Academy of Nutrition and Dietetics

Evidence Analysis Manual: Steps in the Academy Evidence Analysis Process

Academy of Nutrition and Dietetics
Evidence Analysis Library®
April 2016

EVIDENCE ANALYSIS MANUAL: Steps in the Academy Evidence Analysis Process

ISBN: 978-0-88091-429-1

Research, International and Strategic Business Development Team
Academy of Nutrition and Dietetics
120 South Riverside Plaza
Suite 2000
Chicago, IL 60606-6995
800/877-1600
www.eatrightpro.org
www.andeal.org

Updated April 2016

Table of Contents

Preface

How to Use This Manual.

The *Evidence Analysis Manual* was created by the Academy of Nutrition and Dietetics (Academy) to help the systematic review project team - expert workgroup members, project manager, lead analysts, 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 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 from the EAL (www.andeal.org) Methodology section.

Table i. Steps of the Evidence Analysis Process

Steps of the Evidence Analysis Process	Brief Description	Tools
Chapter 1 **Step 1 - Formulate Evidence Analysis Question**	Specify a focused question in a defined area of practice Three key items are used to generate good quality questions: an analytical framework to identify links between factors and outcomes; the PICO format to write questions; and the Nutrition Care Process to serve as a framework.	*Appendix 1: Question Formulation Template* *Appendix 2: The PICO Chart*
Chapter 2 **Step 2 - Gather and Classify Evidence**	Develop a search plan to conduct a detailed literature search. The search plan should clearly define the inclusion and exclusion criteria and identify the key search terms and outcomes necessary to conduct a comprehensive search. The search plan and all literature searches results are documented and assessed for inclusion eligibility. (Classes are: A, B, C, D, M, R, and X.)	*Appendix 3: Search Plan & Results Table* *Appendix 4: Classes of Evidence Reports* *Appendix 5: Algorithm for Classifying Research Design* *Appendix 6: Glossary of Research Design Terms*
Chapter 3 **Step 3 - Critically Appraise Each Article**	Critically assess each included article for methodologic quality. Each study is evaluated based on appropriateness of study design and the quality of how the study was conducted by using the Academy's risk of bias tool called the Quality Criteria Checklist (QCC).	*Appendix 7: Evidence Abstract Worksheet Template* *Appendix 8:Quality Criteria Checklist: Primary Research* *Appendix 9: Checklist: Primary Research Non human* *Appendix 10: Quality Criteria Checklist: Review Article* *Appendix 11: Important Considerations (from checklist) by Study Design* *Appendix 12: Tally of Primary Research Ratings* *Appendix 13: Tally Sheet Example*
Chapter 4 **Step 4 - Summarize Evidence**	Key data from the included articles is extracted. Summarize the evidence extracted from each study into a brief, coherent, and easy-to-read summary. The end result of this phase is called the Evidence Summary.	*Appendix 14: Overview Table* *Appendix15: Overview Table Example*
Chapter 5 **Step 5 - Write and Grade the Conclusion Statement**	Develop a concise conclusion statement for the research question and assign a grade. The grade reflects the overall strength and weakness of evidence in forming the conclusion statement. (The Academy uses Grades I, II, III, IV, and V for strong, fair, weak, expert opinion only, and no evidence, respectively.)	*Appendix16: Conclusion Statement and Grade* *Appendix17: Grade Definitions for Strength of Evidence for Conclusion* *Appendix 18: Grade Definition Table*

Chapter 1

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?

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.

Evidence Mapping

Before even starting the question formulation process, the project manager is busy with preliminary work. Defining the project is the first step toward establishing a project timeline, setting the goals and objectives and allocating the project resources. More importantly, it will help ensure that the best possible questions are formulated and outcomes identified.

An evidence map is a combination of a systematic approach to identifying the existing research on a topic with a description of key characteristics of the existing evidence. It called a "map" because of the use of graphics and the idea that this type of summary and description help clarify where we are and where research needs to go next. Evidence mapping is less exhaustive yet systematic and process highlighting both what is known and where gaps in evidence exist.

To help you prepare for your topic mapping, consider:

- The current research on the topic -
    - What interventions have been studied for effectiveness or harms?
    - What patient populations and conditions have been studied?
    - What settings and situations have been studied?
    - What primary outcomes have been studied?
    - What study designs have been used?
- The gaps that exist on the topic –
    - Which interventions have no research or inadequate evidence?
    - Are there certain interventions needed to develop policy?
    - Have certain populations or outcomes been ignored?

Understanding, and being able to define the project scope, will give the workgroup a focus when executing the project. Understanding the scope provides a foundation for managing the project. It enables goal setting and a timeline to work towards, as well as key points for reporting on the progress of the project to management and other stakeholders.

Ask Good Questions

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

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:

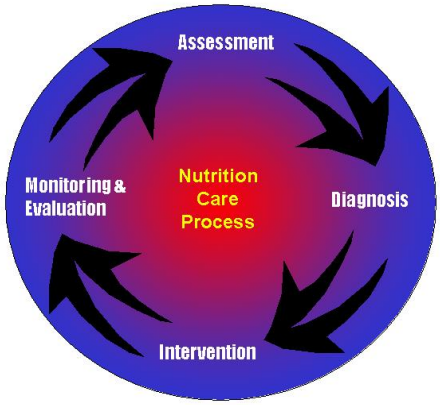
1. **Identify key factors** at each step of the nutrition care process that can affect nutritional intervention outcomes.

