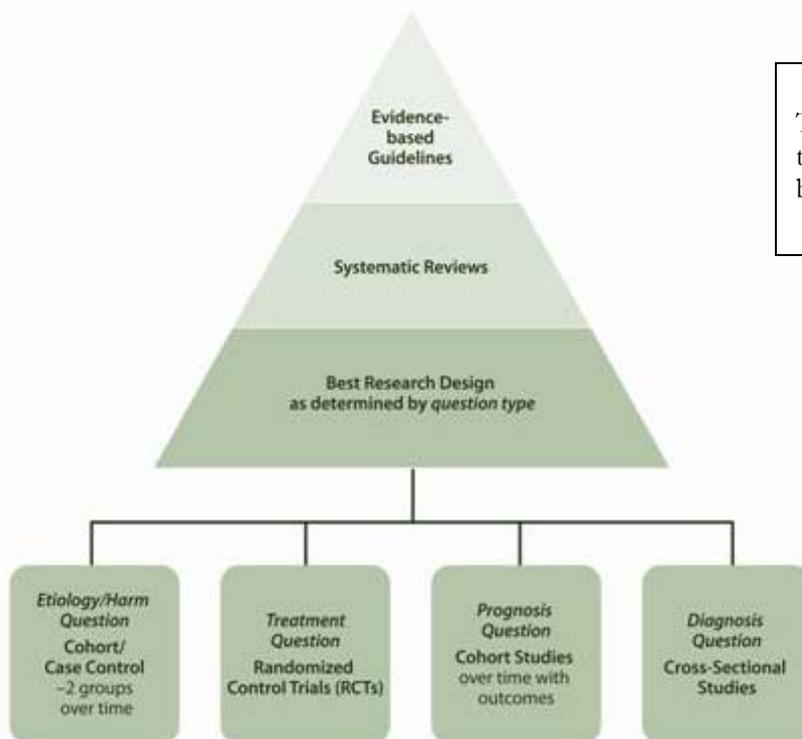
Which type of study is preferred?

The four most common types of evidence analysis questions are: diagnosis, treatment, prognosis and etiology. The type of question you are trying to answer determines the best research design to seek.

For instance, a randomized controlled trial (RCT) would be the most appropriate type of study to answer a question about therapy or treatment. This hierarchy is often shown graphically as a pyramid with expert opinions at the bottom of the pyramid and randomized controlled trials (RCTs) at the top.

However, a RCT would not be the strongest research design to answer a question about prognosis. The highest level of evidence for prognosis is a cohort study. Always look for the strongest evidence you can find to answer your type of question.

Figure 2.1 Hierarchy of Evidence by Research Design



The type of question you are trying to answer determines the best *research design* to use.

In some situations the eligibility of a research article 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 that best answer the research question.

First, divide the studies 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 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 2.1 shows the classification system used by the Academy. A glossary of these research terms are presented in Appendix 6. The type of research design is determined during the critical appraisal step and recorded on the quality checklist template.

Primary Reports		Secondary Reports	
A	Randomized Controlled Trial Cluster Randomized Trial Randomized Crossover Trial	M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Prospective Cohort Study Retrospective Cohort Study		
C	Non-Randomized Controlled Trial Non-Randomized Crossover Trial Case-Control Study Time Series Study Diagnostic, Validity or Reliability Study	R	Narrative review (Review article) Consensus statement Consensus report
D	Non-Controlled Trial Case Study or Case Series Other Descriptive Study Cross-Sectional Study Trend Study Before-After Study	X	Medical opinion

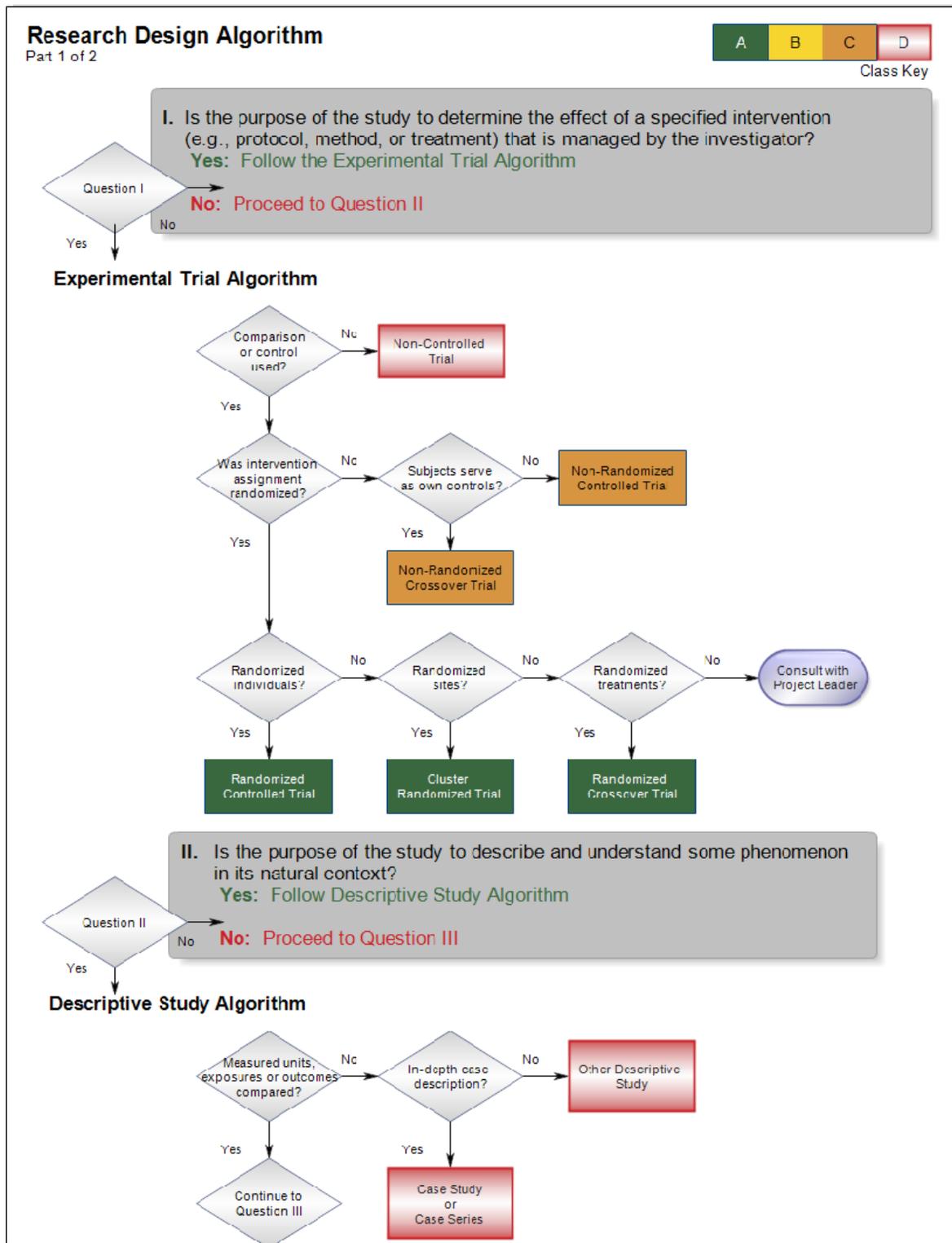
Classifying studies and reports gives an initial picture of the type of studies and level of evidence available. It also helps organize the articles for the next step of critical appraisal.

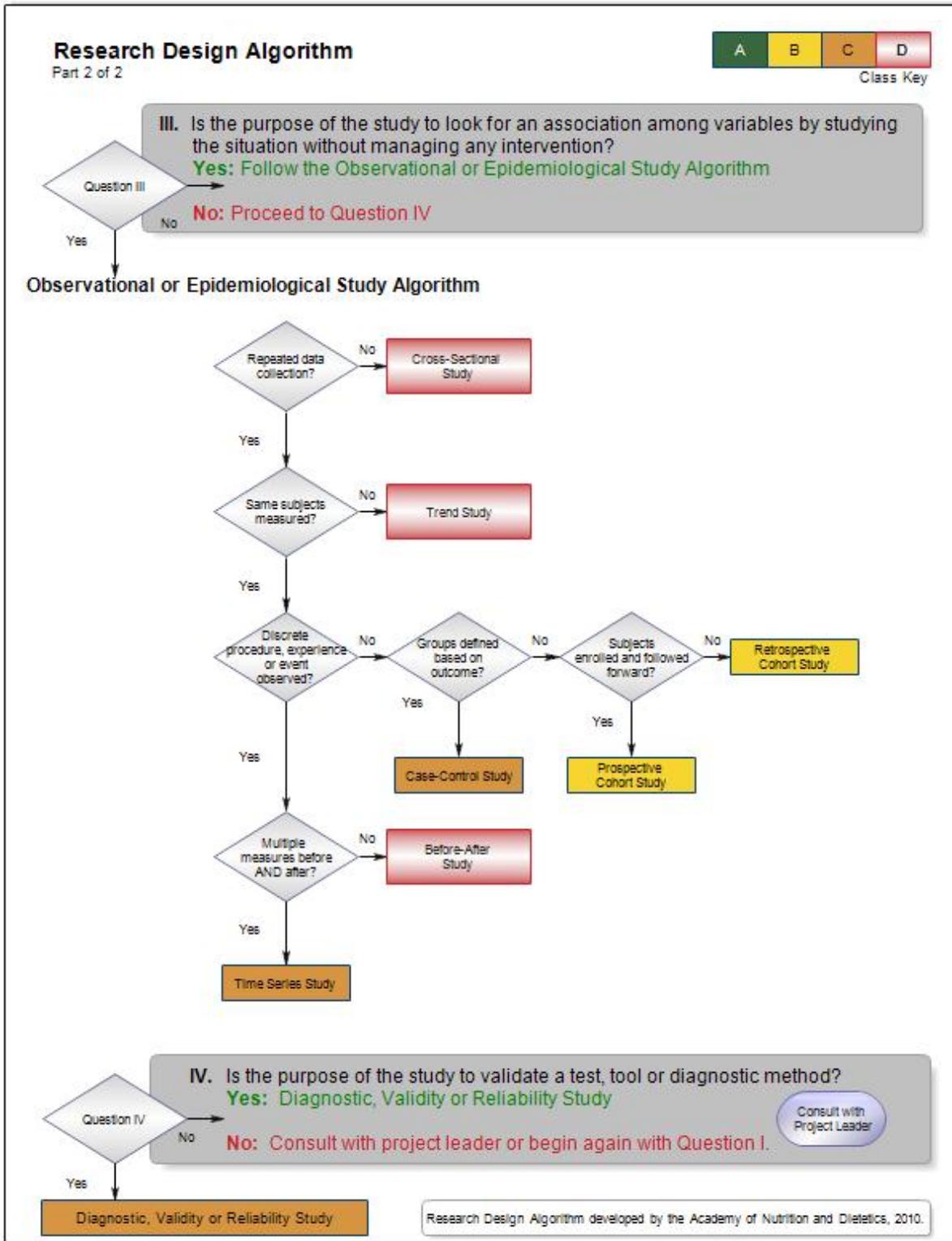
The Academy uses a study design algorithm to help you identify the study design. Refer to Figure 2.2. Algorithm for classifying the research designs of primary studies. This classification is then recorded on the article’s worksheet template.

The Academy web-based presentation, “Research Designs and Threats to Validity” is a helpful tool to assist with the classification of research studies.

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

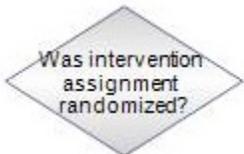
Figure 2.2 Algorithm for Classifying the Research Design of Primary Studies





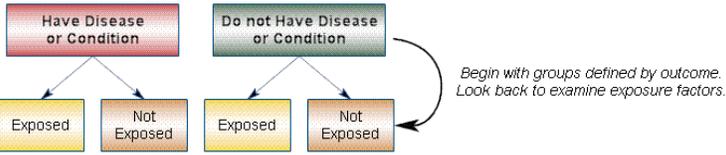
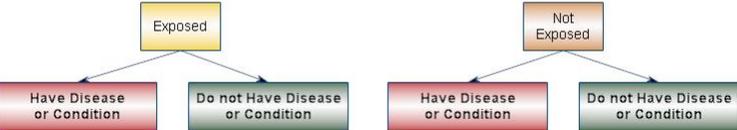
How to Use the Research Design Algorithm

Below is a diamond by diamond guide for using the Research Design Algorithm developed by the Academy of Nutrition and Dietetics, 2010. Included are “Tips” on what to look for – and some “Watch Out!” instructions that may help you avoid common mistakes.

Decision Diamond	Instructions
Experimental Trial Algorithm	
 <p style="text-align: center;">Question 1</p>	<p>There are two key points here: (1) that there was an intervention (which can be called a treatment or other labels), and (2) the researcher managed or designed the intervention.</p> <p>Watch Out!  Not all studies of the outcomes of an intervention are experimental trials. Sometimes a researcher will examine the outcomes of one or more treatments (for example, different types of bariatric surgery) that occur in usual practice without having any influence on what the treatment is or who the patients are that get it. Studies of this type are not experimental trials. A study can be an experimental trial only if the researcher determines who gets what intervention (or, the order of the treatment) and the specifics of the intervention (and the alternatives).</p> <p>Tips: Look for evidence in the text that the researcher designed the intervention protocol and specified which subjects were eligible for intervention.</p>
 <p style="text-align: center;">Comparison or control used?</p>	<p>Yes: There was at least one alternative to the intervention. This could be a group that received no treatment (referred to as the “control”) or the comparison could a different type of treatment.</p> <p>No: If there was no comparison or control group studied, but there was a researcher managed intervention, the study design is a Non-Controlled Trial.</p>
 <p style="text-align: center;">Was intervention assignment randomized?</p>	<p>Yes: The author mentions that randomization is used. Eligible individuals can be randomized to different intervention groups, or less commonly used, existing clusters of individuals can be randomized to different interventions. Randomization can also be used to determine the order in which the same individuals receive two different interventions.</p> <p>No: Go to next question.</p>
 <p style="text-align: center;">Subjects serve as own controls?</p>	<p>Yes: If individuals are given two (or more) different treatments in the same (or a non random) sequence, then the subjects are their own controls and study design is a Non Randomized Crossover Trial.</p> <p>No: If two or more groups are compared (and subjects are in groups by some method that did not involve randomization), then the study design is a Non Randomized Controlled Trial.</p>

	<p>Watch Out! ⚠️ Authors will sometimes have no comparison treatment or control group, but will describe subjects as “their own controls” when they do baseline (before) and after treatment measurements. Just because the same group of subjects is measured at two different time points does not mean that they serve as their own controls. Subjects serve as their own controls when the effects of one intervention can be compared to effects of a comparison intervention in a study where both interventions are given to all subjects.</p>
<p style="text-align: center;">Randomized individuals?</p>	<p>Yes: If individual subjects (people) are randomly assigned to different groups, the study design in a Randomized Controlled Trial (RCT)—the classic experimental study design.</p> <p>Watch Out! ⚠️ Just because randomization occurs does not mean that individual people were randomly assigned to groups. Studies can be randomized by sites (e.g., schools, cities), or treatment order (diet A first or diet B first).</p> <p>No: Go to the next question</p>
<p style="text-align: center;">Randomized sites?</p>	<p>Yes: Rather than randomizing at the individual level, sites with many individuals (e.g., schools, offices, cities) are randomly allocated to intervention alternatives. For instance, imagine a study to test the effectiveness of a school-based physical activity program, ten schools agreed to be in the study. The schools are then randomly assigned to either implement the physical activity program or to an alternative (which could be nothing or a comparison program). This would be a Cluster Randomized Trial.</p> <p>No: If neither individuals nor sites were randomly assigned to treatments or interventions, then the only thing left is that the order of treatments was randomly assigned to the same individuals. The study design would be a Randomized Crossover Trial.</p>
<p>Descriptive Study Algorithm</p>	
<p style="text-align: center;">Question II</p>	<p>The word “phenomena” means any event, circumstance, or experience that is apparent to the senses and that can be scientifically described and appraised. “Natural context” means that the researcher doesn’t change anything. She/he observes “what is”.</p> <p>Tips: Questions II and III are closely related. In both, the researcher is observing the world (e.g., distribution of disease, the way that different therapies are carried out, how patient characteristics relate to each other) without intervening. Descriptive Studies provide an in-depth look at processes, characteristics and patterns.</p>
<p style="text-align: center;">Measured units, exposures or outcomes compared?</p>	<p>Yes: If the study is concerned about measuring and quantifying various factors and looking at the relationship among them it is likely an Observational or Epidemiological Study. Go to Question III.</p> <p>Tips: Sometimes researchers will simply provide information about the incidence or prevalence of diseases or characteristics in a population (e.g., the number of new breast cancer cases in a year, or the average intake of vitamin D among teenagers). These are descriptive studies. Ethnographic studies that apply qualitative methods are also descriptive studies.</p>

	<p>Watch Out! ⚠️ Just because an author describes prevalence rates (e.g., overweight or obesity) for two groups (men versus women) doesn't mean that they test for statistical difference! Look carefully at the study purpose and statistical methods and results. If the authors test a hypothesis (whether two groups were statistically different on a certain characteristic, or whether one characteristic is statistically related to or predicts another characteristic), then the answer is "yes" and you should move on to Question III.</p> <p>No: Go to the next question.</p>
	<p>Yes: When a researcher provides a detailed description of only one or a handful of clinical cases the study design is a Case Study or a Case Series.</p> <p>No: When the point of the study is to describe a situation, either quantitative or qualitative, but the purpose is not to determine what causes what, or to test hypotheses, the study falls into the Other Descriptive Study category.</p>
<p>Observational or Epidemiological Study Algorithm</p>	
	<p>In this group of study designs the researcher does not manipulate group assignment or provide an intervention, but he/she does have hypotheses about the relationship among variables and may be looking for an association between exposures and outcomes.</p> <p>Tips: Expect to see more details about statistical methods including management of intervening factors and potential confounders, and tests of association or statistical difference.</p>
	<p>Yes: If data are collected at more than one time point, go down to the next question.</p> <p>No: The researchers went to the subjects only once to get data. For instance, if the researcher collected information on the exposure (diet intake) and the outcome (weight) at the same time, then this is a Cross-Sectional Study.</p> <p>Watch Out! ⚠️ Many descriptive studies (under Question II) collect data at only one point in time. What sets a Cross-Sectional study off from an Other Descriptive Study is that the author tests a hypothesis or carries out a statistical test for association or predictive relationships.</p>
	<p>Yes: If there are repeated measures on the same subjects, then go down to the next question.</p> <p>No: If the researcher goes to the population to collect data more than one point in time (say, in different years), but the data are collected on different subjects each time, then the study design is a Trend Study.</p> <p>For example, studies that statistically compare variables from different cycles of NHANES are often Trend Studies.</p> <p>Tips: If you are unsure, determine whether the same subjects or different subjects are measured at each time point.</p>