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

Figure 1.1 Nutrition Care Process



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

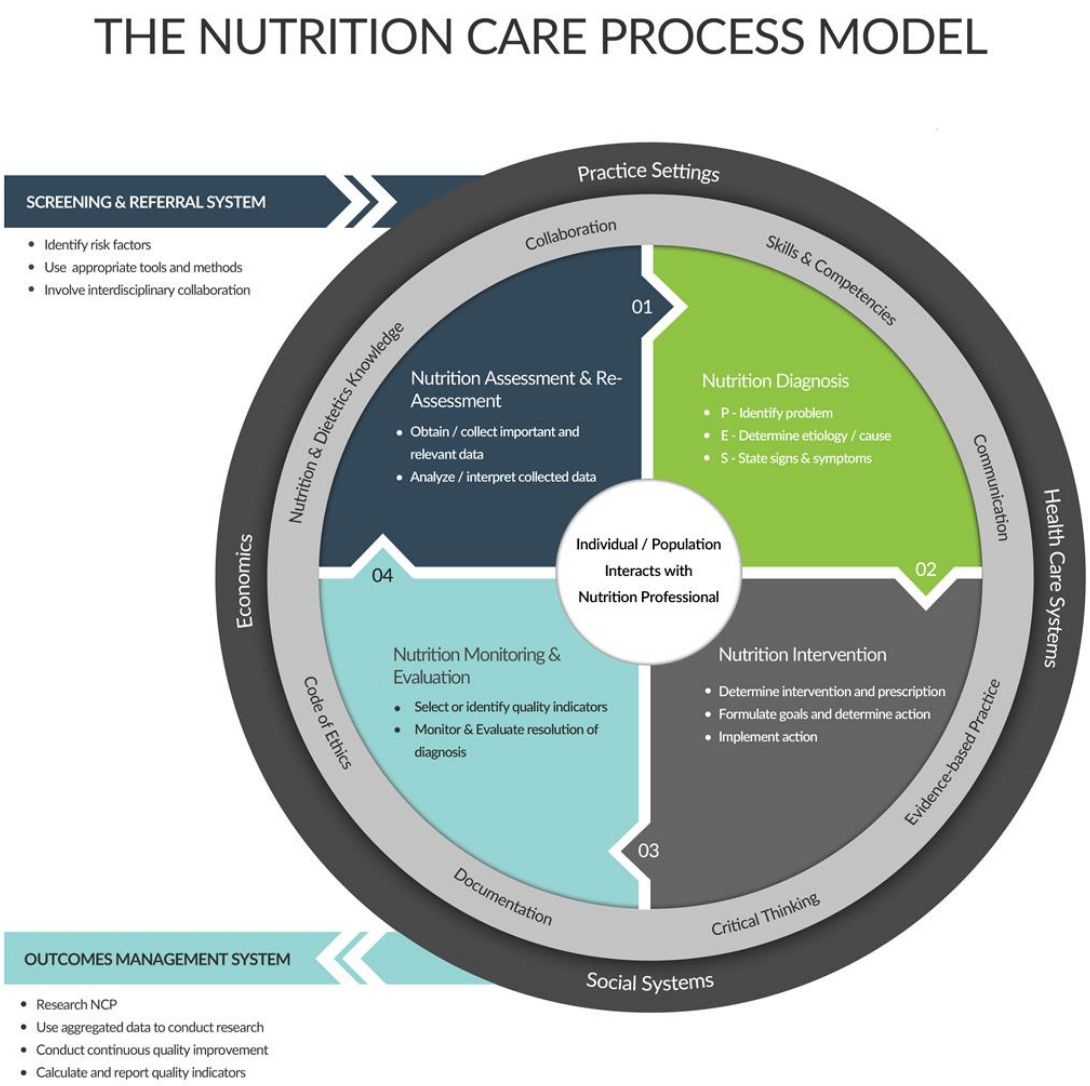
The nutrition care process can serve as the context for the way in which you formulate questions for evidence analysis. It is helpful to keep assessment factors, relevant diagnoses, range of interventions, and the intended outcomes in mind when formulating questions.

Figure 1.2 eNCPT Home Page

The Academy published the *Nutrition Care Process Terminology (eNCPT)* 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. Subscriptions to eNCPT are available from http://ncpt.webauthor.com (Figure 1.2).

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

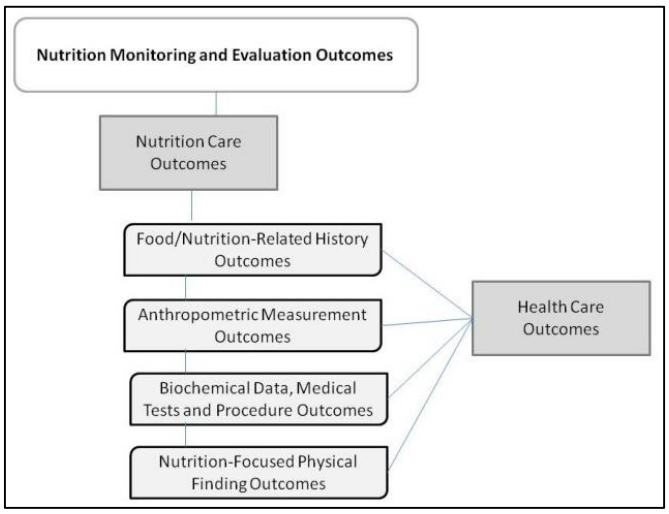
Keep the entire nutrition care process in mind as you begin to formulate questions. Most importantly, keep the end in mind. Ask: What sorts of outcomes do we expect from nutritional care in this area of practice?

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).

Figure 1.4 Outcomes



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 measureable 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 *Nutrition Care Process Terminology (eNCPT).*

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: Nutrition Care Process Terminology (eNCPT) Reference Manual. Academy of Nutrition and Dietetics ©2015.

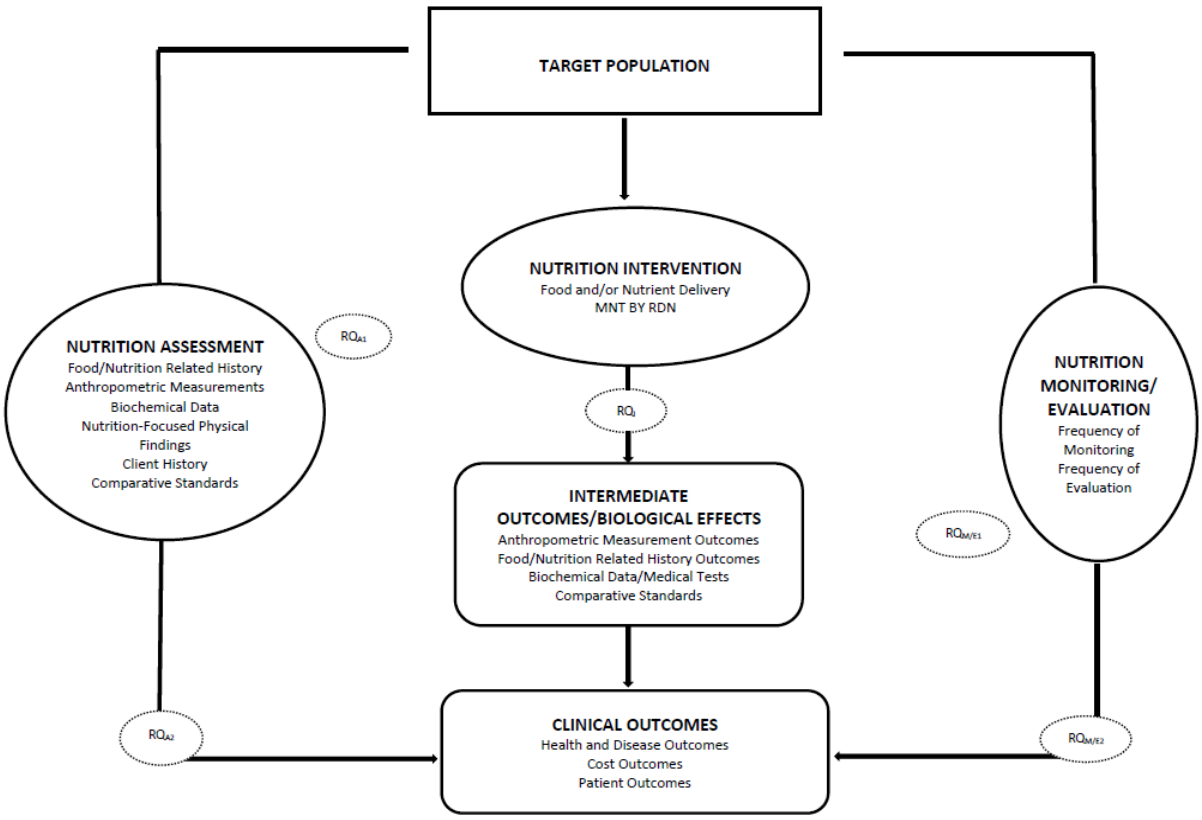
Consider Linkages Among Factors

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.

Figure 1.5. Analytical Framework Template



General Research Questions to Guide Project Development

RQ A1: What nutrition assessment methods should be used in (target population)?

RQ A2: In (target population)

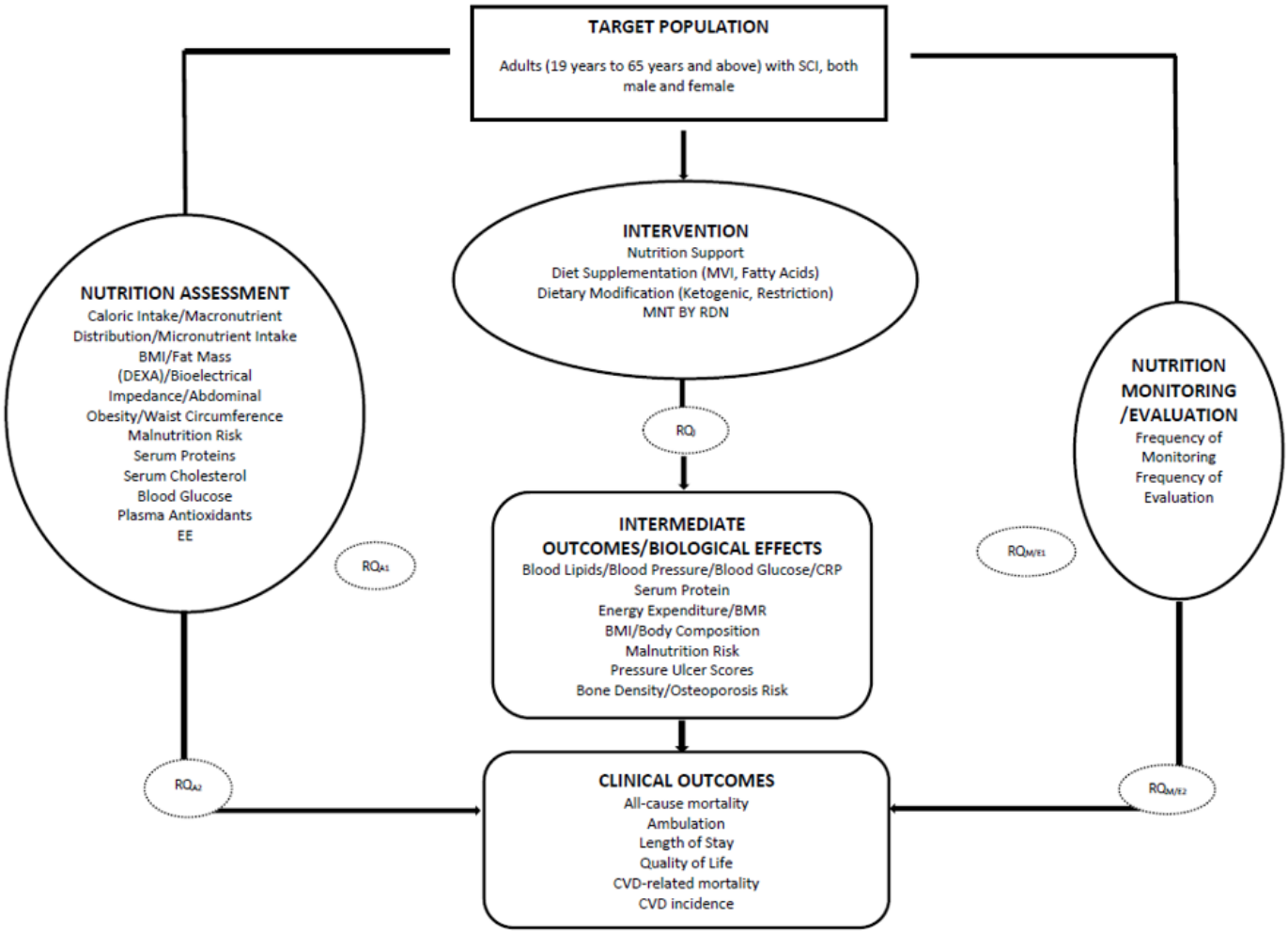
While it may be possible to link every factor in a list of assessment methods or intervention strategies to every expected outcome of the nutrition care process, researching every possible relationship is practically impossible. Evidence analysis draws on the expertise and knowledge of the expert panel 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 *Nutrition Care Process Terminology (eNCPT) 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



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 normoglucose throughout the day? Should lower carbohydrate be recommended at breakfast?

- For asymptomatic adults with elevated low-density lipoprotein cholesterol (LDL-C), what is the most effective intervention for reducing serum LDL-C: access to US Dietary Guidelines for Americans, MNT for hyperlipidemia provided by a registered dietitian, or physician-provided dietary advice?

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

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

- Is the recommendation 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.