	<p>Yes: If the emphasis on measuring status before and after a naturally occurring procedure, experience or event, go down to the next question. For example, a “procedure” could be a particular type of surgery or dietary intervention (where the researcher merely observes what surgeons or dietitians do rather than try to influence their practices). An “experience” or “event” is generally a distinct event in time and space (e.g., becoming a college freshman; or the passage of new regulations on food served in school cafeterias).</p> <p>No: Go to the next question.</p>
	<p>Yes: If cases (individuals with the outcome) are matched to similar individuals who do not have the outcome (controls) the study design is Case-Control Study.</p> <p>No: Go to next question.</p> <p>Tips: If comparison groups are defined in terms of an outcome already present (e.g., obese individuals versus non-obese individuals, or persons who developed complications following a surgical procedure versus persons who did not develop complications following the procedure), and then data about pre-existing exposure is examined (e.g., hours of television viewing, or pre-surgery nutrition consult), then the study design is a Case-Control Study.</p> <p>Watch Out!  Case-control studies can be confused with to Cohort Studies. They key difference between Case-Control and Cohort Studies depends on whether the comparison groups used in the analysis are based on the outcome or the exposure.</p> <p>See figures below.</p> <p>Case Control</p>  <p>Cohort Design <small>Group subjects based on exposure, then examine association with outcome (may be prospective or retrospective)</small></p> 
	<p>Yes: If subjects are enrolled in the study and followed forward through time with many data collection points (that is, the researchers define the variables to answer a set of research questions and then follow the same subjects and collect data over a long period of time), then the design is a Prospective Cohort study.</p>

	<p>No: If data for the study are abstracted from existing longitudinal data sets or archival data sources (with many data collection points on the same individuals over time) then it is a Retrospective Cohort design.</p> <p><i>Tips:</i> A data set that is prospective for one research question may be retrospective for another research question. The difference is how the cohort was created in the beginning. Was it originally set up to answer questions like those in the current study; or is the researcher using an existing data set because it includes variables that allow answering new research questions?</p> <p>Watch Out! ⚠️ Do not confuse Before-After or Trial designs with follow-up measures as a Cohort design. While there is no hard and fast cut-off for how long is “a long period”, in Before-After or Trial designs follow-up measures are taken within months or years (usually less than five years) of the event of interest (the intervention or therapy). Cohort designs generally follow a large number of individuals over the course of many years.</p>
	<p>Yes: If data are collected at several points prior to the procedure, event or experience and again after, the study design is a Time Series Study. An example might be a study of the impact of calorie posting in fast food restaurants on purchases.</p> <p>No: A Before-After Study uses data at baseline or before a program or treatment and after it is completed. One or two follow up measures (e.g. at three months and six months) might be included.</p> <p>Watch Out! ⚠️ A Before-After Study is an observational study where the researcher does not design the intervention. Before-After Studies can be confused with Non-Controlled Trials where the researcher manages the intervention.</p> <p><i>Tips:</i> Time Series studies, with multiple measurements prior to the event or treatment, are relatively rare in nutrition research.</p> <p>Watch Out! ⚠️ Just because a study has multiple follow-up measurements does not make it a Time Series. It must also have more than one measurement before the procedure, event or experience being studied to be a Time Series.</p>
<p>Diagnostic, Validity or Reliability Study</p>	
	<p>Yes: Does the study compare how well two diagnostic, assessment, or screening tools classify individuals in terms of whether or not they have a disease or condition? Does the study assess the validity or reliability of a tool or measurement method (often comparing the results of the tool with a “gold standard”)? These are common examples of a Diagnostic, Validity or Reliability Study.</p>
<p><i>I got to the end, but didn't find an appropriate study design.</i></p>	<p><i>Tips:</i> Sometimes study designs are very complex and incorporate characteristics of multiple types of designs. Other times, authors will call their study one thing, when in reality it is another. If you get to the end and could not decide, ask your Lead Analyst or Project Leader for help.</p>

Step 3: Critically Appraise Each Article

Instructions for Abstracting an article onto the Evidence Worksheet

An 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. Information from all of the worksheets is included in the Evidence Overview Table that supports the conclusion statement.

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

- "Tips": (primary and review article) tips for how to complete the worksheets are found in Table 3.0 and Table 3.1. Additional suggestions are in Table 3.2.
- *Quality Criteria Checklists*: checklists of questions to help you determine the relevance and validity of primary and review articles—found in Tables 3.3, 3.4 and 3.5 and Appendix 8, Appendix 9 and Appendix 10.
- Study Design Table: a table that indicates which questions from the quality criteria checklists are most relevant for different study designs—found in table 3.6 and Appendix 11.

This chapter will describe how to use these tools to accurately complete the *Evidence Worksheet* for each included article on the *Search Plan & Results*.

Abstract Key Information from the Research Article 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.

Purpose of the Worksheet

The worksheet provides 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 the author's conclusion.
- Note reviewer's comments about the study limitations and applicability.
- Note the funding source.

WHY IS THE
WORKSHEET
SO
IMPORTANT?

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

Read the article 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 article with a concise conclusion of the study. Transfer relevant information onto the Evidence Worksheet. (Refer to Table 3.0 for tips on what to abstract from Primary Research.

During the abstracting, use the Quality Criteria Checklist for primary research to assess the quality constructs and domains identified in the AHRQ report on *Systems to Rate the Strength of Scientific Evidence (2002)*³.

³"Systems to Rate the Strength of Scientific Evidence". Agency for Healthcare Research and Quality (AHRQ) March 2002

Secondary Research or Reviews

Most review articles are organized in the same way as primary research reports. The key difference is that in a review article, the published research studies are the “subjects” of 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 found in the method section. These details 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. Note how the author interprets the findings and describes any limitations of the study in the discussion section. An author usually closes the article with a concise conclusion of the study. Transfer relevant information onto the evidence worksheet. Refer to Table 3.1. for tips on what to abstract from Reviews.

During the abstracting process, use the Quality Criteria Checklist for review articles to assess the validity of the study.

Tips for Completing Primary Research and Review Article *Evidence Worksheets*

Below, we provide two *Evidence Worksheets* templates—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 3.0 and Table 3.1. A blank copy of the *Evidence Worksheet* is included in the Appendices.

Table 3.0 *What to Abstract from Primary Research*

Citation:	List the complete bibliographical citation
Study Design:	Name of the study design. Refer to algorithm (Figure 2.3)
Class:	(A, B, C, D) Based on classes of evidence reports (Table 2.3)
Quality Rating:	(+, Ø, -) Based on quality criteria checklist for primary research
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:	<p>Outcome(s) and other indicators</p> <p>Important variables and methods of measurement</p> <p>Was blinding used?</p>
Description of Actual Data Sample:	<p>Relevant descriptors of sample and comparison of groups at baseline</p> <p>Note loss of subjects (withdrawals, dropout, response rate, etc.)</p>
Summary of Results:	<p>Key Findings</p> <p>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)</p>
Author Conclusion:	<p>As stated by the author in body of report</p>
Reviewer Comments:	<p><i>Note strengths and limitations of the study. Identify concerns that affect study validity and generalizability (Always italicize)</i></p>
Funding Source	<p>Who provided the funding for this study?</p>

Table 3.1 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 for reviews
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:	<u># of articles included</u> # 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:	<i>Note strengths and limitations of the review. Identify concerns that affect the validity of the review. How generalizable are the findings? (Always italicize)</i>
Funding Source	Who provided the funding for this study?

Additional Suggestions from Experienced Analysts

This list was compiled from the experiences of evidence analysts and lead analysts who have been working on Academy projects for several years.

Table 3.2 Suggestions from an analyst

Reviewer	
Citation	Always fill in this part in correct format (American Medical Association Style) and italicize periodical title. Example: Author A, Author B. Title of article. <i>Title of Periodical</i> year; volume: first-last page.
Study Design	Be sure to get this right! Discuss with lead analyst if not sure (sometimes it is difficult to tell). To help you, refer to the following items in the Evidence Analysis Manual: <ul style="list-style-type: none"> • Table 2.1 Hierarchy and Classification of Studies • Figure 2.2 Algorithm for Classifying the Research Design of Primary Studies • Appendix 6: Glossary of Terms Related to Research Design; and • Appendix 10 Important Quality Considerations from Checklist by Study Design
Class	Do not forget to use the pull down menu and designate A, B, C, D, etc. Refer to the Evidence Analysis Manual, Appendix 4: Classes of Evidence Reports.
PubMed ID:	Find the citation on PubMed to get this number. Often the Lead Analyst includes this information when the article assignment is created.
RATING:	
After completing the research design and implementation checklist, determine the rating.	
Plus/Positive (+) <i>If most of the answers to the validity questions are “Yes” including criteria 2, 3, 6 and 7 and at least one additional “yes”, the report should be designated with a plus symbol (+) on the Evidence Worksheet.</i>	
Minus/Negative (-) <i>If most (six or more) of the answers to the validity questions are “no,” the report should be designated with a minus (-) symbol on the Evidence Quality Worksheet.</i>	
Neutral (ø) <i>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 (ø) symbol on the Evidence Quality Worksheet.</i>	
Ratings are based solely on the quality criteria checklist. If you have any comments about the rating, explain in the reviewer’s comments section and/or bring it forward as an item for discussion by the expert workgroup.	
Research purpose	Statement of purpose or research question: usually one or two sentences.
Inclusion criteria	<ul style="list-style-type: none"> • Use bullet points • Informed consent if mentioned

Exclusion criteria:	<ul style="list-style-type: none"> • Exclusion criteria 1 • Exclusion criteria 2 , etc. <p>Note: sometimes exclusion criteria are the opposite of inclusion criteria. (e.g., include individuals over the age of 20 = exclude individuals 19 and younger)</p>	
Description of Study Protocol	Recruitment or sampling	<ul style="list-style-type: none"> • Examples: <ul style="list-style-type: none"> ○ Recruited from clinics ○ Consecutive admissions to ICU ○ Random selection of charts with specified diagnosis
	Blinding used	List if the author mentions blinding of subjects, providers, and/or investigators/data collectors. If not mentioned we assume no blinding was used and the prompt – blinding used- <i>can be deleted</i> from worksheet template)
	Description of study protocol:	Give the highlights here including: type of comparisons or groups, method of assignment to groups (random, convenience, etc), number and timing of data collection points, and procedures for follow up of subjects. If there are treatment and control or comparison groups list them.
	Intervention (if applicable)	List the intervention, regimen, risk factors or procedures studied. Include specifics such as type, dose, duration or intensity. This is usually the independent variable. For example, counseling by dietitians and medication management to control blood glucose between 80 and 140 mg/dL. After the intervention information is added to the worksheet, <i>delete the prompt “if applicable.”</i>
	Statistical analysis	<ul style="list-style-type: none"> • Name the statistical tests used • Indicate if multivariate analyses were done to control or adjust for other variables • Intent to treat analyses applies to any type of intervention study (pre-post, nonrandom trial and RTCs) • Report the results of a power analysis if one was conducted. This is the probability that the test will reject a false null hypothesis (or Type 2 error). The author will say something like <i>n subjects were needed for 80% power.</i>
Data Collection Summary:	Timing and method of measurements	<p>Examples:</p> <ul style="list-style-type: none"> • Hemoglobin A1c was tested at baseline and at quarterly clinic visits • Subjects completed a validated food behavior checklist and were weighed at baseline, 6 and 12 months • Pressure ulcer was staged according to xx criteria
	Dependent variables (outcomes)	<p>Examples:</p> <ul style="list-style-type: none"> • Mortality (died while hospitalized) • Change in hemoglobin A1c • Percent of body weight lost
	Independent	Examples:

	variables (intervention or procedure)	<ul style="list-style-type: none"> • Blood glucose controlled between 80-140 mg/dL • Method of nutrition counseling • Specific formulation of enteral feeding product <p>Note: some correlational, descriptive studies do not designate independent and dependent variables. In that case, just list key study variables.</p>
	Other Variables	<p>This is anything else the investigator is tracking to assure the validity of the study or to clarify the relationship between the independent and dependent variable. It could be a confounding or intervening factor, comorbidity, a concurrent treatment, or subject or setting characteristics. List things that are pertinent to the evidence analysis question and its application to dietetic practice</p> <ul style="list-style-type: none"> • Nutrition support protocol at 25 to 30 kcal per kg within 48 hours of admission. • Disease severity • Number of previous weight loss attempts
Description of Actual Data Sample:	Initial n (e.g. 731 (298 males, 433 females)	Be careful here. Sometimes the author will report how many were screened (e.g. N=850) as well as how many were actually entered into the study (n=731). Report the number who made it into the study on the worksheet. If you are in doubt, just list both. Be sure to specify the breakdown by gender (often described as percent male).
	Final n (attrition)	This accounts for dropouts. The purpose for including attrition is that loss of subjects leads to bias and weakens the validity of the study. It is especially problematic when the number lost or the reason for dropout is different between the intervention and control groups. Be careful here; sometimes a dependent variable is mortality. In that case, a subject death is not a drop out and the final n is the same as at the beginning (because the authors accounted for all the subjects) – include the % attrition. A good quality study has a dropout rate of <20%.
	Age	List the age range. There is almost always a Table with subject characteristics (demographic, anthropometric data, etc) compared across groups that will have P values. A difference is not significant unless $P < 0.05$.
	Ethnicity	List if information is available. If it is not described, then state “not described”
	Other relevant setting characteristics	Consider the question: may need to define type of setting (e.g. medical ICU, surgical ICU, mixed ICU, trauma unit), staffing pattern, reimbursement/coverage
	Anthropometrics or other relevant subject characteristics	Were groups same or different on important baseline measures like BMI?
	Location	Report the city, state and/or country. If it is a multi-center trial, specify which country (e.g. multi-center trial in United States)

Summary of Results	Primary findings	<ul style="list-style-type: none"> • It is good to make tables here, but you should not copy all the tables from the article. • Abstract the findings most pertinent to the evidence analysis question. Include quantitative information about the magnitude of effect and include statistical significance. • Put the results that pertain to the dependent variables. If you list something as a dependent variable, give information about the result. • To be reported appropriately, we need to see significance levels like P values or odds ratios with confidence intervals • If it was not significant, it may be helpful to summarize those points in a bulleted list.
	Other findings	Something you have not listed as a dependent variable but is useful information.
Author conclusion		<u>Summarize</u> what the author said. Sometimes this addresses the clinical significance of the findings.
Reviewer comments		<i>You do not have to put anything here. However, if there is a particular strength or limitation you feel is important, write it here. Anything you (the reviewer) write is to be italicized.</i>
Funding Source	Government Industry University/Hospital Not-for-Profit Other	Check all funding source categories that apply. Enter the specific name of the funder in the text field box

Please enter all content in your worksheet according to the Academy style requirements listed below.

Academy Style:

Spacing:

- Use a single space after punctuation (not double-space)
- No comma before “and”
- No comma before “or”
- No spaces before and after =, < and > symbols (e.g., P>0.0001)
- Use an extra space after these symbols when the following number is negative (< -1).

Symbols

- Do not use a slash (/) to separate terms such as +/1; instead use \pm , or the greater than or less than symbol which you can then format the font to underline (\leq or \geq)
- Write fractions as $\frac{3}{4}$ not 3/4.

Punctuation:

- Periods and commas belong inside end-quotes.
- All other punctuation goes outside end-quotes.
- Italicize *title of periodical*.

- Use subscripts and superscripts appropriately: O₂ not CO₂; m² not m2
- P-Value expressed as capital P (P<0.001)
- Spell out integers zero through nine unless followed by decimal (one or 1.0)
- Decimals must be preceded by 0. (P<0.001) *not* (P<.001).
- Spell out percentile; *not* %ile
- Spell out units of time: minutes *not* min; seconds *not* sec, etc.
- Last bulleted item must end with punctuation
- Capitalize L for liter (e.g., dL and L) but *not* for milliliter (*ml is correct*)
- Always use comma separators: 1,000,000.

Avoid the following frequent mistakes.

- Be sure to list units (*patients were followed up at 6,12 and 24*) Is that 6 weeks or 6 months?
- Define acronyms you are using on tables in the results sections. You can put a note under the table. For example not everyone would understand RYGBP. Spell it out somewhere as Roux-en-Y Gastric Bypass (RYGBP).
- Data always “are” (not “is”) because data are plural. Datum is singular.
 - Nutrient data were obtained (**not** *data was* obtained)
- Watch your subject/verb agreement—this must be the most common grammatical error (examples)
 - “Patients received an internal medicine and psychiatry evaluation” (better to say *patients received internal medicine and psychiatry evaluations* or *patients received an internal medicine and a psychiatry evaluation*)
 - “If there are treatment groups and a control, list them” is correct even if the grammar checker says it should read “there is treatment groups and ...” treatment is an adjective modifying groups. It would not be correct to say is (singular) groups (plural).

Complete Quality Criteria Checklist and Determine a 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 analyst examine the article 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. Refer to Table 3.5 to see which questions are most relevant for each study design. 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 article is complex and requires time and concentration. At first, the process takes about 2 hours per article. Time is reduced as the analyst becomes more familiar with the research area and the use of the Evidence Worksheet and the Checklist. Using the online tools facilitates the processes of abstracting articles and maintaining files.

Advantages of the *Quality Criteria Checklists*

The Quality Criteria Checklists were developed to assist the analyst in assessing the article’s research design. Questions included in the criteria checklists address applicability to practice and scientific validity.

The Quality Criteria checklists are used:

- 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/analysts.

WHY USE THE
QUALITY
CRITERIA
CHECKLIST?

Background of the Quality Criteria Checklist for Primary Research and Review Articles

The content of the Quality Criteria Checklist 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).

The 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 analysts and help them to recognize various threats that may undermine sound research and that could lead to invalid conclusions.

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 the Academy’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.

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Quality Criteria Checklists: Primary Research and Primary Research – Non-human Subjects

The Quality Criteria Checklist: Primary Research and Primary Research – Non human Subjects include 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 for Primary Research can be found in Table 3.3 and the Quality Criteria Checklist for Primary Research – Non human Subjects can be found in Table 3.4.

Table 3.3. Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS		Yes	No	Unclear	N/A
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)				
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?				
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?				
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)				
<i>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.</i>					
VALIDITY QUESTIONS		Yes	No	Unclear	N/A
1.	Was the <u>research question</u> clearly stated?				
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?				
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?				
1.3	Were the target population and setting specified?				
2.	Was the <u>selection</u> of study subjects/patients free from bias?				
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?				
2.2	Were criteria applied equally to all study groups?				
2.3	Were health, demographics, and other characteristics of subjects described?				
2.4	Were the subjects/patients a representative sample of the relevant population?				
3.	Were <u>study groups</u> comparable?				
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?				
4.1	Were follow up methods described and the same for all groups?				