Chapter 2

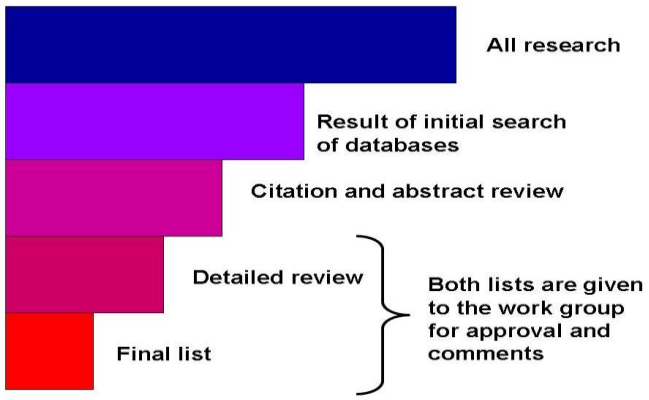
Step 2: Gather and Classify Evidence

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

- Totals: Keep details number of records (articles) identified through the various databases searched including the number of duplicates, screened, full-text articles screened, included and excluded. The Academy uses the PRISMA flow chart.

Reference: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): doi:10.1371/journal.pmed1000097

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. Due to copyright regulations, the articles are not available on the EAL.

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?

[1] The evidence analysis method developed by the Institute for Clinical Systems Improvement (ICSI) (on which the Academy's evidence analysis process is modeled) prescribes identifying "up to six important research reports" that speak to the question. The Academy 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.

- 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)?

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

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

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

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

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

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

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

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

List of Excluded Articles with Reason:

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

Summary of Articles Identified to Review:

Number of Primary Articles Identified: 9

Number of Review Articles Identified: 0

Total Number of Articles Identified: 9

Number of Articles Reviewed but Excluded: 3

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

Classify the Articles by Type of Research Design

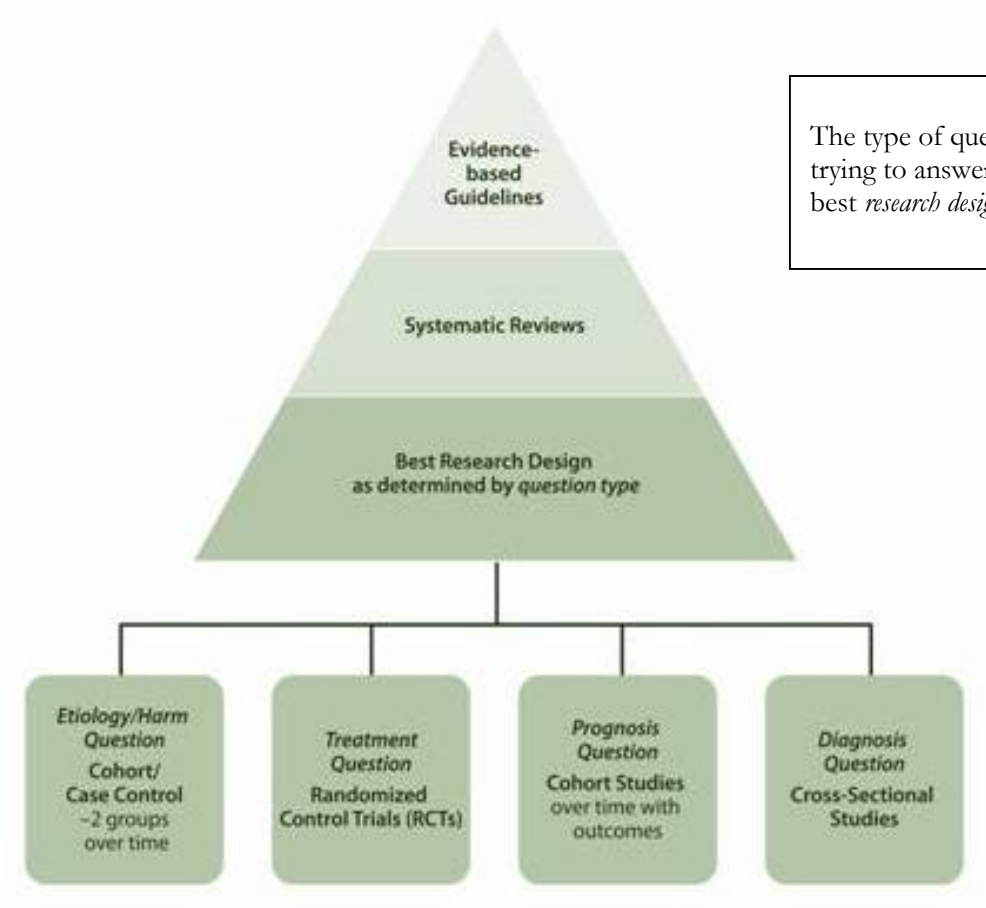
Which type of study is preferred?

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.

Table 2.1. Hierarchy and Classification of Studies[2]