<p>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%.)</p> <p>4.3 Were all enrolled subjects/patients (in the original sample) accounted for?</p> <p>4.4 Were reasons for withdrawals similar across groups?</p> <p>4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?</p>	
<p>5. Was <u>blinding</u> used to prevent introduction of bias?</p> <p>5.1 In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?</p> <p>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.)</p> <p>5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?</p> <p>5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?</p> <p>5.5 In diagnostic study, were test results blinded to patient history and other test results?</p>	<p>Yes No Unclear N/A</p>
<p>6. Were <u>intervention/therapeutic regimens/exposure factor or procedure and any comparison(s)</u> described in detail? Were <u>intervening factors</u> described?</p> <p>6.1 In RCT or other intervention trial, were protocols described for all regimens studied?</p> <p>6.2 In observational study, were interventions, study settings, and clinicians/provider described?</p> <p>6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?</p> <p>6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured?</p> <p>6.5 Were co-interventions (e.g., ancillary treatments, other therapies) described?</p> <p>6.6 Were extra or unplanned treatments described?</p> <p>6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?</p> <p>6.8 In diagnostic study, were details of test administration and replication sufficient?</p>	<p>Yes No Unclear N/A</p>
<p>7. Were <u>outcomes</u> clearly defined and the <u>measurements valid and reliable</u>?</p> <p>7.1 Were primary and secondary endpoints described and relevant to the question?</p> <p>7.2 Were nutrition measures appropriate to question and outcomes of concern?</p> <p>7.3 Was the period of follow-up long enough for important outcome(s) to occur?</p> <p>7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?</p> <p>7.5 Was the measurement of effect at an appropriate level of precision?</p> <p>7.6 Were other factors accounted for (measured) that could affect outcomes?</p> <p>7.7 Were the measurements conducted consistently across groups?</p>	<p>Yes No Unclear N/A</p>
<p>8. Was the <u>statistical analysis</u> appropriate for the study design and type of outcome indicators?</p> <p>8.1 Were statistical analyses adequately described the results reported appropriately?</p> <p>8.2 Were correct statistical tests used and assumptions of test not violated?</p> <p>8.3 Were statistics reported with levels of significance and/or confidence intervals?</p> <p>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)?</p> <p>8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?</p> <p>8.6 Was clinical significance as well as statistical significance reported?</p> <p>8.7 If negative findings, was a power calculation reported to address type 2 error?</p>	<p>Yes No Unclear N/A</p>
<p>9. Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?</p> <p>9.1 Is there a discussion of findings?</p> <p>9.2 Are biases and study limitations identified and discussed?</p>	<p>Yes No Unclear N/A</p>
<p>10. Is bias due to study’s <u>funding or sponsorship</u> unlikely?</p> <p>10.1 Were sources of funding and investigators’ affiliations described?</p>	<p>Yes No Unclear N/A</p>

10.2 Was there no apparent conflict of interest?	
MINUS/NEGATIVE (-) <i>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 Worksheet.</i>	
NEUTRAL (Ø) <i>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 (Ø) symbol on the Evidence Worksheet.</i>	
PLUS/POSITIVE (+) <i>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 Worksheet.</i>	

Table 3.4. Quality Criteria Checklist: Primary Research – Non human Subjects

RELEVANCE QUESTIONS		Yes	No	Unclear	N/A
1.	Would implementing the studied intervention, procedure or product (if found successful) result in improved outcomes for the patients/clients/target population group? (NA for some Epi studies)				
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about?				
3.	Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice?				
4.	Is the intervention, procedure or product feasible for application in dietetic practice?				
<i>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.</i>					
VALIDITY QUESTIONS		Yes	No	Unclear	N/A
1.	Was the <u>research question</u> clearly stated?				
1.1	Was the specific intervention(s) or procedure (independent variable(s)) or exposure factor, process or product of interest identified?				
1.2	Was the outcome(s) (dependent variable(s)) or status or condition of interest clearly indicated?				
1.3	Were the study context and setting specified?				
2.	Was the <u>selection</u> of study subjects/units to be free from bias?				
2.1	Were eligibility criteria (inclusion/exclusion) specified with sufficient detail and without omitting criteria critical to the study?				
2.2	Were criteria applied equally to all units of observation and all study groups?				
2.3	Was the source and other relevant characteristics of units of observation described?				
2.4	Were the selected units a representative sample of the context and setting for application of study findings?				
3.	Were <u>study groups comparable</u> or was an appropriate reference standard used?				
3.1	Was the method of assigning subjects/units of observation described and unbiased? (Method of randomization identified if RCT)				
3.2	Was the distribution of relevant characteristics similar across subjects/units of observation and study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent comparison data preferred over historical data.)				
3.4	If a cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? (Sub-question not used (NA))				
3.5	If diagnostic, validity or reliability study, was there a comparison with an appropriate reference standard?				
	NOTE: Criterion #3 is NA if only one group was studied, comparison groups were not constructed for analysis, and a comparison to a reference standard not made.				
4.	Were methods of handling losses from the original sample (<u>withdrawals</u>) described?				
4.1	Were follow-up methods described and the same for all subjects/units of observation				

<p>and groups?</p> <p>4.2 Were the number, characteristics of withdrawn units (i.e., damaged specimen, dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for the sample and each group?</p> <p>4.3 Were all enrolled subjects/units (in the original sample) accounted for?</p> <p>4.4 Were reasons for withdrawal or loss similar across groups?</p> <p>4.5 If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study?</p>	
<p>5. Was <u>blinding</u> used to prevent introduction of bias?</p> <p>5.1 Were field and research staff and investigators blinded to treatment group, as appropriate?</p> <p>5.2 Were data collectors blinded for outcomes assessment? (If the outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)</p> <p>5.3 In a cross-sectional study, were measurements of outcomes and risk factors blinded?</p> <p>5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?</p> <p>5.5 In diagnostic, reliability or validity study, were test results blinded to unit of observation history and other test results??</p>	<p>Yes No Unclear N/A</p>
<p>6. Was the <u>intervention/treatment regimen/exposure factor, procedure, process or product of interest and any comparison(s) described in detail? Were <u>intervening factors</u> described?</u></p> <p>6.1 Were protocols described for all alternatives studied?</p> <p>6.2 Was the context (study setting, intervention or exposure details or process, involved personnel, etc) described?</p> <p>6.3 Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?</p> <p>6.4 Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured, and are data free from bias?</p> <p>6.5 Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?</p> <p>6.6 Were extra or unplanned interventions or environmental influences during the study period described?</p> <p>6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all units of observation and all groups?</p> <p>6.8 In diagnostic, validity or reliability study, were details of test administration and replication sufficiently described?</p>	<p>Yes No Unclear N/A</p>
<p>7. Were <u>outcomes</u> or condition or status of interest clearly defined and the <u>measurements valid and reliable</u>?</p> <p>7.1 Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?</p> <p>7.2 Were nutrition-related outcomes measures, if included, appropriate to the study question and outcomes of concern?</p> <p>7.3 Was the period of follow-up long enough for important outcome(s) to occur?</p> <p>7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?</p> <p>7.5 Was the measurement of outcomes or effect at an appropriate level of precision?</p> <p>7.6 Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?</p> <p>7.7 Were the measurements conducted consistently across units of observation, groups and time periods?</p>	<p>Yes No Unclear N/A</p>
<p>8. Was the <u>statistical analysis</u> appropriate for the study design and type of outcome indicators?</p> <p>8.1 Were statistical analyses adequately described and the results reported appropriately?</p> <p>8.2 Were correct statistical tests used and assumptions of test not violated?</p> <p>8.3 Were statistics reported with levels of significance and/or confidence intervals?</p> <p>8.4 Was there a clear description of subjects/units observed included in each analysis? If</p>	<p>Yes No Unclear N/A</p>

<p>appropriate, was there a dose-response analysis?</p> <p>8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?</p> <p>8.6 Was clinical or pragmatic significance as well as statistical significance reported?</p> <p>8.7 Was a power calculation reported to address adequate sample size to measure effect and avoid type 2 error? (This is especially important if findings are negative.)</p>	
<p>9. Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?</p> <p>9.1 Is there an adequate discussion of findings?</p> <p>9.2 Are biases and study limitations identified and discussed?</p>	Yes No Unclear N/A
<p>10. Is bias due to study's <u>funding or sponsorship</u> unlikely?</p> <p>10.1 Were sources of funding and investigators' affiliations described?</p> <p>10.2 Was there no apparent conflict of interest?</p>	Yes No Unclear N/A
<p>MINUS/NEGATIVE (-) <i>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 Worksheet.</i></p>	
<p>NEUTRAL (Ø) <i>If the answers to validity criteria questions 2, 3, 6, and 7 are "Yes" but several other criteria indicate study weaknesses, the report should be designated with a neutral (Ø) symbol on the Evidence Worksheet.</i></p>	
<p>PLUS/POSITIVE (+) <i>If most (six or more) of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7), the report should be designated with a plus symbol (+) on the Evidence Worksheet.</i></p>	
<p>When a validity criteria question is NA <i>If any of the ten validity questions are NA, the report requires a majority of "Yes" answers (including 2,3,6, 7, as applicable) for a plus (+), or a majority of "No" answers for a minus (-) rating</i></p>	

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.

Table 3.5. Quality Criteria Checklist: Review Articles

RELEVANCE QUESTIONS		Yes	No	Unclear	N/A
1.	Will the answer if true, have a direct bearing on the health of patients?				
2.	Is the outcome or topic something that patients/clients/population groups would care about?				
3.	Is the problem addressed in the review one that is relevant to dietetics practice?				
4.	Will the information, if true, require a change in practice?				
<p><i>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.</i></p>					
VALIDITY QUESTIONS		Yes	No	Unclear	N/A
1.	Was the question for the review clearly focused and appropriate?				
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?				
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?				
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?				
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?				

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 issues 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 (-)					
<i>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.</i>					
NEUTRAL (Ø)					
<i>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 (Ø) symbol on the Evidence Worksheet.</i>					
PLUS/POSITIVE (+)					
<i>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 Worksheet.</i>					

When these criteria for review articles are applied to narrative reviews from past years, it is practically impossible to get a positive rating. This is because authors seldom reported 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 may earn a positive (+) rating.

Instructions for Using the Quality Criteria Checklist

First, read carefully the research article. Then, while abstracting the key information onto the Evidence Worksheet, consider each of the relevance and validity questions on the Quality Criteria Checklist and answer a “yes” or “no” to each one. A record of the answers to each question is useful for checking work and verifying consistency among analysts (i.e., inter-rater reliability). The project manager, lead analyst and the expert work group will review and approve the abstracted worksheet and the checklist.

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 3.6), 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 article.

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 overall designation (negative -, neutral Ø, or positive +). The determination is added to the appropriate item on the Evidence Worksheet.

Table 3.6 Study Design, Distinguishing Characteristics, and Important Considerations

Study Design Type	Class	Distinguishing Characteristics	Most Important Quality Considerations (from Quality Checklist)
EXPERIMENTAL & QUASI-EXPERIMENTAL TRIALS		Investigator managed independent variable (the intervention)	
Randomized Controlled Trial Cluster Randomized Trial	A A	Randomization (at individual or site [a cluster of individuals] level) used to assign subjects to two or more groups	2.1, 3.1, 3.2, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Randomized Crossover Trial Non-randomized Crossover Trial	A C	Subjects receive two interventions in a random or non-random sequence, with a washout period between them	2.1, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Non-randomized Controlled Trial	C	Subjects assigned to two or more groups using a non-random method	2.1 - 2.3, 3.2, 4.2 - 4.4, 5.1, 5.2, 6.3, 6.4, 7.4, 7.6, 8.5
Non Controlled Trial	D	Only one group studied, no comparison group	2.1, 2.3, 4.3, 5.2, 6.3 - 6.6, 7.4, 7.6, 8.5
DESCRIPTIVE STUDIES		No comparison, no intervention, describes “what is”	
Case Study or Case Report Case Series	D D	Detailed description of the unfolding course of events for one or a few subjects, including treatments, intervening factors and outcomes	2.1, 2.4, 4.3, 7.4 3 – Not applicable
Other Descriptive Studies	D	In depth quantitative and/or qualitative description	1.3, 2.1, 2.4, 7.4 3 – Not applicable
OBSERVATIONAL STUDIES		Investigation of procedure, experience or event with no researcher intervention	
Before-After Study	D	Data collected at baseline and one or more times after a therapeutic or preventive procedure, experience or event	2.1, 2.3, 2.4, 4.2, 6.2 - 6.6, 7.3, 7.4, 7.6, 8.5 3 – NA if only one group
Time Series	C	Data from the same subjects at a series of points over time, including prior to, during, and	2.1, 2.3, 2.4, 4.2, 6.2, 6.4 - 6.6, 7.4, 7.6 3 – NA if only one group

		following the introduction of a therapeutic or preventive procedure, event, or natural exposure	
EPIDEMIOLOGICAL ANALYTIC STUDIES		Comparisons constructed analytically, no researcher intervention, examines relationship among exposure factors and outcomes	
Prospective Cohort	B	Enrollment based on defining characteristic or factor and screening to verify absence of outcome of interest Large number of subjects tracked for long period of time Repeated data collection on “exposures” and status regarding outcomes of interest	2.1, 3.4, 4.2, 5.3, 6.3, 6.4, 7.1, 7.3, 7.4, 7.6, 8.5
Retrospective Cohort	B	Existing database used to create a cohort and look back for a temporal relationship between exposure factors and development of the outcome	2.1, 2.4, 3.4, 5.3, 6.3 - 6.6, 7.1, 7.3, 7.4, 7.6, 8.5
Case Control Study	C	“Cases” with the outcome are identified then matched with non-case (“controls”) from the same population Looks back to determine if exposures differ between cases and controls	2.1, 3.5, 4.2, 5.4, 7.4, 7.6, 7.7, 8.5 6.7 consider role of recall bias
Cross-Sectional Study	D	One round of data collection where exposure factors and outcome status is measured at the same time Statistical tests used to examine association among variables	2.1, 2.4, 3.4, 4.2, 4.3, 5.3, 6.4, 7.4, 7.6
Trend Study	D	Same data collected in different samples from the same population over time Like a series of cross-sectional studies	2.1, 2.4, 3.4, 4.2, 5.3, 6.4, 7.4, 7.6, 7.7, 8.5
DIAGNOSTIC, VALIDITY, OR RELIABILITY STUDIES		Comparison made with reference standard	
Diagnostic Study	C	Used to determine the sensitivity or specificity of a diagnostic or assessment method	1.3, 2.4, 3.6, 4.5, 6.8 5.5—Diagnostic Study only
Validity Study	C		
Reliability Study	C	Used to determine the “truthfulness” or accuracy of a	

		test, tool or procedure used to measure or classify Comparisons made to determine consistency and reproducibility of results from a test, tool or procedure	
--	--	----------------------------------------------------------------------------------------------------------------------------------------------------------------	--

Display all Checklists Relevant to a Particular Question in a Single Table

Because we are interested in the findings of many research studies as they relate to a particular question, the information from each Quality Criteria Checklist is combined into a single report. All checklists that are connected to worksheets linked to the same evidence analysis question are compiled into a Quality Criteria Summary. This table is linked to the evidence summary and is generated electronically after the analyst has completed the quality criteria checklist for each article (see Table 3.7).

The Summary allows members of the expert workgroup to quickly view 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.

Users of the evidence library can also view this information in the tabular format. The side-by-side comparison of 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 the Summary online is another example of the Academy's commitment to transparency.

Table 3.7 Example of a Quality Criteria Summary from Diabetes 1 and 2 EAL®

	Ash et al. 200	Berne et al 200	Brinkworth et a	Brown SA, et al	Derosa et al 20	Hanefeld et al 2	Hollander PA, et	Kelley et al 200	Li et al 2005	Manning et al 1	Maver-Davis et	McNulty et al 20	Mietz et al 2000
Overall Quality Rating	+	+	+	+	+	+	+	+	⊖	+	+	+	+
Relevance Questions													
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dieteticspractice?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Validity Questions													
1. Was the research question clearly stated?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the selection of study subjects/patients free from bias?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Were study groups comparable?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	???	Yes	Yes	Yes	Yes
4. Was method of handling withdrawals described?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Was blinding used to prevent introduction of bias?	Yes	Yes	No		Yes	Yes	Yes	Yes	Yes	???	Yes	Yes	Yes
6. Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Were outcomes clearly defined and the measurements valid and reliable?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

At the end of Step 3 the following materials are available for each question on the Portal. The expert panel can review these items on the Preview site.

- The Question
- *Sort List / Search Plan & Results*
- Full text of each article
- Abstracted Worksheets for each article
- Quality Criteria Checklists for each article
- Quality Criteria Summary combining all checklists

Step 4: Summarize Evidence

Create the Overview Table and Write the Evidence Summary

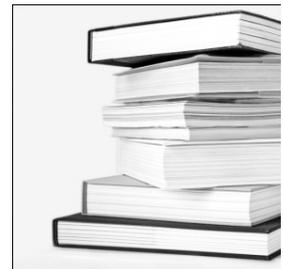
The Evidence Summary consists of two parts: the Overview Table and the narrative synthesis.

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

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?



The Overview Table Template allows you to assess which studies will be the most important for answering your question. (See the example overview table and the overview table template in Table 4.0 and in Appendix 14.) The headings in an overview table include factors that the work group or the research indicates are important considerations when comparing and synthesizing the research findings.

Table 4.0 Overview Table Template

Author, Year, Study Design, Class Rating	Study Type / Purpose	Study Populations	Intervention	Outcomes	Limitations

Information in the first column is automatically populated from worksheets.

In most instances, the studies that have strong research designs, positive quality ratings and/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. The team for each topic and question, will need to decide what are the critical comparison factors. These factors for will be the headings for the columns in the table.

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. Note which comparison factors researchers most often take into account.

Filling out the overview table should not be an arduous task. The information for the overview table can be transferred from the Evidence Worksheets.