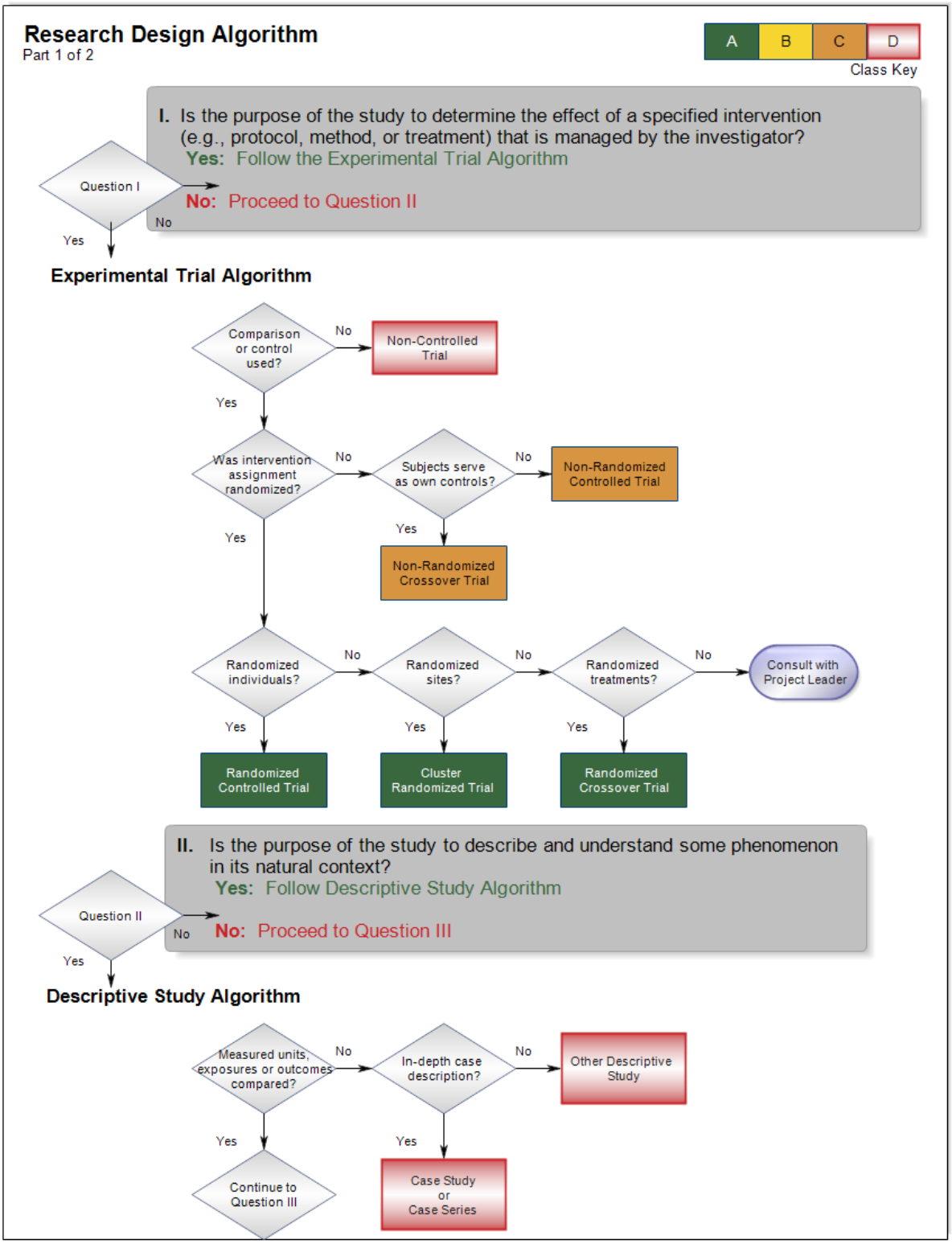
Primary Reports		Secondary Reports	
A	Randomized Controlled Trial Cluster Randomized Trial Randomized Crossover Trial	**M**	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Prospective Cohort Study Retrospective Cohort Study		
C	Non-Randomized Controlled 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

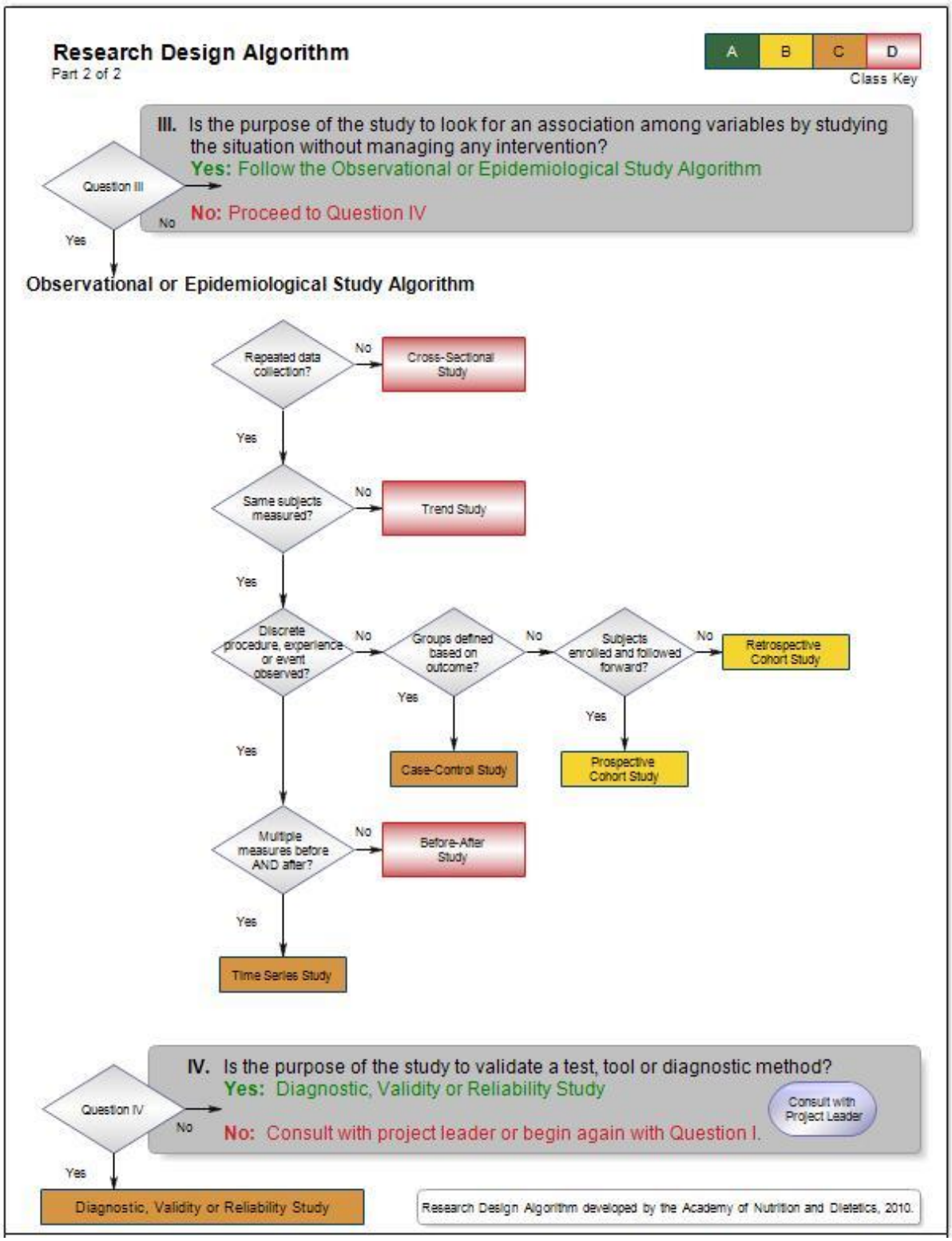
Classifying studies and reports gives an initial picture of the type of studies and level of evidence available. It also helps organize the articles for the next step of critical appraisal.

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 or DET template.