OVERVIEW
TABLES
ALLOW
YOU TO
COMPARE
STUDIES
AT A
GLANCE

Table 4.1 Example of Overview Table from Health Disparities Nutrition Assessment EAL® Project

Question: *What elements of cross-cultural communication enhance the effectiveness of nutrition assessment or intervention?*

Author, Year, Study Design, Class, Rating	Study Purpose	Study Population	Intervention	Outcomes	Conclusion	Limitations
<p>Brown SA, Garcia AA et al, 2002</p> <p>Study Design: Prospective, randomly, repeated measures study</p> <p>Class: A</p> <p>Rating: ⚪</p>	<p>To determine if there would be significant differences between in metabolic control, diabetes (DM) knowledge, or DM-related health beliefs at 3, 6, and 12 mos between subjects in experimental groups compared with subjects in 1-year wait-listed control groups</p>	<p>Treatment group: N=126, 60% female, mean age 54.7±8.2 yrs, 90% preferred Spanish language, mean HbA1c 11.1±3.00, mean BMI 32.33±5.97kg/m²</p> <p>Control group: N=126, 68% female, mean age 53.2±8.3 yrs, 87% preferred Spanish language, HbA1c 11.80±3.02, mean BMI 32.12±6.35kg/m²</p>	<p>52 hrs of intensive instruction in DM self-management, including:</p> <p>a) 3 mos of wkly 2-hr sessions on nutrition, glucose self-monitoring, exercise, and other self-care topics</p> <p>b) 6 mos of bi-wkly sessions</p> <p>c) 3 mos of monthly sessions</p> <p>Problem-solving and food preparation demos were included</p> <p>Culturally-competent interventions included utilization of bilingual nurses and RDs, were offered in Spanish, and focused on health recommendations consistent with Mexican-American preferences</p>	<p>Significant Δ occurred between groups in FBG (194.95±63.27 mg/dl treatment vs. 210.51±66.65 control, P=0.019), HgA1c (10.89±2.55 treatment vs. 11.64±2.83 control, P=0.011), and DM knowledge (42.94±4.87% treatment vs. 40.92±4.87% control, P<0.001)</p>	<p>A culturally competent intervention resulted in improved outcomes measures for Mexican-American subjects with DM</p>	<p>Control group received DM education in the form of answers to questions during measurement visits, due to ethical considerations</p>
<p>Elder JP, Ayala GX et al, 2006</p> <p>Study Design: Randomized Control Trial</p> <p>Class: A</p> <p>Rating: ⚪</p>	<p>To examine the 1-year impact of behavior change approaches to reduce dietary fat and fiber in Spanish-language dominant Latinas</p>	<p>357 Spanish-language dominant Latinas</p> <p>Mean age: 39.71±9.93yrs; 79% married</p> <p>60% with income <\$2000/mo; avg family size 5 persons</p> <p>58.4% with educational level of middle school or less</p> <p>All participants were from the San Diego, CA area</p>	<p>Randomization to 1 of 3 groups for the 14-week study:</p> <p>1) "Promotoras," consisting of wkly dietary counseling via lay health advisors (promotoras) at home or telephone calls over a 14-wk period + 12 tailored newsletters with homework assignments delivered via mail to participant's home</p> <p>2) "Tailored," consisting of 12 tailored print newsletters and homework assignments delivered via mail</p> <p>3) "Control," consisting of 12 "off the shelf" materials targeted at Spanish speaking Latinos delivered via mail</p>	<p>Significant difference (SD) between the promotora and tailored group in total fat, total glucose and fructose (P<0.05), and trend toward significance in intake of total energy and total CHO (P<0.1)</p> <p>The promotora group was 5D from control group in intake of total energy and total CHO (P<0.05), and trend toward a SD in intake of total fat and sat fat (P<0.1)</p>	<p>The high interactivity of the promotora intervention, including home visits and phone calls, may have been the most salient reinforcer and may have led to further individual tailoring, making this type of intervention more effective than the comparison groups in the short term</p>	<p>The investigators did not provide information regarding the number of promotora visits completed in person vs. by phone</p>
<p>Ingram M, Gallegos G et al, 2005</p> <p>Study Design: Cross-sectional</p> <p>Class: D</p> <p>Rating: ⚪</p>	<p>To assess the impact that DM self-management education and support have on the patients' control of their DM</p>	<p>A group of Hispanic patients with DM living in the area of the US-Mexico border. Patients were enrolled from 2 locations:</p> <p>Yuma, AZ: 376 enrolled, 81% (306) graduated, 79% (243) reached for F/U interview, 66% female, 70% >50 yrs of age, mean weight 174.3 lbs</p> <p>Santa Cruz, AZ: 406 enrolled, 33% (133) graduated, 30% (40) reached for F/U interview, 70% female, 50% >50 yrs, mean weight 184.6 lbs</p> <p>In both locations, a majority had not graduated from high school</p>	<p>A 5-wk series of free DM education classes designed to impart the knowledge and skills necessary to be physically active, control dietary intake, monitor BG, take medications, and increase awareness of complications</p> <p>Classes were held 1 x per week; 2 hrs per class</p> <p>Use of community health workers (CHW) ("promotoras de salud") was central to the educational model</p>	<p>A significant ↓ in the avg random BG measurement among participants in both programs</p> <p>Both programs achieved a significant ↓ in DBP among participants</p> <p>In Yuma there was a significant ↓ in HbA1c from 0.4 to 8.7 among those who initiated the program with a HbA1c>9</p> <p>A significant portion of participants in both counties reported ↑ self-management behaviors, including diet, foot care, and glucose monitoring (Santa Cruz: diet 45-80%, foot care 60-80%, glucose monitoring 38-63%, P<0.001, n.s., respectively; Yuma: diet data incomplete, foot care 80-98%, glucose monitoring 61-98%, P=unknown, P<0.001, P<0.001, respectively)</p>	<p>Program participants achieved significant improvement in self-management behaviors, HbA1c, random BG levels and BP readings</p>	<p>This study was limited by inconsistencies in program implementation between the 2 sites and a high dropout rate. Differences in site resources resulted, in some cases, in data gaps</p>
<p>Schillinger D, Hammer H et al, 2008</p> <p>Study Design: Randomized Trial</p> <p>Class: A</p> <p>Rating: ⚪</p>	<p>To describe the reach of self-management support (SMS) strategies across three complementary dimensions: participation among clinics, providers and patients; representativeness of patients; and patient engagement with SMS</p>	<p>339 patients with DM ≥17 yrs old, 59% female</p> <p>19.8% insured by MediCal, 21.5% insured by Medicare, 50.2 uninsured, 8.6 other insurance</p> <p>53.4% English-speaking, 35.7% Spanish-speaking, 10.9% Cantonese-speaking</p>	<p>Randomization to either standard care (N=115, no systematic SMS), automated telephone disease management (ADTM) or monthly medical group visits (MGV)</p>	<p>ADTM: Engagement levels were high, with 93.8% responding to ≥1 ADTM call, with no SD found for language and literacy. Among patients with ≥1 nurse call-back, the proportion that generated ≥1 action plan was high (88.0%), with similar levels across language and literacy. The ADTM composite engagement product was 22.2, with higher products among those with limited English proficiency and those with limited literacy in both English and Spanish</p> <p>GVM: Engagement levels were modest, with language- and literacy-related patterns identified. 69.6% attended ≥1 GVM session, with higher rates among Cantonese (92.3%, P=0.02) and Spanish speakers (79%, P=0.02). Among patients who attended ≥1 GVM, the proportion that generated ≥1 action plan was high (88.5%), with similar levels across language and literacy groups. The GVM composite engagement product for GVM was 4.8 with lower products for both those with limited English proficiency and those with limited literacy in both English and Spanish</p>	<p>Persons with DM who are socioeconomically vulnerable and ethnically and linguistically diverse, in a public sector safety net system, appear interested in receiving DM SMS</p> <p>ADTM reached a greater proportion of the target population than GVM, and yielded higher rates of engagement for those with limited literacy and limited English proficiency</p>	<p>Small subgroup sample sizes</p>

Write a Brief Statement of the Relevant Findings of Each Study

On the worksheet, all of the results from that particular research article are listed; in the evidence summary, only the results that answer the evidence analysis question are included. Summarize the findings of each study as they relate to the question you are trying to answer in one to three sentences. These brief statements of findings will be included in the final evidence summary.

S U M M A R I Z E
T H E
F I N D I N G S
O F E A C H
A R T I C L E .

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).

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

- Arciero 1993[**author and publication**] 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 2003 [author and publication] 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].
- A Fredrix 1990 [author and publication] 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 1991 [author and publication] 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 1996 [author and publication] 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 [outcome of interest]. 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]

Write the Evidence Summary

After summarizing each article as it relates to your question, consider how the different articles relate to each other. Use the overview table to help identify common patterns in the research.

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 is meant by examining the overview table for “themes.”

The next step is to synthesize the research articles into a summary of the evidence. Be sure all of the resources are available (articles, worksheets, overview tables, and specific summary statements) and refer to them as needed.

The information included in 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, it may be necessary to provide your reader with 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 some dietitians may not be familiar with this tool, the expert workgroup believed it was important to clarify how they defined “strong design.”

Definition of High Quality Study from Indirect Calorimetry Project:

Studies identified as “strong design” 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.

Step 5: Write and Grade 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.

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 conclusion.

Below is an example of a conclusion statement taken from the Spinal Cord Injury and Nutrition EAL[®] Project.

Example from the Disorders of Lipid Metabolism Project

Question: Does medical nutrition therapy (MNT) given by a Registered Dietitian (RD) result in changes in patients' levels of dietary fat, saturated fat, serum cholesterol and cardiac risk factors?

Conclusion: *Medical Nutrition Therapy (MNT) provided by Registered Dietitians (RDs) promotes changes in dietary intake of fat and saturated fat and positively impacts changes in serum lipid levels. When patients attended two to four MNT sessions over six to twelve weeks, they reduced daily dietary fat (5% to 8%), saturated fat (2% to 4%) and energy intake (232-710 kcal per day). Serum total cholesterol (TC) was lowered by 7% to 21% and low-density lipoprotein cholesterol (LDL-C) was lowered by 7% to 22%. Triglycerides (TG) were lowered from 11% to 31%.*

Prepare the Evidence for the Expert Panel to Review

Once you have drafted the preliminary evidence summary and conclusion statement you are ready to bring everything together. It is now time for the expert panel to review all of the evidence available to answer the question.

Below is a list of the materials needed by the expert panel to finalize the conclusion statement and assign it a grade based on the strength of the evidence.

- Question
- Preliminary Evidence Summary
- Overview Table
- Sort List / Search Plan & Results
- Evidence Worksheets for every article
- Quality Criteria Checklists for every article
- Table summarizing Quality Criteria Checklists

The expert panel will also have access to the original research articles. Additional resources that the expert work group may need in the grading session are the evidence analysts – and lead analysts. Because the evidence analyst has been the one to analyze each research article in detail, they are often called upon by the expert workgroup members to answer questions about a particular piece of research. The lead analyst should always be available to answer questions during the expert work group’s grading session.

THE
EVIDENCE
ANALYST IS A
CRITICAL
RESOURCE
FOR THE
WORKING
GROUP

Grade the Strength of the Evidence Supporting the Conclusion Statement

The expert panel reviews all the documents produced during the evidence analysis process and reaches a consensus on the strength of the evidence supporting the conclusion statement.

Before the expert panel grading session, expert panel members will review all the materials listed in the previous section. The expert workgroup members ensure that the information from the research article is abstracted accurately on the worksheets.

In some expert workgroups all of the members are responsible for reviewing all of the articles and worksheets. Other expert workgroups have found it useful to divide the task by assigning one or two of the research articles to each member to read.

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

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

The expert panel may accept the preliminary evidence summary, make only minor changes, or completely rewrite this material. Once the expert panel is satisfied with the Evidence Summary and Conclusion Statement, they will assign a grade. The expert panel should review the *Academy’s Grade Definitions* and the Conclusion Grading Table (Table 5.0) to make sure they understand the criteria for the different grades. These tools will assist the work group in their deliberations regarding the strength of the evidence.

Grade Definitions: Strength of the Evidence for a Conclusion Statement

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 Academy of Nutrition and Dietetics 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.

*The addition of Grade V was adopted in September 2004. As the systematic reviews were accomplished by the Work Groups and the trained Evidence Analysts, situations occurred where none of the original four grades were applicable resulting in the designation of “not assignable.” The designation of Grade V was added to capture the ‘not assignable’ category. Of note, ICSI also reviewed and modified their grading system and in November 2003 they adopted a “not assignable” grade.

Table 5.0 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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
Clinical impact <ul style="list-style-type: none"> 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

The Final Step

The final step is to make the results of the evidence analysis available to practitioners so that the research can be translated into practice. The Academy of Nutrition and Dietetics utilizes multiple methods to accomplish this goal.

Academy Evidence Analysis Library[®]

- For each project (or topic), the evidence analysis questions, conclusion statements, grades, evidence summaries, overview tables, worksheets, quality criteria checklists, and search plan and results are published online in the **Library** section of the EAL[®].
- All Academy members have free access to all of the content on the EAL[®] as a member benefit. Other organizations, individuals and libraries have purchased subscriptions in order to view the online EAL[®].
- The members of the Academy evidence analysis project team including expert work group members, project managers, lead analysts, analysts and Academy staff are acknowledged in the Contributors section of the EAL[®].

Academy Evidence Based Nutrition Practice Guidelines

- Evidence-based Nutrition Practice Guidelines are a series of guiding statements and treatment algorithms which are developed using a systematic process for identifying, analyzing and synthesizing scientific evidence. They are designed to assist the registered dietitian and patient/client in making decisions about appropriate nutrition care for specific disease states or conditions in typical settings. (Scope of Dietetics Practice Framework Definition of Terms 2008)
- Many Academy evidence analysis disease-specific projects become evidence-based nutrition practice guidelines and are published online in the **Guidelines** section of the EAL[®]. Nutrition Practice Guidelines published online include Adult Weight Management, Celiac Disease, Chronic Kidney Disease, COPD, Critical Illness, Diabetes, Disorders of Lipid Metabolism, Gestational Diabetes, Heart Failure, HIV/AIDS, Hypertension, Oncology, Pediatric Weight Management, Spinal Cord Injury, Vegetarian Nutrition and Unintended Weight Loss in Older Adults.

Systematic Review Articles

- After the evidence analysis is completed, members of the Evidence Analysis Team who worked together on a particular project sometimes write a systematic review and submit it to a journal, such as the *Journal of the Academy of Nutrition and Dietetics*.
- A list of the published articles based on Evidence Analysis Library[®] projects can be found on the Publications page in the **Resources** section of the Library.

Academy Position Statements

- Information from the evidence analysis projects on the EAL[®] is incorporated into Academy Position Papers which are then published in the *Journal of the Academy of Nutrition and Dietetics* and made available on Academy's website, www.eatright.org.

Academy Evidence-Based Toolkits

- Evidence-Based Toolkits are a set of companion documents which are disease or condition specific and detail how the registered dietitian (RD) or registered dietitian/dietetic technician registered (DTR) team applies the evidence based nutrition practice guideline in practice. (Scope of Dietetics Practice Framework Definition of Terms 2008)
- Toolkits typically include: documentation forms, outcomes monitoring sheets, client education resources, case studies, and Medical Nutrition Therapy (MNT) protocol for treatment of the disease or condition.
- Toolkits assist the practitioner in incorporating the Nutrition Care Process/Standardized Language as the standard for care.
- Toolkits are available for purchase from the online **Store** section of the EAL[®] as an electronic downloadable item.

Academy EAL[®] Educator Modules

- Educator modules have been developed to provide tools to the educator who wishes to incorporate content from the EAL[®] into the classroom.
- Educator modules assist in teaching students about the evidence analysis process as well as specific topics on the EAL[®]. It includes case studies, assignments, presentations and temporary subscriptions for students.
- Educator Modules are available for purchase from the online **Store** section of the EAL[®] as an electronic downloadable item.

Academy EAL[®] PowerPoint Presentations

- PowerPoint Presentations summarize all recommendations and ratings in the Evidence-based nutrition practice guidelines.
- PowerPoint Presentations are ready for you to use for meetings, in-service presentations and/or classes.
- These presentations are available for purchase from the online **Store** section of the EAL[®] as an electronic downloadable item.

Acknowledgement

The Academy of Nutrition and Dietetics is grateful to the project managers, lead analysts, analysts, workgroup members, and Academy staff who contribute to the Academy Evidence Analysis Library[®]. For a full listing, please visit the **Contributors** section of the EAL[®] (<http://www.adaevidencelibrary.com/contributors>)

Appendices

Appendix 1: 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 in the population of interest.

ANALYTICAL FRAMEWORK				
SCREENING			MONITORING AND EVALUATION	
<input type="text"/>	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> These blank boxes can be filled with the appropriate domains needed </div>		<input type="text"/>	<input type="text"/>
<input type="text"/>			<input type="text"/>	<input type="text"/>
ASSESSMENT	DIAGNOSIS	INTERVENTION	NUTRITION CARE OUTCOMES	HEALTHCARE OUTCOMES
FOOD/NUTRITION-RELATED HISTORY	INTAKE	FOOD AND/OR NUTRIENT DELIVERY	FOOD/NUTRITION-RELATED HISTORY	HEALTH AND DISEASE OUTCOMES
ANTHROPOMETRIC MEASUREMENTS	CLINICAL	NUTRITION EDUCATION	ANTHROPOMETRIC MEASUREMENTS	COST OUTCOMES
BIOCHEMICAL DATA, MEDICAL TESTS, AND PROCEDURES	BEHAVIORAL-ENVIRONMENTAL	NUTRITION COUNSELING	BIOCHEMICAL DATA, MEDICAL TESTS, AND PROCEDURES	PATIENT OUTCOMES
NUTRITION FOCUSED PHYSICAL FINDINGS		COORDINATION OF CARE	NUTRITION FOCUSED PHYSICAL FINDINGS	
CLIENT HISTORY	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> These blank boxes can be filled with the appropriate domains needed </div>		COMPARATIVE STANDARDS	
COMPARATIVE STANDARDS				

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

Third, list questions:

- Linking assessment or diagnostic factors to intervention factors
- Linking assessment or diagnostic factors to nutrition care outcomes
- Linking interventions to health care outcomes
- Linking interventions to nutrition care outcomes

Appendix 2: The PICO Format

Specify question for evidence analysis using “PICO”

Specify **P**opulation, **I**ntervention, **C**omparison, and desired **O**utcome.