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

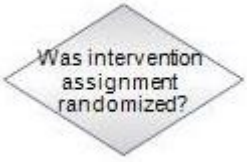
Figure 2.2 Algorithm for Classifying the Research Design of Primary Studies



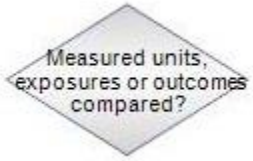

Research Design Algorithm
Part 2 of 2
A
B
C
D
Class Key
III. Is the purpose of the study to look for an association among variables by studying the situation without managing any intervention?
Yes: Follow the Observational or Epidemiological Study Algorithm
No: Proceed to Question IV
Question III
No
Yes
Observational or Epidemiological Study Algorithm
Repeated data collection?
No
Cross-Sectional Study
Yes
Same subjects measured?
No
Trend Study
Yes
Discrete procedure, experience or event observed?
No
Groups defined based on outcome?
No
Subjects enrolled and followed forward?
No
Retrospective Cohort Study
Yes
Case-Control Study
Yes
Prospective Cohort Study
Yes
Multiple measures before AND after?
No
Before-After Study
Yes
Time Series Study
IV. Is the purpose of the study to validate a test, tool or diagnostic method?
Yes: Diagnostic, Validity or Reliability Study
No: Consult with project leader or begin again with Question I.
Consult with Project Leader
Question IV
No
Yes
Diagnostic, Validity or Reliability Study
Research Design Algorithm developed by the Academy of Nutrition and Dietetics, 2010.

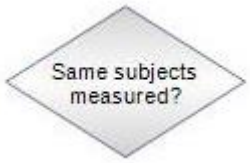
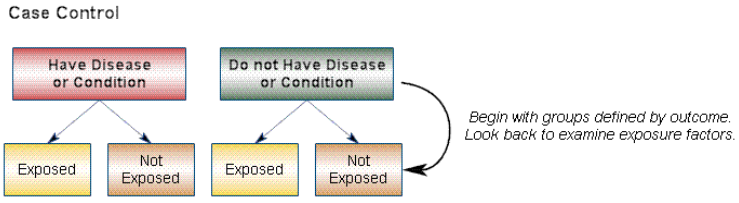
How to Use the Research Design Algorithm

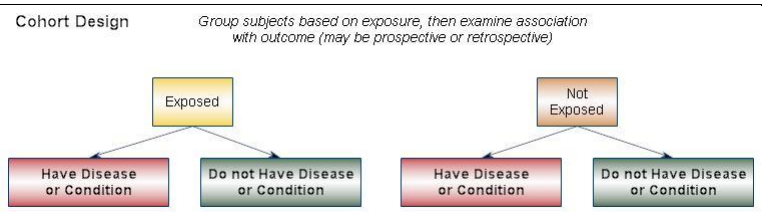
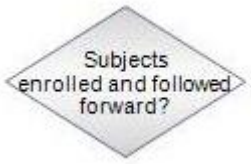
Below is a diamond by diamond guide for using the Research Design Algorithm developed by the Academy of Nutrition and Dietetics, 2010. Included are "Tips" on what to look for – and some "Watch Out!" instructions that may help you avoid common mistakes.

Decision Diamond	Instructions
Experimental Trial Algorithm	
	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. ***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). ***Tips:*** Look for evidence in the text that the researcher designed the intervention protocol and specified which subjects were eligible for intervention.
	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. 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**.
	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. No: Go to next question.
	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**.

	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.** **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.
	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. ***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). No: Go to the next question
	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**. 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**.
Descriptive Study Algorithm	
	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". ***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.

	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. ***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. ***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. No: Go to the next question.
	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**. 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.
Observational or Epidemiological Study Algorithm	
	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. ***Tips:*** Expect to see more details about statistical methods including management of intervening factors and potential confounders, and tests of association or statistical difference.
	Yes: If data are collected at more than one time point, go down to the next question. 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**. ***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.

	Yes: If there are repeated measures on the same subjects, then go down to the next question. 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**. For example, studies that statistically compare variables from different cycles of NHANES are often Trend Studies. ***Tips:*** If you are unsure, determine whether the same subjects or different subjects are measured at each time point.
	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). No: Go to the next question.
	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**. No: Go to next question. ***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. ***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. See figures below. 

	
	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. 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. ***Tips:*** 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? ***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.
	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. 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. ***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. ***Tips:*** Time Series studies, with multiple measurements prior to the event or treatment, are relatively rare in nutrition research. ***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.

Diagnostic, Validity or Reliability Study	
	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.
I got to the end, but didn't find an appropriate study design.	***Tips:*** 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.

Chapter 3

Step 3: Critically Appraise Each Article

Instructions for Abstracting Key Information

The evidence analyst is responsible for critically reviewing each research article and abstracting key information on to the onto the data extraction worksheet. The abstracted information is used later by the expert panel to write the conclusion statement (answer to the question) and grade the strength of the evidence. Abstracted information is used to create table and/or charts that supports the conclusion statement.

The Academy developed two (2) templates for the analyst to critically review each research article and abstract key information. Both will identify the study details that allow determination of study quality; summarize major findings; report study outcomes; record author's conclusion; note the funding source; note reviewed comments about the study limitations and applicability. Both templates include the Quality Criteria Checklist which is used to assess the article's research design.

The Worksheet fields are the same regardless of the project topic. The DET is customized for each project based on the outcomes to be collected.

- **Worksheet (2004-2015)** – A template used to collect details from the research articles used by the workgroups to determine the evidence and conclusion. It has global fields so all projects collect the same information. Overview tables summarize the findings. It allows the EAL user to assess the most important findings. Table headings include factors that the work group or the research indicates are important considerations when comparing and synthesizing the research findings.

- **Data Extraction Tool (DET) (2015 – current)** – This is a highly structured tool designed to extract data to carry out a more rigorous and in-depth synthesis. This template was developed in 2014 and will be used in new EAL projects. Overview tables are not necessary. The relevant outcome data can be exported to Excel for further analysis.

Abstracting 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

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 *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. Download blank copies of the *Evidence Worksheet* from the Methodology section of the EAL (www.andeal.org).

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:	Outcome(s) and other indicators Important variables and methods of measurement Was blinding used?

Description of Actual Data Sample:	Relevant descriptors of sample and comparison of groups at baseline Note loss of subjects (withdrawals, dropout, response rate, etc.)
Summary of Results:	Key Findings Abstract results including quantitative data and statistics. Be specific. Often tables are created in this section. (Include statistical significance – P values, confidence intervals, relative risk, odds ratios, likelihood ratio, number needed to treat, if available)
Author Conclusion:	As stated by the author in body of report
Reviewer Comments:	*Note strengths and limitations of the study. Identify concerns that affect study validity and generalizability (Always italicize)*
Funding Source	Who provided the funding for this study?