	Population (Patient Or Problem)	Intervention (cause, treatment, or prognostic factor)	Comparison Intervention (if necessary)	Outcomes
TIPS For Building PICO Questions:	Describe group (of patients). Balance precision with brevity.	What intervention are you considering? <i>Be specific.</i>	What is the main alternative to compare with the intervention? <i>Be specific.</i>	What could this intervention really affect? <i>Be specific.</i>

Question for Evidence Analysis:

Appendix 3: Search Plan & Results Template

Use a *Search Plan & Results* worksheet to help you organize your decision. The *Search Plan & Results 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 2.1 presents an excerpt of a *Search Plan & Results* 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 Search Plan & Results Template

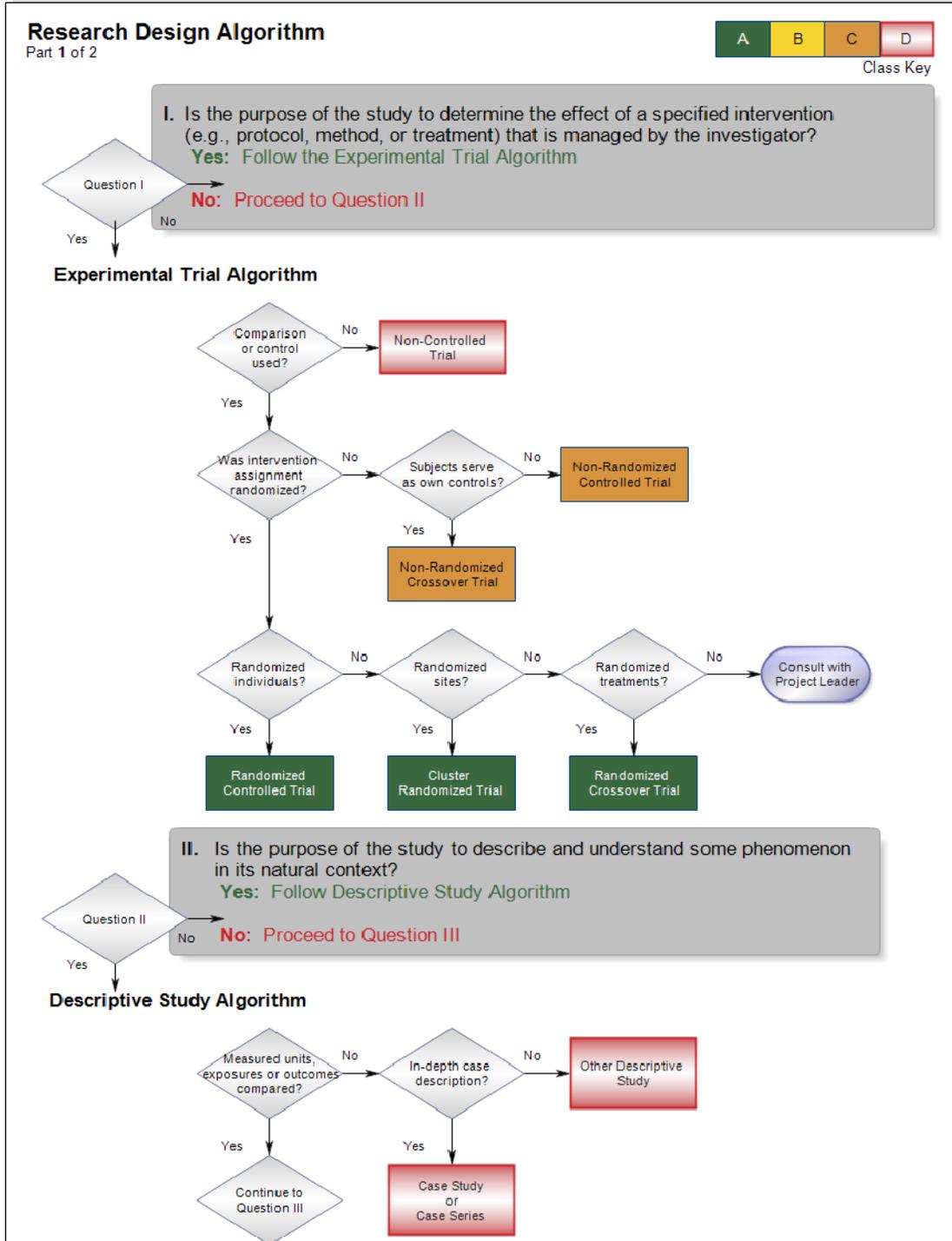
Question:	
Date of Literature Review:	
Inclusion Criteria:	<ul style="list-style-type: none"> • Age • Setting • Health Status • Nutrition-Related Problem or Condition • Study Design Preference • Size of Study Groups • Study Drop-Out Rate • Year Range • Authorship • Language
Exclusion Criteria:	<ul style="list-style-type: none"> • Age

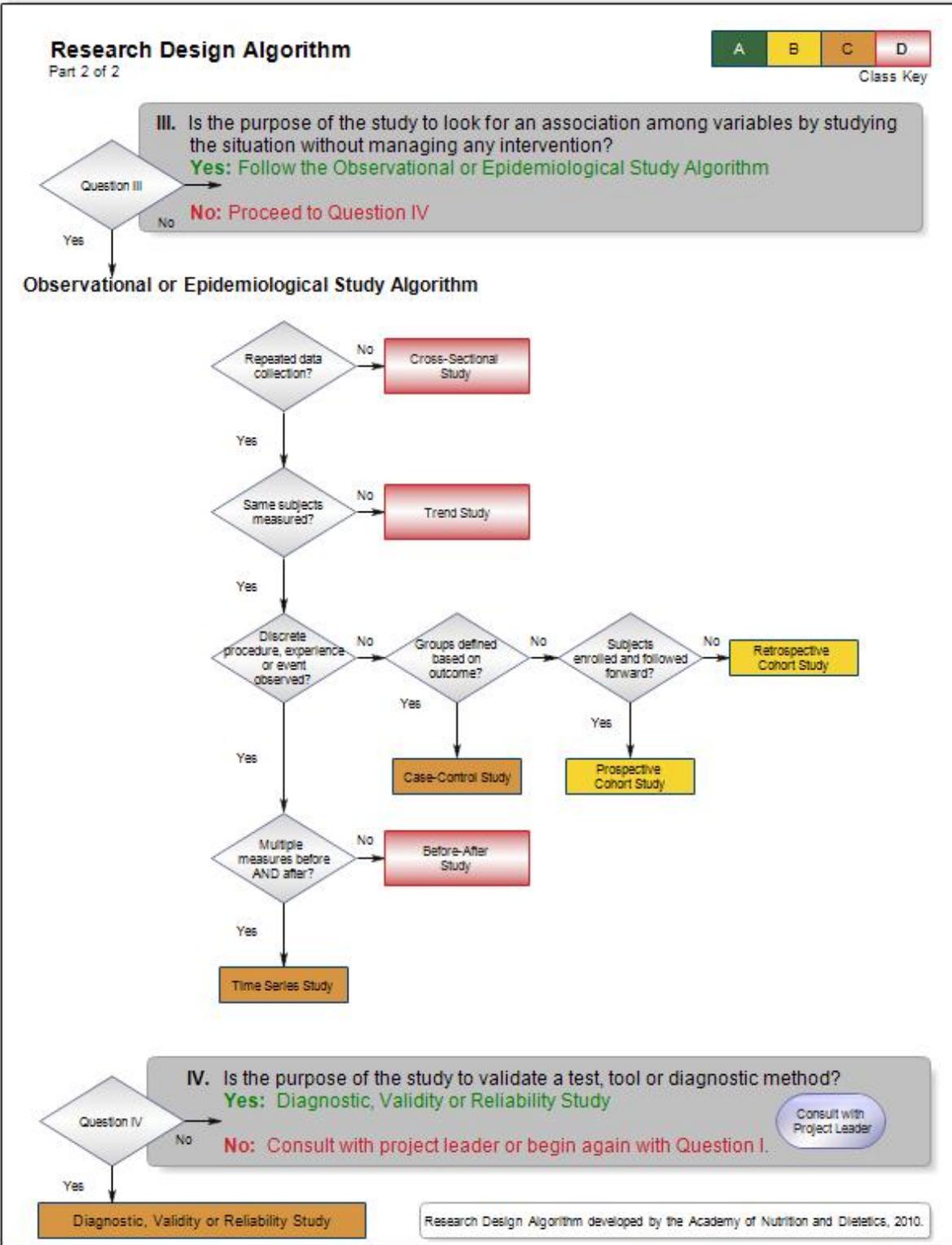
	<ul style="list-style-type: none"> • Setting • Health Status • Nutrition-Related Problems or Condition • Study Design Preference • Size of Study Groups • Study Drop-Out Rate • Year Range • Authorship • Language
Search Terms: Search Vocabulary	
Electronic Databases:	<ul style="list-style-type: none"> • Database • Search Terms • Hits
Inclusion List:	
List of Articles Included from Handsearch or Other Means	
List of Excluded Articles with Reason:	
Summary of Articles Identified to Review	<ul style="list-style-type: none"> • Number of Included Primary Research Articles Identified from all sources • Number of Included Review Articles Identified from all sources • Total Number of Included Articles • Number of Articles Considered but Excluded • Total Number of Articles Considered

Appendix 4: Hierarchy and Classification of Studies

Primary Reports		Secondary Reports	
A	Randomized Controlled Trial Cluster Randomized Trial Randomized Crossover Trial	M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Prospective Cohort Study Retrospective Cohort Study		
C	Non-Randomized Controlled Trial Non-Randomized Crossover Trial Case-Control Study Time Series Study Diagnostic, Validity or Reliability Study	R	Narrative review (Review article) Consensus statement Consensus report
D	Non-Controlled Trial Case Study or Case Series Other Descriptive Study Cross-Sectional Study Trend Study Before-After Study	X	Medical opinion

Appendix 5: Algorithm for Classifying Research Design





Appendix 6: Glossary of Terms Related to Research Design

Before-After Study

A pre-post investigation of a discrete procedure, experience or event that is not managed by the researcher. Data are collected at baseline and one or more times after the procedure, experience or event.

Case Control Study

A study which involves identifying patients who have the outcome of interest (cases) and matching them with individuals who have similar characteristics, but do not have the outcome of interest (controls), and then looking back to see if these two groups differed with regard to the exposure of interest (i.e., the hypothesized causal or contributing factors).

Case Study or Case Series

A descriptive study of one (case study or case report) or a series of patients (case series) defined by eligibility criteria, and where the unfolding course of events (disease progression, therapies, outcomes, etc.) is described in detail. The study researchers do not manipulate interventions. This study design is used to provide a detailed description of an uncommon disease or condition, a unique situation, or the introduction of a new technique.

Cluster Randomized Trial

A special type of a randomized controlled trial (RCT) where groups of individuals (e.g., clinic sites, classrooms, communities), rather than independent individuals, are randomized to the intervention alternatives.

Cohort Study

A study that involves the identification of a group (cohort) of individuals with specific characteristics in common and follows them over time to gather data about exposure to factors and the development of the outcome of interest. Comparison groups can be defined at the beginning or created later using data from the study (e.g., age group, smokers/non-smokers, amount of a specific food group consumed). **Prospective cohort** studies enroll individuals and then collect data at many intervals. **Retrospective cohort** studies use an existing longitudinal data set to look back for a temporal relationship between exposure factors and outcome development. In the medical field, many studies labeled a “population-based clinical study” could be classified as retrospective cohort studies.

Cost Benefit Analysis or Cost Effectiveness Analysis

An analysis that assesses the cost of an intervention in relation to the magnitude of outcome achieved. In cost benefit analysis, the inputs (i.e., intervention alternatives) and the resulting outcomes are quantified and expressed in monetary terms. In cost effectiveness analysis, inputs (i.e., intervention alternatives) are expressed in monetary terms but the outcomes are expressed in a standard unit, such as quality adjusted life years (QALY) or hospitalizations avoided. These are considered a synthesis of primary studies when data from multiple studies are used to derive estimates of inputs and outcomes.

Crossover Study Design

A study where two or more experimental therapies are administered, one after the other, in a specified or a random sequence, to the same group of patients. Usually there is a washout (no treatment) period between therapies. Individuals serve as their own controls. A crossover study is a special type of a randomized or non-randomized trial.

Cross-Sectional study

A study where exposure factors (e.g., individual or environmental risk factor, nutrition education) and outcomes (e.g., disease occurrence, eating behavior) are observed or measured at one point in time in a sample from the population of interest, usually by survey or interview. In this design, a researcher examines the association among factors and outcomes using a statistical test for association, but cannot infer cause and effect.

Descriptive Study

Descriptive studies, as a research category, use a variety of methods to observe existing natural or man-made phenomena without influencing it (no researcher intervention). Data are gathered, organized and analyzed to depict and describe “what is”. Descriptive studies can be quantitative and/or qualitative and provide an in-depth look at processes, characteristics and patterns. Descriptive studies can result in a theory or framework, but they do not try to determine cause and effect.

Diagnostic, Validity or Reliability Study

Types of studies that are designed to determine the sensitivity and specificity of diagnostic and assessment methods and the accuracy and/or consistency of tests or tools used to measure variables and concepts.

Epidemiological Study

Epidemiological studies, as a research category, are analytical studies of the determinants of health and illness in specific populations. Studies are designed to determine the relationship among exposure factors (which can be risk factors or protective factors) and outcomes. Epidemiologic studies are observational; the researcher does not manage any intervention. The most common epidemiological study designs are case-control, cohort, and cross-sectional studies.

Intention to Treat Analysis

A method of analysis for intervention trials in which all patients originally assigned to a treatment group are included in the analysis for that group, regardless of whether or not they completed or received that treatment.

Longitudinal

A general term that indicates data are collected from the same subjects at several points over time. It is not a specific study design.

Magnitude of Effect

Refers to how much change can be attributed to the treatment or intervention in a particular study.

Meta-analysis

A systematic, quantitative method that combines the results of all relevant studies to produce an overall estimate. A meta-analysis can be part of a systematic review, but not all systematic reviews include meta-analysis.

Narrative Review

A summary report of the state of knowledge on a particular topic. Narrative reviews are less rigorous than systematic reviews in that search methods, study inclusion criteria, and quality of the studies are often not reported.

Non-Controlled Trial

A type of intervention trial where only one group is used (there is no comparison group); but the studied intervention is defined and managed by the researcher.

Non-Randomized Controlled Trial

A study where subjects are assigned to intervention (protocol, method or treatment) alternatives by a method that is not random. The researcher does define and manage the alternatives, which could be treatment and control or two or more different interventions.

Observational Study

Observational studies include a wide range of studies in which the course of events is studied as it unfolds. The researcher does not intervene. Changes or differences that occur between groups are used to draw inferences about the association of variables and the relationships between possible causal factors and outcomes.

Phenomena

Any event, circumstance, or experience that is apparent to the senses and that can be scientifically described or appraised.

Prospective Cohort Study

See Cohort Study.

Randomized Controlled Trial (RCT)

Individuals meeting eligibility requirements are randomly assigned into an experimental group or a control group. The experimental intervention (protocol, method or treatment) and its alternative(s) are clearly defined and their implementation is closely managed by the researcher.

Retrospective Cohort Study

See Cohort Study.

Review Article

See Narrative Review or Systematic Review.

Systematic Review

A summary of the scientific literature on a specific topic or question that uses explicit methods to conduct a comprehensive literature search and identify relevant studies, critically appraise the quality of each study, and summarize the body of literature or evidence to answer the question.

Time Series

A study collecting data from the same subjects at a series of points over time during which a discrete preventive or therapeutic procedure, life experience, or event takes place. Data are collected prior to, and after (and sometimes during) the event in order to reach conclusions about its effect. Some studies labeled as “longitudinal” are time series studies.

Trial

An experimental or quasi-experimental study to determine the effect of an intervention.

Trend Study

A study in which the same or similar data about exposures and outcomes are collected from the same population many times, but each time a different sample is used. A trend study is like a series of cross-sectional studies. An example is NHANES.

Appendix 7: Evidence Abstract Worksheet Template

Citation:																	
Study Design:																	
Class:	Based on classes of evidence reports																
Quality Rating:	+, Ø, - Based on Quality Criteria Checklist																
Research Purpose:																	
Inclusion Criteria:																	
Exclusion Criteria:																	
Description of Study Protocol:	<p>Recruitment</p> <p>Design (These prompts assist you in determining which information to abstract from research article.)</p> <p>Blinding used (if applicable)</p> <p>Intervention (if applicable)</p> <p>Statistical Analysis</p>																
Data Collection Summary:	<p>Timing of Measurements</p> <p>Dependent Variables</p> <ul style="list-style-type: none"> • Variable 1: brief description (how measured?) • Variable 2: brief description (how measured?) • etc. <p>Independent Variables</p> <p>Control Variables</p>																
Description of Actual Data Sample:	<p>Initial N: (e.g., 731 (298 males, 433 females))</p> <p>Attrition (final N):</p> <p>Age:</p> <p>Ethnicity:</p> <p>Other relevant demographics:</p> <p>Anthropometrics (e.g., were groups same or different on important measures)</p> <p>Location:</p>																
Summary of Results:	<table border="1"> <thead> <tr> <th colspan="4">Key Findings</th> </tr> <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> </thead> <tbody> <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> </tbody> </table>	Key Findings				Variables	Treatment Group Measures and confidence intervals	Control group Measures and confidence intervals	Statistical Significance of Group Difference	Dep var 1	Mean, CI. e.g., 4.5±2.2	Mean, CI. e.g., 1.5±2.0	Stat signif difference between groups e.g., p=.002	Dep var 2			
Key Findings																	
Variables	Treatment Group Measures and confidence intervals	Control group Measures and confidence intervals	Statistical Significance of Group Difference														
Dep var 1	Mean, CI. e.g., 4.5±2.2	Mean, CI. e.g., 1.5±2.0	Stat signif difference between groups e.g., p=.002														
Dep var 2																	

	<table border="1"> <tr> <td data-bbox="456 201 646 237">Etc.</td> <td data-bbox="646 201 906 237"></td> <td data-bbox="906 201 1182 237"></td> <td data-bbox="1182 201 1502 237"></td> </tr> <tr> <td colspan="4" data-bbox="456 237 1502 279">Other Findings</td> </tr> </table>	Etc.				Other Findings			
Etc.									
Other Findings									
Author Conclusion:									
Review Comments:	<i>Italicize reviewer and expert panel comments.</i>								
Funding Source	Determine the funding source: Government, Industry, University/Hospital , Not-for-Profit and/or Other.								

Appendix 8: Quality Criteria Checklist: Primary Research

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 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
<i>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.</i>					
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 of study subjects/patients</u> 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</u> comparable?	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?				

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4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	Were <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 <u>intervention/therapeutic regimens/exposure factor or procedure</u> and any <u>comparison(s)</u> described in detail? Were <u>intervening factors</u> described?	Yes	No	Unclear	N/A
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 <u>outcomes</u> clearly defined and the <u>measurements</u> 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 <u>statistical analysis</u> 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 <u>conclusions supported by results</u> 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 <u>funding or sponsorship</u> 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 (-)					
<i>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 Worksheet.</i>					

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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 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 Worksheet.

Appendix 9: Quality Criteria Checklist: Primary Research: Non-human Subjects

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 Checklist: Primary Research: Non-human Subjects

RELEVANCE QUESTIONS		Yes	No	Unclear	N/A
1.	Would implementing the studied intervention, procedure or product (if found successful) result in improved outcomes for the patients/clients/target population group? (NA for some Epi studies)				
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about?				
3.	Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice?				
4.	Is the intervention, procedure or product feasible for application in dietetic practice?				
<i>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.</i>					
VALIDITY QUESTIONS		Yes	No	Unclear	N/A
1.	Was the <u>research question</u> clearly stated?				
1.1	Was the specific intervention(s) or procedure (independent variable(s)) or exposure factor, process or product of interest identified?				
1.2	Was the outcome(s) (dependent variable(s)) or status or condition of interest clearly indicated?				
1.3	Were the study context and setting specified?				
2.	Was the <u>selection</u> of study subjects/units to be free from bias?				
2.1	Were eligibility criteria (inclusion/exclusion) specified with sufficient detail and without omitting criteria critical to the study?				
2.2	Were criteria applied equally to all units of observation and all study groups?				
2.3	Was the source and other relevant characteristics of units of observation described?				
2.4	Were the selected units a representative sample of the context and setting for application of study findings?				
3.	Were <u>study groups comparable</u> or was an appropriate reference standard used?				
3.1	Was the method of assigning subjects/units of observation described and unbiased? (Method of randomization identified if RCT)				
3.2	Was the distribution of relevant characteristics similar across subjects/units of observation and study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent comparison data preferred over historical data.)				
3.4	If a 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 diagnostic, validity or reliability study, was there a comparison with an appropriate reference standard?				
	NOTE: Criterion #3 is NA if only one group was studied, comparison groups were not constructed for analysis, and a comparison to a reference standard not made.				
4.	Were methods of handling losses from the original sample (withdrawals) described?				
4.1	Were follow-up methods described and the same for all subjects/units of observation				

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<p>and groups?</p> <p>4.2 Were the number, characteristics of withdrawn units (i.e., damaged specimen, dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for the sample and each group?</p> <p>4.3 Were all enrolled subjects/units (in the original sample) accounted for?</p> <p>4.4 Were reasons for withdrawal or loss similar across groups?</p> <p>4.5 If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study?</p>	
<p>5. Was <u>blinding</u> used to prevent introduction of bias?</p> <p>5.1 Were field and research staff and investigators blinded to treatment group, as appropriate?</p> <p>5.2 Were data collectors blinded for outcomes assessment? (If the outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)</p> <p>5.3 In a cross-sectional study, were measurements of outcomes and risk factors blinded?</p> <p>5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?</p> <p>5.5 In diagnostic, reliability or validity study, were test results blinded to unit of observation history and other test results??</p>	<p>Yes No Unclear N/A</p>
<p>6. Was the <u>intervention/treatment regimen/exposure factor, procedure, process or product of interest and any comparison(s)</u> described in detail? Were <u>intervening factors</u> described?</p> <p>6.1 Were protocols described for all alternatives studied?</p> <p>6.2 Was the context (study setting, intervention or exposure details or process, involved personnel, etc) described?</p> <p>6.3 Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?</p> <p>6.4 Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured, and are data free from bias?</p> <p>6.5 Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?</p> <p>6.6 Were extra or unplanned interventions or environmental influences during the study period described?</p> <p>6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all units of observation and all groups?</p> <p>6.8 In diagnostic, validity or reliability study, were details of test administration and replication sufficiently described?</p>	<p>Yes No Unclear N/A</p>
<p>7. Were <u>outcomes or condition or status of interest</u> clearly defined and the <u>measurements valid and reliable</u>?</p> <p>7.1 Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?</p> <p>7.2 Were nutrition-related outcomes measures, if included, appropriate to the study question and outcomes of concern?</p> <p>7.3 Was the period of follow-up long enough for important outcome(s) to occur?</p> <p>7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?</p> <p>7.5 Was the measurement of outcomes or effect at an appropriate level of precision?</p> <p>7.6 Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?</p> <p>7.7 Were the measurements conducted consistently across units of observation, groups and time periods?</p>	<p>Yes No Unclear N/A</p>
<p>8. Was the <u>statistical analysis</u> appropriate for the study design and type of outcome indicators?</p> <p>8.1 Were statistical analyses adequately described and the results reported appropriately?</p> <p>8.2 Were correct statistical tests used and assumptions of test not violated?</p> <p>8.3 Were statistics reported with levels of significance and/or confidence intervals?</p> <p>8.4 Was there a clear description of subjects/units observed included in each analysis? If appropriate, was there a dose-response analysis?</p> <p>8.5 Were adequate adjustments made for effects of confounding factors that might have</p>	<p>Yes No Unclear N/A</p>

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<p>affected the outcomes (e.g., multivariate analyses)?</p> <p>8.6 Was clinical or pragmatic significance as well as statistical significance reported?</p> <p>8.7 Was a power calculation reported to address adequate sample size to measure effect and avoid type 2 error? (This is especially important if findings are negative.)</p>	
<p>9. Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?</p> <p>9.1 Is there an adequate discussion of findings?</p> <p>9.2 Are biases and study limitations identified and discussed?</p>	Yes No Unclear N/A
<p>10. Is bias due to study's <u>funding or sponsorship</u> unlikely?</p> <p>10.1 Were sources of funding and investigators' affiliations described?</p> <p>10.2 Was there no apparent conflict of interest?</p>	Yes No Unclear N/A
<p>MINUS/NEGATIVE (-) <i>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 Worksheet.</i></p>	
<p>NEUTRAL (Ø) <i>If the answers to validity criteria questions 2, 3, 6, and 7 are "Yes" but several other criteria indicate study weaknesses, the report should be designated with a neutral (Ø) symbol on the Evidence Worksheet.</i></p>	
<p>PLUS/POSITIVE (+) <i>If most (six or more) of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7), the report should be designated with a plus symbol (+) on the Evidence Worksheet.</i></p>	
<p>When a validity criteria question is NA <i>If any of the ten validity questions are NA, the report requires a majority of "Yes" answers (including 2, 3, 6, 7, as applicable) for a plus (+), or a majority of "No" answers for a minus (-) rating.</i></p>	

Appendix 10: Quality Criteria Checklist: 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 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
<i>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.</i>					
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 issues 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 (-) <i>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.</i>					
NEUTRAL (∅) <i>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 Worksheet.</i>					
PLUS/POSITIVE (+) <i>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 Worksheet.</i>					

Appendix 11: Important Considerations from Checklist by Study Design

Study Design Type	Class	Distinguishing Characteristics	Most Important Quality Considerations (from Quality Checklist)
EXPERIMENTAL & QUASI-EXPERIMENTAL TRIALS		Investigator managed independent variable (the intervention)	
Randomized Controlled Trial Cluster Randomized Trial	A A	Randomization (at individual or site [a cluster of individuals] level) used to assign subjects to two or more groups	2.1, 3.1, 3.2, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Randomized Crossover Trial Non-randomized Crossover Trial	A C	Subjects receive two interventions in a random or non-random sequence, with a washout period between them	2.1, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Non-randomized Controlled Trial	C	Subjects assigned to two or more groups using a non-random method	2.1 - 2.3, 3.2, 4.2 - 4.4, 5.1, 5.2, 6.3, 6.4, 7.4, 7.6, 8.5
Non Controlled Trial	D	Only one group studied, no comparison group	2.1, 2.3, 4.3, 5.2, 6.3 - 6.6, 7.4, 7.6, 8.5
DESCRIPTIVE STUDIES		No comparison, no intervention, describes “what is”	
Case Study or Case Report Case Series	D D	Detailed description of the unfolding course of events for one or a few subjects, including treatments, intervening factors and outcomes	2.1, 2.4, 4.3, 7.4 3 – Not applicable
Other Descriptive Studies	D	In depth quantitative and/or qualitative description	1.3, 2.1, 2.4, 7.4 3 – Not applicable
OBSERVATIONAL STUDIES		Investigation of procedure, experience or event with no researcher intervention	
Before-After Study	D	Data collected at baseline and one or more times after a therapeutic or preventive procedure, experience or event	2.1, 2.3, 2.4, 4.2, 6.2 - 6.6, 7.3, 7.4, 7.6, 8.5 3 – NA if only one group
Time Series	C	Data from the same subjects at a series of points over time, including prior to, during, and following the introduction of a therapeutic or preventive procedure, event, or natural exposure	2.1, 2.3, 2.4, 4.2, 6.2, 6.4 - 6.6, 7.4, 7.6 3 – NA if only one group
EPIDEMIOLOGICAL ANALYTIC STUDIES		Comparisons constructed analytically, no researcher intervention, examines relationship among exposure factors and outcomes	
Prospective Cohort	B	Enrollment based on defining characteristic or factor and screening to verify absence of outcome of interest Large number of subjects tracked	2.1, 3.4, 4.2, 5.3, 6.3, 6.4, 7.1, 7.3, 7.4, 7.6, 8.5

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		for long period of time Repeated data collection on “exposures” and status regarding outcomes of interest	
Retrospective Cohort	B	Existing database used to create a cohort and look back for a temporal relationship between exposure factors and development of the outcome	2.1, 2.4, 3.4, 5.3, 6.3 - 6.6, 7.1, 7.3, 7.4, 7.6, 8.5
Case Control Study	C	“Cases” with the outcome are identified then matched with non- case (“controls”) from the same population Looks back to determine if exposures differ between cases and controls	2.1, 3.5, 4.2, 5.4, 7.4, 7.6, 7.7, 8.5 6.7 consider role of recall bias
Cross-Sectional Study	D	One round of data collection where exposure factors and outcome status is measured at the same time Statistical tests used to examine association among variables	2.1, 2.4, 3.4, 4.2, 4.3, 5.3, 6.4, 7.4, 7.6
Trend Study	D	Same data collected in different samples from the same population over time Like a series of cross-sectional studies	2.1, 2.4, 3.4, 4.2, 5.3, 6.4, 7.4, 7.6, 7.7, 8.5
DIAGNOSTIC, VALIDITY, OR RELIABILITY STUDIES		Comparison made with reference standard	
Diagnostic Study	C	Used to determine the sensitivity or specificity of a diagnostic or assessment method	1.3, 2.4, 3.6, 4.5, 6.8 5.5—Diagnostic Study only
Validity Study	C	Used to determine the	
Reliability Study	C	“truthfulness” or accuracy of a test, tool or procedure used to measure or classify Comparisons made to determine consistency and reproducibility of results from a test, tool or procedure	

Appendix 12: Tally Sheet of Quality Criteria Ratings

	Author A	Author B	Author C	Author D
Year				
Relevance Questions				
1				
2				
3				
4				
Validity Questions				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
Quality Rating (+,0,-)				

For each question, a table should be created to combine the answers from the quality criteria checklists completed for each article. The online tool will generate this table for each question from the completed checklists and make this tally available to all users of the Academy Evidence Analysis Library®.

Appendix 13: Sample Tally Sheet from the EAL®

	Ash et al. 2003	Berne et al 2001	Brinkworth et al	Brown SA, et al.	Derosa et al 2010	Hanefeld et al 2	Hollander PA, et	Kelley et al 2001	Li et al 2005	Manning et al 1	Mayer-Davis et	McNulty et al 20	Metz et al 2000
Overall Quality Rating													
Relevance Questions													
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Validity Questions													
1. Was the research question clearly stated?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the selection of study subjects/patients free from bias?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Were study groups comparable?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	???	Yes	Yes	Yes	Yes
4. Was method of handling withdrawals described?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Was blinding used to prevent introduction of bias?	Yes	Yes	No		Yes	Yes	Yes	Yes	Yes	???	Yes	Yes	Yes
6. Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Were outcomes clearly defined and the measurements valid and reliable?	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix 14: Overview Table Template

Author, Year, Study Design, Class Rating	Study Type / Purpose	Study Population	Intervention	Outcomes	Conclusions

Information in the first column is automatically populated from worksheets.

Appendix 15: Example of an Overview Table from the EAL[®] Health Disparities Project

Question: *What elements of cross-cultural communication enhance the effectiveness of nutrition assessment or intervention?*

Author, Year, Study Design, Class, Rating	Study Purpose	Study Population	Intervention	Outcomes	Conclusion	Limitations
<p>Brown SA, Garcia AA et al, 2002</p> <p>Study Design: Prospective, randomly, repeated measures study</p> <p>Class: A</p> <p>Rating: </p>	<p>To determine if there would be significant differences between in metabolic control, diabetes (DM) knowledge, or DM-related health beliefs at 3, 6, and 12 mos between subjects in experimental groups compared with subjects in 1-year wait-listed control groups</p>	<p>Treatment group: N=126, 60% female, mean age 54.7±8.2 yrs, 90% preferred Spanish language, mean HbA1c 11.1±3.0, mean BMI 32.33±5.97kg/m²</p> <p>Control group: N=126, 68% female, mean age 53.3±8.3 yrs, 87% preferred Spanish language, HbA1c 11.80±3.02, mean BMI 32.12±6.35kg/m²</p>	<p>52 hrs of intensive instruction in DM self-management, including:</p> <p>a) 3 mos of wily 2-hr sessions on nutrition, glucose self-monitoring, exercise, and other self-care topics</p> <p>b) 6 mos of bi-wkly sessions</p> <p>c) 3 mos of monthly sessions</p> <p>Problem-solving and food preparation demos were included</p> <p>Culturally-competent interventions included utilization of bilingual nurses and RDs, were offered in Spanish, and focused on health recommendations consistent with Mexican-American preferences</p>	<p>Significant Δ occurred between groups in FBG (19.4.95±63.27 mg/dl treatment vs. 210.51±66.65 control, P=0.010), HgA1c (10.89±2.56 treatment vs. 11.64±2.85 control, P=0.011), and DM knowledge (42.94±4.87% treatment vs. 40.92±4.67% control, P<0.001)</p>	<p>A culturally competent intervention resulted in improved outcomes measures for Mexican-American subjects with DM</p>	<p>Control group received DM education in the form of answers to questions during measurement visits, due to ethical considerations</p>
<p>Elder JP, Ayala GX et al, 2006</p> <p>Study Design: Randomized Control Trial</p> <p>Class: A</p> <p>Rating: </p>	<p>To examine the 1-year impact of behavior change approaches to reduce dietary fat and fiber in Spanish-language dominant Latinas</p>	<p>357 Spanish-language dominant Latinas</p> <p>Mean age: 39.71±9.93yrs; 79% married</p> <p>60% with income <\$2000/mo; avg family size 3 persons</p> <p>58.4% with educational level of middle school or less</p> <p>All participants were from the San Diego, CA area</p>	<p>Randomization to 1 of 3 groups for the 14-week study:</p> <p>1) "Promotoras," consisting of wily dietary counseling via lay health advisors (promotoras) at home or telephone calls over a 14-wk period + 12 tailored newsletters with homework assignments delivered via mail to participant's home</p> <p>2) "Tailored," consisting of 12 tailored print newsletters and homework assignments delivered via mail</p> <p>3) "Control," consisting of 12 "off the shelf" newsletters targeted at Spanish speaking Latinos delivered via mail</p>	<p>Significant difference (SD) between the groups for the 14-week study:</p> <p>The promotora group was SD from control group in intake of total energy and total CHO (P<0.05), and trend toward significance in intake of total energy and total CHO (P<0.1)</p>	<p>The high interactivity of the promotora intervention including home visits and phone calls, may have been the most salient reinforcer and may have led to further individual tailoring, making this type of intervention more effective than the comparison groups in the short term</p>	<p>The investigators did not provide information regarding the number of promotora visits completed in person vs. by phone</p>
<p>Ingram H, Gallegos G et al, 2005</p> <p>Study Design: Cross-sectional</p> <p>Class: D</p> <p>Rating: </p>	<p>To assess the impact that DM self-management education and support have on the patients' control of their DM</p>	<p>A group of Hispanic patients with DM living in the area of the US-Mexico border. Patients were enrolled from 2 locations:</p> <p>Yuma, AZ: 376 enrolled, 81% [306] graduated, 79% [243] reached for F/U interview, 66% female, 70% >30 yrs of age, mean weight 174.1 lbs</p> <p>Santa Cruz, AZ: 406 enrolled, 33% [135] graduated, 30% [40] reached for F/U interview, 70% female, 30% >30 yrs, mean weight 184.6 lbs</p> <p>In both locations, a majority had not graduated from high school</p>	<p>A 5-wk series of free DM education classes designed to impart the knowledge and skills necessary to be physically active, control dietary intake, monitor BG, take medications, and increase awareness of complications</p> <p>Classes were held 1 x per week; 2 hrs per class</p> <p>Use of community health workers (CHW) ("promotoras de salud") was central to the educational model</p>	<p>A significant Δ in the avg random BG measurement among participants in both programs</p> <p>Both programs achieved a significant Δ in DBP among participants</p> <p>In Yuma there was a significant Δ in HbA1c from 9.4 to 8.7 among those who initiated the program with a HbA1c>9</p> <p>A significant portion of participants in both counties reported 1 self-management behaviors, including diet, foot care, and glucose monitoring (Santa Cruz: diet 45-30%, foot care 80-100%, glucose monitoring 38-53%, P<0.001, P<0.01, n.s., respectively. Yuma: diet data incomplete, foot care 85-90%, glucose monitoring 51-60%, P<0.001, P<0.001, P<0.001, respectively)</p>	<p>Program participants achieved significant improvement in self-management behaviors, HbA1c, random BG levels, and BP readings</p>	<p>This study was limited by inconsistencies in program implementation between the 2 sites and a high dropout rate. Differences in site resources resulted, in some cases, in data gaps</p>
<p>Schillinger D, Hanmer H et al, 2008</p> <p>Study Design: Randomized Trial</p> <p>Class: A</p> <p>Rating: </p>	<p>To describe the reach of self-management support (SMS) strategies across three complementary dimensions: participation among clinics, providers and patients; representativeness of patients; and patient engagement with SMS</p>	<p>339 patients with DM ≥17 yrs old, 59% female</p> <p>19.8% insured by MediCal, 21.5% insured by Medicare, 50.2 uninsured, 8.6 other insurance</p> <p>53.4% English-speaking, 25.7% Spanish-speaking, 15.9% Cantonese-speaking</p>	<p>Randomization to either standard care (N=115, no systematic SMS), automated telephone disease management (ATDM) or monthly medical group visits (MGV)</p>	<p>ATDM: Engagement levels were high, with 92.8% responding to ≥1 ATDM call, with no SD found for language and literacy. Among patients with ≥1 nurse call-back, the proportion that generated ≥1 action plan was high (88.0%), with similar levels across language and literacy. The ATDM composite engagement product was 22.2, with higher products among those with limited English proficiency and those with limited literacy in both English and Spanish</p> <p>GVM: Engagement levels were modest, with language- and literacy-related patterns identified. 69.6% attended ≥1 GVM session, with higher rates among Cantonese (92.3%, P=0.02) and Spanish speakers (75%, P=0.02). Among patients who attended ≥1 GVM, the proportion that generated ≥1 action plan was high (88.3%), with similar levels across language and literacy groups. The GVM composite engagement product for GVM was 4.8 with lower products for both those with limited English proficiency and those with limited literacy in both English and Spanish</p>	<p>Persons with DM who are socioeconomically vulnerable and ethnically and linguistically diverse, in a public sector safety net system, appear interested in receiving DM SMS</p> <p>ATDM reached a greater proportion of the target population than GVM, and yielded higher rates of engagement for those with limited literacy and limited English proficiency</p>	<p>Small subgroup sample sizes</p>

Appendix 16: Conclusion Statement and Grade

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 findings and their likely clinical impact.)

Conclusion Grade:

(Assign an overall grade for the strength of the evidence supporting the conclusion statement. Refer to grade definitions and the Conclusion Grading Table on the following pages.)

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

Linked:

- *Sort List / Search Plan & Results*
- *Evidence Summary*
- *Overview Table*
- *Evidence Worksheets* for every article
- *Quality Criteria Checklists for every article*
- *Table summarizing Quality Criteria Checklists*

After reviewing all the evidence, the expert work group will approve a brief conclusion statement (the answer to the question) and assign a grade.

Appendix 17: Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation

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.

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 Academy of Nutrition and Dietetics 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.

*Academy 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.

Appendix 18: Conclusion Grading Table

Strength of Evidence Elements	Grades				
	I Good	II Fair	III Limited	IV Expert Opinion Only	V Grade Not Assignable
Quality <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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
Clinical Impact <ul style="list-style-type: none"> 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

Appendix 19: IDNT Terminology, 3rd Edition

Nutrition Assessment and Monitoring and Evaluation Terminology

This is a combined list of Nutrition Assessment and Monitoring and Evaluation terms. Indicators that are shaded are used ONLY for nutrition assessment. The rest of the indicators are used for assessment and monitoring and evaluation.

FOOD/NUTRITION-RELATED**HISTORY (FH)**

Food and nutrient intake, food and nutrient administration, medication/herbal supplement use, knowledge/beliefs/attitudes, behavior, food and supply availability, physical activity and function, nutrition-related patient/client-centered measures.