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:	# of articles included # of articles identified Number and type of studies reviewed Sample size of studies, and characteristics of the study participants

Summary of Results:	What are the main results of the review? Be specific. Abstract results including quantitative data and statistics, especially effect sizes Tables that summarize results can be useful.
Author Conclusion:	As stated by the author in body of report
Reviewer Comments:	*Note strengths and limitations of the review. Identify concerns that affect the validity of the review. How generalizable are the findings? (Always italicize)*
Funding Source	Who provided the funding for this study?

Abstracting Key Information from the Research Article into the *Data Extraction Template (DET)*

A systematic review is a critical assessment and evaluation of all research studies that meet a search criteria and address a particular question. Before you attempt to abstract details about the study into the DET you will need to carefully read the article. While abstracting the article, pay close attention to outcomes to be collected.

Purpose of the DET

In 2014, the Academy developed a new tool - the **DET** (data extraction tool) template. In addition to collecting the study characteristics like the Worksheet, the DET focuses on outcomes depending on the scope of each project.

The DET template provides an organized way to:

- Abstract key information for future reference.
- Report outcomes and results.
- 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.

Instructions for Filling out the DET

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

The main types of information needed for data extraction include:

- Design Information (how was the study set-up)
- Information on the Sample (who was in the study)
- Information on the Intervention / Exposure / Test (what was done to the subjects)
- Outcomes Reported
- Results

Table 3.2 What to Abstract for the DET

Study Characteristics	
Code	Author, year and PubMed ID
Quality Rating:	Select from the drop-down: (+ positive, - negative, Ø neutral) Based on quality criteria checklist for primary research
Author and Year	Last name of authors and year of publication
Article Title	Full article title
Authors	List all of the authors last name and first initial
Journal	Name of journal
Year of publication	Year (4 digits)
Volume	Volume #
Issue	Issue #
Page Numbers	Journal page #s
Study Design	Select the type of study design from the drop-down menu
Inclusion Criteria	Enter the approved criteria for including an article.
Exclusion Criteria	Enter the approved exclusion criteria. Why were articles excluded
Research Purpose	Purpose

Blinding Efforts	Report the blinding efforts (if any).
Study Location	City, State/Province, Country
Source(s) of Funding	Who provided the funding for this study?
Fields are created for each project based on the scope of the project and outcomes /results to be collected. Fields can include:	
Group Characteristics	May include study numbers (initial, final, dropout rate); Sex of subjects; Age; Race/Ethnicity;
Interventions / Exposures	The key elements for data to be extracted will be determined by the lead analysts and "seeded" into the template prior to the data extraction process for the project. A project might be focusing only on dietary interventions, behavioral interventions, physical activity, or any combination of factors within an intervention.
Outcomes Reported	Add fields for each outcome that is needed to answer the question. Continuous measures of an outcome are separate "outcomes" than the same measure categorized.
Results	Add fields four each Result reported; Time Point; and Measure. A Comparison field will automatically show up when more than one time point is added.

Identify Groups or Arms

Before you can enter sample characteristics data in the DET, you will need to define the 'Groups". We use the term "Groups" to define what are sometimes call the "Arms" of the study. There are comparison groups that the authors want to examine. For instance:

Figure 3.0 Sample Groups

Sometimes, a study will include a couple of treatment (intervention) arms and a placebo group. Evidence analysts need to carefully read the article to identify the "Groups".

Sample Characteristics – What you Need and Where to Find Them

Once the analyst has identified the Groups (Arms), you then need to extract information on the sample characteristics

- Identifying sample characteristics is crucial for evidence analysis because it helps us determine to whom, where, and under what conditions our findings apply
- Before you extract sample characteristics, you need to define the study Groups (or Arms). While this is generally straight-forward in experimental and diagnostic accuracy designs, it can be a bit tricky for observational studies
- Authors typically give you all the information you need at the beginning of the Methods and Results sections.

Identify Intervention, Exposure and Test Characteristics

When extracting information from the various studies, it is critical to gather detail on the intervention, exposure or test. And, the key is to gather the ***same information*** across studies. It is also important that the information is extracted in a way to be able to compare across studies – in a **standardized** way.

By the time the DET is assigned to you, the lead analyst and expert workgroup will have already identified a set of characteristics that you should identify from each study. Communication between the evidence analyst, lead analyst and project manager is critical to successful data extraction. In addition, DETs cannot be linked to different projects since the interventions / exposures, etc. may be different for other projects.

Finding the Information

So where does the evidence analyst find information on the intervention, exposure or test characteristics? For most part, you can find the detailed descriptions of the interventions, exposures or tests in the Methods section, often in the section labeled as Procedures, Measurements or Intervention. However, it is not unusual for large studies to report the details of the intervention or methods in a *separate* article. Secondly, when capturing information on the variables controlled for in a particular analysis, you may want to look at the table footnotes.

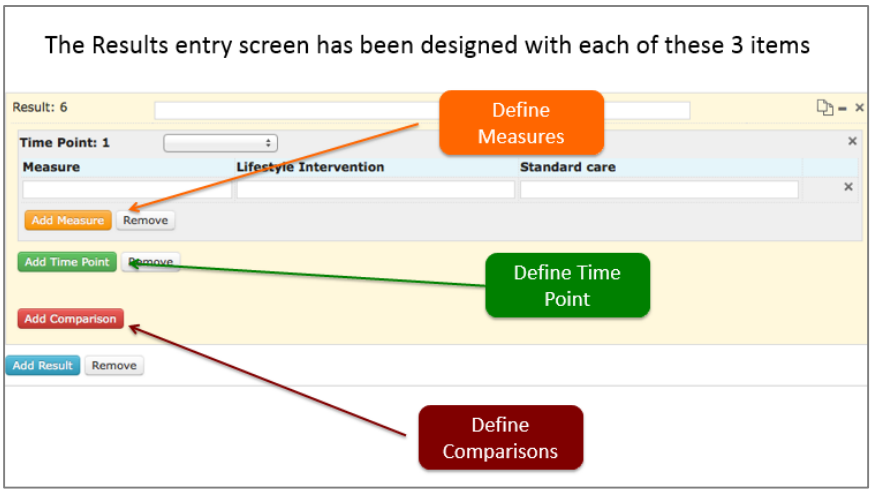
Extracting Results

There are three key pieces of information needed to extract for each outcome:

1. The **Time Points** when measurements were taken.
2. The particular **Measures** reported at each time point.

3. The statistical **Comparisons** within and between groups reported by the authors.

Figure 3.1 DET Results Section



Complete Quality Criteria Checklist and Determine a Rating

As the report is being examined, refer to the appropriate Quality Criteria Checklist (QCC) 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 *QCC* 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.