Food and Nutrient Intake (1)

Composition and adequacy of food and nutrient intake, and meal and snack patterns.

Energy Intake (1.1)

Total energy intake from all sources, including food, beverages, supplements, and via enteral and parenteral routes.

Energy intake (1.1.1)

- Total energy intake FH-1.1.1.1

Food and Beverage Intake (1.2)

Type, amount, and pattern of intake of foods and food groups, indices of diet quality, intake of fluids, breast milk and infant formula

Fluid/beverage intake (1.2.1)

- Oral fluids FH-1.2.1.1
 Food-derived fluids FH-1.2.1.2
 Liquid meal replacement or supplement FH-1.2.1.3

Food intake (1.2.2)

- Amount of food FH-1.2.2.1
 Types of food/meals FH-1.2.2.2
 Meal/snack pattern FH-1.2.2.3
 Diet quality index FH-1.2.2.4
 Food variety FH-1.2.2.5

Breast milk/infant formula intake (1.2.3)

- Breast milk intake FH-1.2.3.1
 Infant formula intake FH-1.2.3.2

Enteral and Parenteral Nutrition Intake (1.3)

Specialized nutrition support intake from all sources, e.g., enteral and parenteral routes.

Enteral nutrition intake (1.3.1)

- Formula/solution FH-1.3.1.1
 Feeding tube flush FH-1.3.1.2

Parenteral nutrition intake (1.3.2)

- Formula/solution FH-1.3.2.1
 IV fluids FH-1.3.2.2

Bioactive Substance Intake (1.4)

Alcohol, plant stanol and sterol esters, soy protein, psyllium and β-glucan, and caffeine intake from all sources, e.g., food, beverages, supplements, and via enteral and parenteral routes.

Alcohol intake (1.4.1)

- Drink size/volume FH-1.4.1.1
 Frequency FH-1.4.1.2
 Pattern of alcohol consumption FH-1.4.1.3

Bioactive substance intake (1.4.2)

- Plant sterol and stanol esters FH-1.4.2.1
 Soy protein FH-1.4.2.2
 Psyllium and β-glucan FH-1.4.2.3
 Food additives (specify) FH-1.4.2.4
 Other (specify) FH-1.4.2.5

Caffeine intake (1.4.3)

- Total caffeine FH-1.4.3.1

Macronutrient Intake (1.5)

Fat and cholesterol, protein, carbohydrate, and fiber intake from all sources including food, beverages, supplements, and via enteral and parenteral routes.

Fat and cholesterol intake (1.5.1)

- Total fat FH-1.5.1.1
 Saturated fat FH-1.5.1.2
 Trans fatty acids FH-1.5.1.3
 Polyunsaturated fat FH-1.5.1.4
 Monounsaturated fat FH-1.5.1.5
 Omega-3 fatty acids FH-1.5.1.6
 Dietary cholesterol FH-1.5.1.7
 Essential fatty acids FH-1.5.1.8

Protein intake (1.5.2)

- Total protein FH-1.5.2.1
 High biological value protein FH-1.5.2.2
 Casein FH-1.5.2.3
 Whey FH-1.5.2.4
 Amino acids FH-1.5.2.5
 Essential amino acids FH-1.5.2.6

Carbohydrate intake (1.5.3)

- Total carbohydrate FH-1.5.3.1
 Sugar FH-1.5.3.2
 Starch FH-1.5.3.3
 Glycemic index FH-1.5.3.4
 Glycemic load FH-1.5.3.5
 Source of carbohydrate FH-1.5.3.6
 Insulin-to-carbohydrate ratio FH-1.5.3.7

Fiber intake (1.5.4)

- Total fiber FH-1.5.4.1
 Soluble fiber FH-1.5.4.2
 Insoluble fiber FH-1.5.4.3

Micronutrient Intake (1.6)

Vitamin and mineral intake from all sources, e.g., food, beverages, supplements, and via enteral and parenteral routes.

Vitamin intake (1.6.1)

- A (1) Riboflavin (7)
 C (2) Niacin (8)
 D (3) Folate (9)
 E (4) B6 (10)
 K (5) B12 (11)
 Thiamin (6) Multivitamin (12)
 Other (specify) _____ (13)

Mineral/element intake (1.6.2)

- Calcium (1) Potassium (5)
 Chloride (2) Phosphorus (6)
 Iron (3) Sodium (7)
 Magnesium (4) Zinc (8)

- Multi-mineral (9)
 Multi-trace element (10)
 Other, (specify) _____ (11)

Food and Nutrient Administration (2)

Current and previous diets and/or food modifications, eating environment, and enteral and parenteral nutrition administration.

Diet History (2.1)

Description of food and drink regularly provided or consumed, past diets followed or prescribed and counseling received, and the eating environment.

Diet order (2.1.1)

- General, healthful diet FH-2.1.1.1
 Modified diet FH-2.1.1.2
 (specify) _____
 Enteral nutrition order FH-2.1.1.3
 (specify) _____
 Parenteral nutrition order FH-2.1.1.4
 (specify) _____

Diet experience (2.1.2)

- Previously prescribed diets FH-2.1.2.1
 Previous diet/nutrition education/counseling FH-2.1.2.2
 Self-selected diet/s followed FH-2.1.2.3
 Dieting attempts FH-2.1.2.4

Eating environment (2.1.3)

- Location FH-2.1.3.1
 Atmosphere FH-2.1.3.2
 Caregiver/companion FH-2.1.3.3
 Appropriate breastfeeding accommodations/facility FH-2.1.3.4
 Eats alone FH-2.1.3.5

Enteral and parenteral nutrition administration (2.1.4)

- Enteral access FH-2.1.4.1
 Parenteral access FH-2.1.4.2

Medication and Herbal Supplement Use (3)

Prescription and over-the counter medications, including herbal preparations and complementary medicine products used.

Medication and herbal supplements (3.1)

- Medications, specify prescription or OTC FH-3.1.1
 Herbal/complementary products (specify) FH-3.1.2
 Misuse of medication (specify) FH-3.1.3

Knowledge/Beliefs/Attitudes (4)

Understanding of nutrition-related concepts and conviction of the truth and feelings/emotions toward some nutrition-related statement or phenomenon, along with readiness to change nutrition-related behaviors.

Food and nutrition knowledge (4.1)

- Area(s) and level of knowledge FH-4.1.1
- Diagnosis specific or global nutrition-related knowledge score FH-4.1.2

Beliefs and attitudes (4.2)

- Conflict with personal/family value system FH-4.2.1
- Distorted body image FH-4.2.2
- End-of-life decisions FH-4.2.3
- Motivation FH-4.2.4
- Preoccupation with food/nutrients FH-4.2.5
- Preoccupation with weight FH-4.2.6
- Readiness to change nutrition-related behaviors FH-4.2.7
- Self-efficacy FH-4.2.8
- Self-talk/cognitions FH-4.2.9
- Unrealistic nutrition-related goals FH-4.2.10
- Unscientific beliefs/attitudes FH-4.2.11
- Food preferences (*specify*) FH-4.2.12
- Emotions (*specify*) FH-4.2.13

Behavior (5)

Patient/client activities and actions, which influence achievement of nutrition-related goals.

Adherence (5.1)

- Self-reported adherence score FH-5.1.1
- Nutrition visit attendance FH-5.1.2
- Ability to recall nutrition goals FH-5.1.3
- Self-monitoring at agreed upon rate FH-5.1.4
- Self-management as agreed upon FH-5.1.5

Avoidance behavior (5.2)

- Avoidance FH-5.2.1
- Restrictive eating FH-5.2.2
- Cause of avoidance behavior FH-5.2.3

Bingeing and purging behavior (5.3)

- Binge eating behavior FH-5.3.1
- Purging behavior FH-5.3.2

Mealtime behavior (5.4)

- Meal duration FH-5.4.1
- Percent of meal time spent eating FH-5.4.2
- Preference to drink rather than eat FH-5.4.3
- Refusal to eat/chew FH-5.4.4
- Spitting food out FH-5.4.5
- Rumination FH-5.4.6
- Patient/client/caregiver fatigue during feeding process resulting in inadequate intake FH-5.4.7
- Willingness to try new foods FH-5.4.8
- Limited number of accepted foods FH-5.4.9
- Rigid sensory preferences FH-5.4.10

Social network (5.5)

- Ability to build and utilize social network FH-5.5.1

Factors Affecting Access to Food and Food/Nutrition-Related Supplies (6)

Factors that affect intake and availability of a sufficient quantity of safe, healthful food as well as food/nutrition-related supplies.

Food/nutrition program participation (6.1)

- Eligibility for government programs FH-6.1.1
- Participation in government programs FH-6.1.2
- Eligibility for community programs FH-6.1.3
- Participation in community programs FH-6.1.4

Safe food/meal availability (6.2)

- Availability of shopping facilities FH-6.2.1
- Procurement, identification of safe food FH-6.2.2
- Appropriate meal preparation facilities FH-6.2.3
- Availability of safe food storage FH-6.2.4
- Appropriate storage technique FH-6.2.5

Safe water availability (6.3)

- Availability of potable water FH-6.3.1
- Appropriate water decontamination FH-6.3.2

Food and nutrition-related supplies availability (6.4)

- Access to food and nutrition-related supplies FH-6.4.1
- Access to assistive eating devices FH-6.4.2
- Access to assistive food preparation devices FH 6.4.3

Physical Activity and Function (7)

Physical activity, cognitive and physical ability to engage in specific tasks, e.g., breastfeeding, self-feeding.

Breastfeeding (7.1)

- Initiation of breastfeeding FH-7.1.1
- Duration of breastfeeding FH-7.1.2
- Exclusive breastfeeding FH-7.1.3
- Breastfeeding problems FH-7.1.4

Nutrition-related ADLs and IADLs (7.2)

- Physical ability to complete tasks for meal preparation FH-7.2.1
- Physical ability to self-feed FH-7.2.2
- Ability to position self in relation to plate FH-7.2.3
- Receives assistance with intake FH 7.2.4
- Ability to use adaptive eating devices FH 7.2.5
- Cognitive ability to complete tasks for meal preparation FH-7.2.6
- Remembers to eat, recalls eating FH-7.2.7
- Mini Mental State Examination Score FH-7.2.8

- Nutrition-related activities of daily living (ADL) score FH-7.2.9
- Nutrition-related instrumental activities of daily living (IADL) score FH-7.2.10

Physical activity (7.3)

- Physical activity history FH-7.3.1
- Consistency FH-7.3.2
- Frequency FH-7.3.3
- Duration FH-7.3.4
- Intensity FH-7.3.5
- Type of physical activity FH-7.3.6
- Strength FH-7.3.7
- TV/screen time FH-7.3.8
- Other sedentary activity time FH-7.3.9
- Involuntary physical movement FH-7.3.10
- NEAT FH-7.3.11

Nutrition-Related Patient/Client-Centered Measures (8)

Patient/client's perception of his or her nutrition intervention and its impact on life.

Nutrition quality of life (8.1)

- Nutrition quality of life responses FH-8.1.1

ANTHROPOMETRIC MEASUREMENTS (AD)

Height, weight, body mass index (BMI), growth pattern indices/percentile ranks, and weight history.

Body composition/growth/weight history (1.1)

- Height/length AD-1.1.1
- Weight AD-1.1.2
- Frame size AD-1.1.3
- Weight change AD-1.1.4
- Body mass index AD-1.1.5
- Growth pattern indices/percentile ranks AD-1.1.6
- Body compartment estimates AD-1.1.7

BIOCHEMICAL DATA, MEDICAL TESTS AND PROCEDURES (BD)

Laboratory data, (e.g., electrolytes, glucose, and lipid panel) and tests (e.g., gastric emptying time, resting metabolic rate).

Acid-base balance (1.1)

- Arterial pH BD-1.1.1
- Arterial bicarbonate BD-1.1.2
- Partial pressure of carbon dioxide in arterial blood, PaCO₂ BD-1.1.3
- Partial pressure of oxygen in arterial blood, PaO₂ BD-1.1.4
- Venous pH BD-1.1.5
- Venous bicarbonate BD-1.1.6

Electrolyte and renal profile (1.2)

- BUN BD-1.2.1
- Creatinine BD-1.2.2
- BUN:creatinine ratio BD-1.2.3
- Glomerular filtration rate BD-1.2.4
- Sodium BD-1.2.5
- Chloride BD-1.2.6
- Potassium BD-1.2.7
- Magnesium BD-1.2.8
- Calcium, serum BD-1.2.9
- Calcium, ionized BD-1.2.10
- Phosphorus BD-1.2.11
- Serum osmolality BD-1.2.12
- Parathyroid hormone BD-1.2.13

Essential fatty acid profile (1.3)

- Triene:Tetraene ratio BD-1.3.1

Gastrointestinal profile (1.4)

- Alkaline phosphatase BD-1.4.1
- Alanine aminotransferase, ALT BD-1.4.2
- Aspartate aminotransferase, AST BD-1.4.3
- Gamma glutamyl transferase, GGT BD-1.4.4
- Gastric residual volume BD-1.4.5
- Bilirubin, total BD-1.4.6
- Ammonia, serum BD-1.4.7
- Toxicology report, including alcohol BD-1.4.8
- Prothrombin time, PT BD-1.4.9
- Partial thromboplastin time, PTT BD-1.4.10
- INR (ratio) BD-1.4.11
- Fecal fat BD-1.4.12
- Amylase BD-1.4.13
- Lipase BD-1.4.14
- Other digestive enzymes (*specify*) BD-1.4.15
- D-xylose BD-1.4.16
- Hydrogen breath test BD-1.4.17
- Intestinal biopsy BD-1.4.18
- Stool culture BD-1.4.19
- Gastric emptying time BD-1.4.20
- Small bowel transit time BD-1.4.21
- Abdominal films BD-1.4.22
- Swallow study BD-1.4.23

Glucose/endocrine profile (1.5)

- Glucose, fasting BD-1.5.1
- Glucose, casual BD-1.5.2
- HgbA1c BD-1.5.3

<input type="checkbox"/> Preprandial capillary plasma glucose	BD-1.5.4
<input type="checkbox"/> Peak postprandial capillary plasma glucose	BD-1.5.5
<input type="checkbox"/> Glucose tolerance test	BD-1.5.6
<input type="checkbox"/> Cortisol level	BD-1.5.7
<input type="checkbox"/> IGF-binding protein	BD-1.5.8
<input type="checkbox"/> Thyroid function tests (TSH, T4, T3)	BD-1.5.9
Inflammatory profile (1.6)	
<input type="checkbox"/> C-reactive protein	BD-1.6.1
Lipid profile (1.7)	
<input type="checkbox"/> Cholesterol, serum	BD-1.7.1
<input type="checkbox"/> Cholesterol, HDL	BD-1.7.2
<input type="checkbox"/> Cholesterol, LDL	BD-1.7.3
<input type="checkbox"/> Cholesterol, non-HDL	BD-1.7.4
<input type="checkbox"/> Total cholesterol:HDL cholesterol	BD-1.7.5
<input type="checkbox"/> LDL:HDL	BD-1.7.6
<input type="checkbox"/> Triglycerides, serum	BD-1.7.7
Metabolic rate profile (1.8)	
<input type="checkbox"/> Resting metabolic rate, measured	BD-1.8.1
<input type="checkbox"/> RQ	BD-1.8.2
Mineral profile (1.9)	
<input type="checkbox"/> Copper, serum or plasma	BD-1.9.1
<input type="checkbox"/> Iodine, urinary excretion	BD-1.9.2
<input type="checkbox"/> Zinc, serum or plasma	BD-1.9.3
<input type="checkbox"/> Other	BD-1.9.4
Nutritional anemia profile (1.10)	
<input type="checkbox"/> Hemoglobin	BD-1.10.1
<input type="checkbox"/> Hematocrit	BD-1.10.2
<input type="checkbox"/> Mean corpuscular volume	BD-1.10.3
<input type="checkbox"/> Red blood cell folate	BD-1.10.4
<input type="checkbox"/> Red cell distribution width	BD-1.10.5
<input type="checkbox"/> B12, serum	BD-1.10.6
<input type="checkbox"/> Methylmalonic acid, serum	BD-1.10.7
<input type="checkbox"/> Folate, serum	BD-1.10.8
<input type="checkbox"/> Homocysteine, serum	BD-1.10.9
<input type="checkbox"/> Ferritin, serum	BD-1.10.10
<input type="checkbox"/> Iron, serum	BD-1.10.11
<input type="checkbox"/> Total iron-binding capacity	BD-1.10.12
<input type="checkbox"/> Transferrin saturation	BD-1.10.13
Protein profile (1.11)	
<input type="checkbox"/> Albumin	BD-1.11.1
<input type="checkbox"/> Prealbumin	BD-1.11.2
<input type="checkbox"/> Transferrin	BD-1.11.3
<input type="checkbox"/> Phenylalanine, plasma	BD-1.11.4
<input type="checkbox"/> Tyrosine, plasma	BD-1.11.5
<input type="checkbox"/> Amino acid, other, specify	BD-1.11.6
<input type="checkbox"/> Antibody level, specify	BD-1.11.7
Urine profile (1.12)	
<input type="checkbox"/> Urine color	BD-1.12.1
<input type="checkbox"/> Urine osmolality	BD-1.12.2
<input type="checkbox"/> Urine specific gravity	BD-1.12.3
<input type="checkbox"/> Urine test, specify	BD-1.12.4
<input type="checkbox"/> Urine volume	BD-1.12.5
Vitamin profile (1.13)	
<input type="checkbox"/> Vitamin A, serum or plasma retinol	BD-1.13.1
<input type="checkbox"/> Vitamin C, plasma or serum	BD-1.13.2
<input type="checkbox"/> Vitamin D, 25-hydroxy	BD-1.13.3
<input type="checkbox"/> Vitamin E, plasma alpha-tocopherol	BD-1.13.4
<input type="checkbox"/> Thiamin, activity coefficient for erythrocyte transketolase activity	BD-1.13.5
<input type="checkbox"/> Riboflavin, activity coefficient for erythrocyte glutathione reductase activity	BD-1.13.6
<input type="checkbox"/> Niacin, urinary N ¹ methyl-	BD-1.13.7

nicotinamide concentration	
<input type="checkbox"/> Vitamin B6, plasma or serum	BD-1.13.8
pyridoxal 5' phosphate concentration	
<input type="checkbox"/> Other	BD-1.13.9

NUTRITION-FOCUSED PHYSICAL FINDINGS (PD)

Findings from an evaluation of body systems, muscle and subcutaneous fat wasting, oral health, suck/swallow/breathe ability, appetite, and affect.

Nutrition-focused physical findings (1.1)

<input type="checkbox"/> Overall appearance	PD-1.1.1
(specify) _____	
<input type="checkbox"/> Body language	PD-1.1.2
(specify) _____	
<input type="checkbox"/> Cardiovascular-pulmonary	PD-1.1.3
(specify) _____	
<input type="checkbox"/> Extremities, muscles and bones	PD-1.1.4
(specify) _____	
<input type="checkbox"/> Digestive system (mouth to rectum)	PD-1.1.5
(specify) _____	
<input type="checkbox"/> Head and eyes	PD-1.1.6
(specify) _____	
<input type="checkbox"/> Nerves and cognition	PD-1.1.7
(specify) _____	
<input type="checkbox"/> Skin	PD-1.1.8
(specify) _____	
<input type="checkbox"/> Vital signs	PD-1.1.9
(specify) _____	

CLIENT HISTORY (CH)

Current and past information related to personal, medical, family, and social history.

Personal History (1)

General patient/client information such as age, gender, race/ethnicity, language, education, and role in family.

Personal data (1.1)

<input type="checkbox"/> Age	CH-1.1.1
<input type="checkbox"/> Gender	CH-1.1.2
<input type="checkbox"/> Race/Ethnicity	CH-1.1.3
<input type="checkbox"/> Language	CH-1.1.4
<input type="checkbox"/> Literacy factors	CH-1.1.5
<input type="checkbox"/> Education	CH-1.1.6
<input type="checkbox"/> Role in family	CH-1.1.7
<input type="checkbox"/> Tobacco use	CH-1.1.8

Personal data (1.1), cont'd

<input type="checkbox"/> Physical disability	CH-1.1.9
<input type="checkbox"/> Mobility	CH-1.1.10

Patient/Client/Family Medical/Health History (2)

Patient/client or family disease states, conditions, and illnesses that may have nutritional impact.

Patient/client OR family nutrition-oriented medical/health history (2.1)

Specify issue(s) and whether it is patient/client history (P) or family history (F)

<input type="checkbox"/> Patient/client chief nutrition complaint (specify) _____	CH-2.1.1	P or F
<input type="checkbox"/> Cardiovascular (specify) _____	CH-2.1.2	P or F
<input type="checkbox"/> Endocrine/metabolism (specify) _____	CH-2.1.3	P or F
<input type="checkbox"/> Excretory (specify) _____	CH-2.1.4	P or F
<input type="checkbox"/> Gastrointestinal (specify) _____	CH-2.1.5	P or F

<input type="checkbox"/> Gynecological (specify) _____	CH-2.1.6	P or F
<input type="checkbox"/> Hematology/oncology (specify) _____	CH-2.1.7	P or F
<input type="checkbox"/> Immune (e.g., food allergies) (specify) _____	CH-2.1.8	P or F
<input type="checkbox"/> Integumentary (specify) _____	CH-2.1.9	P or F
<input type="checkbox"/> Musculoskeletal (specify) _____	CH-2.1.10	P or F
<input type="checkbox"/> Neurological (specify) _____	CH-2.1.11	P or F
<input type="checkbox"/> Psychological (specify) _____	CH-2.1.12	P or F
<input type="checkbox"/> Respiratory (specify) _____	CH-2.1.13	P or F
<input type="checkbox"/> Other (specify) _____	CH-2.1.14	P or F

Treatments/therapy/complementary/alternative medicine (2.2)

Documented medical or surgical treatments, complementary and alternative medicine that may impact nutritional status of the patient

<input type="checkbox"/> Medical treatment/therapy (specify) _____	CH-2.2.1
<input type="checkbox"/> Surgical treatment (specify) _____	CH-2.2.2
<input type="checkbox"/> Complementary/alternative medicine (specify) _____	CH-2.2.3
<input type="checkbox"/> Palliative/end-of-life care (specify) _____	CH-2.2.4

Social History (3)

Patient/client socioeconomic status, housing situation, medical care support and involvement in social groups.

Social history (3.1)

<input type="checkbox"/> Socioeconomic factors (specify) _____	CH-3.1.1
<input type="checkbox"/> Living/housing situation (specify) _____	CH-3.1.2
<input type="checkbox"/> Domestic issues (specify) _____	CH-3.1.3
<input type="checkbox"/> Social and medical support (specify) _____	CH-3.1.4
<input type="checkbox"/> Geographic location of home (specify) _____	CH-3.1.5
<input type="checkbox"/> Occupation (specify) _____	CH-3.1.6
<input type="checkbox"/> Religion (specify) _____	CH-3.1.7

Social history (3.1), cont'd

<input type="checkbox"/> History of recent crisis (specify) _____	CH-3.1.8
<input type="checkbox"/> Daily stress level	CH-3.1.9

COMPARATIVE STANDARDS (CS)

Energy Needs (1)

Estimated energy needs (1.1)

<input type="checkbox"/> Total energy estimated needs	CS-1.1.1
<input type="checkbox"/> Method for estimating needs	CS-1.1.2

Macronutrient Needs (2)

Estimated fat needs (2.1)

<input type="checkbox"/> Total fat estimated needs	CS-2.1.1
<input type="checkbox"/> Type of fat needed	CS-2.1.2
<input type="checkbox"/> Method for estimating needs	CS-2.1.3

Estimated protein needs (2.2)

<input type="checkbox"/> Total protein estimated needs	CS-2.2.1
<input type="checkbox"/> Type of protein needed	CS-2.2.2

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<input type="checkbox"/> Method for estimating needs	CS-2.2.3			
Estimated carbohydrate needs (2.3)		Micronutrient Needs (4)		
<input type="checkbox"/> Total carbohydrate estimated needs	CS-2.3.1	Estimated vitamin needs (4.1)		
<input type="checkbox"/> Type of carbohydrate needed	CS-2.3.2	<input type="checkbox"/> A (1)	<input type="checkbox"/> Riboflavin (7)	
<input type="checkbox"/> Method for estimating needs	CS-2.3.3	<input type="checkbox"/> C (2)	<input type="checkbox"/> Niacin (8)	
Estimated fiber needs (2.4)		<input type="checkbox"/> D (3)	<input type="checkbox"/> Folate (9)	
<input type="checkbox"/> Total fiber estimated needs	CS-2.4.1	<input type="checkbox"/> E (4)	<input type="checkbox"/> B6 (10)	
<input type="checkbox"/> Type of fiber needed	CS-2.4.2	<input type="checkbox"/> K (5)	<input type="checkbox"/> B12 (11)	
<input type="checkbox"/> Method for estimating needs	CS-2.4.3	<input type="checkbox"/> Thiamin (6)		
Fluid Needs (3)		<input type="checkbox"/> Other (<i>specify</i>) (12)		
Estimated fluid needs (3.1)		<input type="checkbox"/> Method for estimating needs (13)		
<input type="checkbox"/> Total fluid estimated needs	CS-3.1.1	Estimated mineral needs (4.2)		
<input type="checkbox"/> Method for estimating needs	CS-3.1.2	<input type="checkbox"/> Calcium (1)	<input type="checkbox"/> Potassium (5)	
		<input type="checkbox"/> Chloride (2)	<input type="checkbox"/> Phosphorus (6)	
		<input type="checkbox"/> Iron (3)	<input type="checkbox"/> Sodium (7)	
			<input type="checkbox"/> Magnesium (4)	
			<input type="checkbox"/> Zinc (8)	
			<input type="checkbox"/> Other (<i>specify</i>) (9)	
			<input type="checkbox"/> Method for estimating needs (10)	
			Weight and Growth Recommendation (5)	
			Recommended body weight/body mass	
			Index/growth (5.1)	
			<input type="checkbox"/> Ideal/reference body weight (IBW)	CS-5.1.1
			<input type="checkbox"/> Recommended body mass index (BMI)	CS-5.1.2
			<input type="checkbox"/> Desired growth pattern	CS-5.1.3

Nutrition Diagnostic Terminology

INTAKE**NI**

Defined as “actual problems related to intake of energy, nutrients, fluids, bioactive substances through oral diet or nutrition support”

Energy Balance (1)

Defined as “actual or estimated changes in energy (kcal) balance”

- Unused NI-1.1
- Increased energy expenditure NI-1.2
- Unused NI-1.3
- Inadequate energy intake NI-1.4
- Excessive energy intake NI-1.5
- Predicted suboptimal energy intake NI-1.6
- Predicted excessive energy intake NI-1.7

Oral or Nutrition Support Intake (2)

Defined as “actual or estimated food and beverage intake from oral diet or nutrition support compared with patient goal”

- Inadequate oral intake NI-2.1
- Excessive oral intake NI-2.2
- Inadequate enteral nutrition infusion NI-2.3
- Excessive enteral nutrition infusion NI-2.4
- Less than optimal enteral nutrition NI-2.5
- Inadequate parenteral nutrition infusion NI-2.6
- Excessive parenteral nutrition infusion NI-2.7
- Less than optimal parenteral nutrition NI-2.8
- Limited food acceptance NI-2.9

Fluid Intake (3)

Defined as “actual or estimated fluid intake compared with patient goal”

- Inadequate fluid intake NI-3.1
- Excessive fluid intake NI-3.2

Bioactive Substances (4)

Defined as “actual or observed intake of bioactive substances, including single or multiple functional food components, ingredients, dietary supplements, alcohol”

- Inadequate bioactive substance intake NI-4.1
- Excessive bioactive substance intake NI-4.2
- Excessive alcohol intake NI-4.3

Nutrient (5)

Defined as “actual or estimated intake of specific nutrient groups or single nutrients as compared with desired levels”

- Increased nutrient needs (specify) _____ NI-5.1
- Malnutrition NI-5.2
- Inadequate protein-energy intake NI-5.3
- Decreased nutrient needs (specify) _____ NI-5.4
- Imbalance of nutrients NI-5.5

Fat and Cholesterol (5.6)

- Inadequate fat intake NI-5.6.1
- Excessive fat intake NI-5.6.2
- Inappropriate intake of fats (specify) _____ NI-5.6.3

Protein (5.7)

- Inadequate protein intake NI-5.7.1
- Excessive protein intake NI-5.7.2
- Inappropriate intake of protein or amino acids (specify) _____ NI-5.7.3

Carbohydrate and Fiber (5.8)

- Inadequate carbohydrate intake NI-5.8.1
- Excessive carbohydrate intake NI-5.8.2
- Inappropriate intake of types of carbohydrate (specify) _____ NI-5.8.3
- Inconsistent carbohydrate intake NI-5.8.4
- Inadequate fiber intake NI-5.8.5
- Excessive fiber intake NI-5.8.6

Vitamin (5.9)

- Inadequate vitamin intake NI-5.9.1 (specify) _____
- A (1) Riboflavin (7)
- C (2) Niacin (8)
- D (3) Folate (9)
- E (4) B6 (10)
- K (5) B12 (11)
- Thiamin (6)
- Other (specify) _____ (12)
- Excessive vitamin intake NI-5.9.2 (specify) _____
- A (1) Riboflavin (7)
- C (2) Niacin (8)
- D (3) Folate (9)
- E (4) B6 (10)
- K (5) B12 (11)
- Thiamin (6)
- Other (specify) _____ (12)

Mineral (5.10)

- Inadequate mineral intake NI-5.10.1 (specify) _____
- Calcium (1) Potassium (5)
- Chloride (2) Phosphorus (6)
- Iron (3) Sodium (7)
- Magnesium (4) Zinc (8)
- Other (specify) _____ (9)
- Excessive mineral intake NI-5.10.2 (specify) _____
- Calcium (1) Potassium (5)
- Chloride (2) Phosphorus (6)
- Iron (3) Sodium (7)
- Magnesium (4) Zinc (8)
- Other (specify) _____ (9)

Multi-nutrient (5.11)

- Predicted suboptimal nutrient intake NI-5.11.1
- Predicted excessive nutrient intake NI-5.11.2

CLINICAL**NC**

Defined as “nutritional findings/problems identified that relate to medical or physical conditions”

Functional (1)

Defined as “change in physical or mechanical functioning that interferes with or prevents desired nutritional consequences”

- Swallowing difficulty NC-1.1
- Biting/Chewing (masticatory) difficulty NC-1.2
- Breastfeeding difficulty NC-1.3
- Altered GI function NC-1.4

Biochemical (2)

Defined as “change in capacity to metabolize nutrients as a result of medications, surgery, or as indicated by altered lab values”

- Impaired nutrient utilization NC-2.1
- Altered nutrition-related laboratory values (specify) _____ NC-2.2
- Food–medication interaction NC-2.3
- Predicted food–medication interaction NC-2.4

Weight (3)

Defined as “chronic weight or changed weight status when compared with usual or desired body weight”

- Underweight NC-3.1
- Unintended weight loss NC-3.2
- Overweight/obesity NC-3.3
- Unintended weight gain NC-3.4

BEHAVIORAL-**ENVIRONMENTAL****NB**

Defined as “nutritional findings/problems identified that relate to knowledge, attitudes/beliefs, physical environment, access to food, or food safety”

Knowledge and Beliefs (1)

Defined as “actual knowledge and beliefs as related, observed, or documented”

- Food- and nutrition-related knowledge deficit NB-1.1
- Harmful beliefs/attitudes about food- or nutrition-related topics (use with caution) NB-1.2
- Not ready for diet/lifestyle change NB-1.3
- Self-monitoring deficit NB-1.4
- Disordered eating pattern NB-1.5
- Limited adherence to nutrition-related recommendations NB-1.6
- Undesirable food choices NB-1.7

Physical Activity and Function (2)

Defined as “actual physical activity, self-care, and quality-of-life problems as reported, observed, or documented”

- Physical inactivity NB-2.1
- Excessive physical activity NB-2.2
- Inability or lack of desire to manage self-care NB-2.3
- Impaired ability to prepare foods/meals NB-2.4
- Poor nutrition quality of life NB-2.5
- Self-feeding difficulty NB-2.6

Food Safety and Access (3)

Defined as “actual problems with food safety or access to food, water, or nutrition-related supplies”

- Intake of unsafe food NB-3.1
- Limited access to food or water NB-3.2
- Limited access to nutrition-related supplies NB-3.3

Nutrition Intervention Terminology

Nutrition Prescription

The patient/client's individualized recommended dietary intake of energy and/or selected foods or nutrients based on current reference standards and dietary guidelines and the patient/client's health condition and nutrition diagnosis (*specify*).

FOOD AND/OR NUTRIENT DELIVERY

ND

Meal and Snacks (1)

Regular eating event (meal); food served between regular meals (snack).

- General/healthful diet ND-1.1
- Modify distribution, type, or amount of food and nutrients within meals or at specified time ND-1.2
- Specific foods/beverages or groups ND-1.3
- Other ND-1.4
(specify) _____

Enteral and Parenteral Nutrition (2)

Nutrition provided through the GI tract via tube, catheter, or stoma (enteral) or intravenously (centrally or peripherally) (parenteral).

Enteral Nutrition (2.1)

Nutrition provided through the GI tract.

- Formula/solution ND-2.1.1
- Insert enteral feeding tube ND-2.1.2
- Site care ND-2.1.3
- Feeding tube flush ND-2.1.4

Parenteral Nutrition/IV Fluids (2.2)

Nutrition and fluids provided intravenously.

- Formula/solution ND-2.2.1
- Site care ND-2.2.2
- IV fluids ND-2.2.3

Supplements (3)

Medical Food Supplements (3.1)

Commercial or prepared foods or beverages that supplement energy, protein, carbohydrate, fiber, fat intake.

- Type
- Commercial beverage ND-3.1.1
 - Commercial food ND-3.1.2
 - Modified beverage ND-3.1.3
 - Modified food ND-3.1.4
 - Purpose ND-3.1.5
(specify) _____

Vitamin and Mineral Supplements (3.2)

Supplemental vitamins or minerals.

- Multivitamin/mineral ND-3.2.1
- Multi-trace elements ND-3.2.2
- Vitamin ND-3.2.3
 - A (1)
 - C (2)
 - D (3)
 - E (4)
 - K (5)
 - Thiamin (6)
 - Other (specify) _____ (12)
- Mineral ND-3.2.4
 - Calcium (1)
 - Chloride (2)
 - Riboflavin (7)
 - Niacin (8)
 - Folate (9)
 - B6 (10)
 - B12 (11)
 - Potassium (5)
 - Phosphorus (6)

- Iron (3)
- Magnesium (4)
- Other (specify) _____ (9)
- Sodium (7)
- Zinc (8)

Bioactive Substance Management (3.3)

Addition or change in provision of bioactive substances.

- Plant sterol and stanol esters ND-3.3.1
- Soy protein ND-3.3.2
- Psyllium and β -glucan ND-3.3.3
- Food additives ND-3.3.4
- Other ND-3.3.5
(specify) _____

Feeding Assistance (4)

Accommodation or assistance in eating.

- Adaptive equipment ND-4.1
- Feeding position ND-4.2
- Meal set-up ND-4.3
- Mouth care ND-4.4
- Other ND-4.5
(specify) _____

Feeding Environment (5)

Adjustment of the factors where food is served that impact food consumption.

- Lighting ND-5.1
- Odors ND-5.2
- Distractions ND-5.3
- Table height ND-5.4
- Table service/set up ND-5.5
- Room temperature ND-5.6
- Other ND-5.7
(specify) _____

Nutrition-Related Medication

Management (6)

Modification of a medication or herbal to optimize patient/client nutritional or health status.

- Medications ND-6.1
(specify prescription or OTC) _____
- Herbal/complementary products ND-6.2
(specify) _____

NUTRITION EDUCATION

E

Nutrition Education—Content (1)

Instruction or training intended to lead to nutrition-related knowledge.

- Purpose of the nutrition education E-1.1
- Priority modifications E-1.2
- Survival information E-1.3
- Nutrition relationship to health/disease E-1.4
- Recommended modifications E-1.5
- Other or related topics E-1.6
- Other E-1.7
(specify) _____

Nutrition Education—Application (2)

Instruction or training leading to nutrition-related

result interpretation or skills.

- Result interpretation E-2.1
- Skill development E-2.2
- Other E-2.3
(specify) _____

NUTRITION COUNSELING

C

Theoretical Basis/Approach (1)

The theories or models used to design and implement an intervention.

- Cognitive-Behavioral Theory C-1.1
- Health Belief Model C-1.2
- Social Learning Theory C-1.3
- Transtheoretical Model/
Stages of Change C-1.4
- Other C-1.5
(specify) _____

Strategies (2)

Selectively applied evidence-based methods or plans of action designed to achieve a particular goal.

- Motivational interviewing C-2.1
- Goal setting C-2.2
- Self-monitoring C-2.3
- Problem solving C-2.4
- Social support C-2.5
- Stress management C-2.6
- Stimulus control C-2.7
- Cognitive restructuring C-2.8
- Relapse prevention C-2.9
- Rewards/contingency management C-2.10
- Other C-2.11
(specify) _____

COORDINATION OF

NUTRITION CARE

RC

Coordination of Other Care During Nutrition Care (1)

Facilitating services with other professionals, institutions, or agencies during nutrition care.

- Team meeting RC-1.1
- Referral to RD with different expertise RC-1.2
- Collaboration/referral to other providers RC-1.3
- Referral to community agencies/
programs (specify) _____ RC-1.4

Discharge and Transfer of Nutrition Care to New Setting or Provider (2)

Discharge planning and transfer of nutrition care from one level or location of care to another.

- Collaboration/referral to other providers RC-2.1
- Referral to community agencies/
programs (specify) _____ RC-2.2