There is an assessment of bias by two trained analysts, blinded to each other's answers. Disagreements are identified and a consensus is reached by the project manager.

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

WHY USE THE *QUALITY CRITERIA CHECKLIST*?

- To provide a tool to enable systematic, objective rating of primary research and review articles
- To support inter-rater agreement among reviewers/analysts.

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.

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

The Quality Criteria Checklist (QCC): 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	
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes No Unclear N/A
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes No Unclear N/A
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A
4. Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.	
VALIDITY QUESTIONS	
1. Was the <u>research question</u> clearly stated? 1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified? 1.2 Was the outcome(s) (dependent variable(s)) clearly indicated? 1.3 Were the target population and setting specified?	Yes No Unclear N/A
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?	Yes No Unclear N/A
3. Were <u>study groups comparable</u>? 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")?	Yes No Unclear N/A

4.	**Was method of handling <u>withdrawals</u> described?**	Yes No Unclear N/A	
4.1	Were follow up methods described and the same for all groups?		
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)		
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?		
4.4	Were reasons for withdrawals similar across groups?		
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?		
5.	**Was <u>blinding</u> used to prevent introduction of bias?**	Yes No Unclear N/A	
5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?		
5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)		
5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?		
5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?		
5.5	In diagnostic study, were test results blinded to patient history and other test results?		
6.	**Were <u>intervention</u>/therapeutic regimens/exposure factor or procedure and any comparison(s) 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	n observational study, were interventions, study settings, and clinicians/provider described?		
6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?		
6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?		
6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?		
6.6	Were extra or unplanned treatments described?		
6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?		
6.8	In diagnostic study, were details of test administration and replication sufficient?		
7.	**Were <u>outcomes</u> clearly defined and the <u>measurements valid and reliable</u>?**	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? 10.1 Were sources of funding and investigators' affiliations described? 10.2 Was there no apparent conflict of interest?	Yes No Unclear N/A
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.*	
NEUTRAL (∅) *If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence 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.*	

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

RELEVANCE QUESTIONS	
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)	Yes No Unclear N/A
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about?	Yes No Unclear N/A
3. Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A
4. Is the intervention, procedure or product feasible for application in dietetic practice?	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.	
VALIDITY QUESTIONS	
1. Was the <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?	Yes No Unclear N/A
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?	Yes No Unclear N/A
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))	Yes No Unclear N/A

	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?**	Yes No Unclear N/A
	4.1	Were follow-up methods described and the same for all subjects/units of observation and groups?	
	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?	
	4.3	Were all enrolled subjects/units (in the original sample) accounted for?	
	4.4	Were reasons for withdrawal or loss similar across groups?	
	4.5	If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study?	
5.		**Was <u>blinding</u> used to prevent introduction of bias?**	Yes No Unclear N/A
	5.1	Were field and research staff and investigators blinded to treatment group, as appropriate?	
	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.)	
	5.3	In a 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, reliability or validity study, were test results blinded to unit of observation history and other test results??	
6.		**Was the intervention/treatment regimen/exposure factor, procedure, process or product of interest and any comparison(s) described in detail? Were <u>intervening factors</u> described?**	Yes No Unclear N/A
	6.1	Were protocols described for all alternatives studied?	
	6.2	Was the context (study setting, intervention or exposure details or process, involved personnel, etc) described?	
	6.3	Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured, and are data free from bias?	
	6.5	Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?	
	6.6	Were extra or unplanned interventions or environmental influences during the study period described?	
	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?	
	6.8	In diagnostic , validity or reliability study, were details of test administration and replication sufficiently described?	
7.		**Were <u>outcomes</u> or condition or status of interest clearly defined and the <u>measurements valid and reliable</u>?**	Yes No Unclear N/A
	7.1	Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?	
	7.2	Were nutrition-related outcomes measures, if included, appropriate to the study 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 outcomes or effect at an appropriate level of precision?	
	7.6	Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?	
	7.7	Were the measurements conducted consistently across units of observation, groups and time periods?	

8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes No Unclear N/A
8.1	Were statistical analyses adequately described and 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 there a clear description of subjects/units observed included in each analysis? If appropriate, was there 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 or pragmatic significance as well as statistical significance reported?	
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.)	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes No Unclear N/A
9.1	Is there an adequate discussion of findings?	
9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes No Unclear N/A
10.1	Were sources of funding and investigators' affiliations described?	
10.2	Was there no apparent conflict of interest?	
MINUS/NEGATIVE (-)		
If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.		
NEUTRAL (∅)		
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 (∅) symbol on the Evidence Worksheet.		
PLUS/POSITIVE (+)		
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.		
When a validity criteria question is NA		
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 or "No" answers for a minus (-) rating		

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		
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes No Unclear N/A
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes No Unclear N/A
3.	Is the problem addressed in the review one that is relevant to dietetics practice?	Yes No Unclear N/A
4.	Will the information, if true, require a change in practice?	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		

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

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 ∅, 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	2.1, 2.3, 2.4, 4.2, 6.2 - 6.6, 7.3, 7.4, 7.6, 8.5

		therapeutic or preventive procedure, experience or event	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 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 Validity Study Reliability Study	C C C	Used to determine the sensitivity or specificity of a diagnostic or assessment method 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	1.3, 2.4, 3.6, 4.5, 6.8 5.5—Diagnostic Study only

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. 2003	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	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 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 or DET for each article
- Quality Criteria Checklists for each article
- Quality Criteria Summary combining all checklists

Chapter 4

Step 4: Summarize the Evidence

Create Tables and Write the Evidence Summary

An Evidence Summary is a systematic, scientifically rigorous approach to summarizing the knowledge of the included research studies, so that the variations in studies and contradictory study results can be understood within a single conclusion; it provides a status of the science conclusion. The evidence summary typically includes the type of studies, population studies, number of subjects, methods used, main findings and study limitations. Creating an evidence summary involves combining relevant and scientifically valid information into a brief, coherent, and easy-to-read summary.

Create Tables

Study overview tables are designed 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 project team will need to determine the critical comparison factors for each topic and question. These factors for will be the headings for the columns in the table. 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.

TABLES ALLOW YOU TO COMPARE STUDIES AT A GLANCE

The Worksheet Overview Table

The ***Worksheet*** 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). 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 Worksheet Overview Table

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. The information for the overview table is transferred from the Evidence Worksheets.

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.

Table 4.1 Example of Overview Table from Sodium EAL® Project

Question: *Is there a relationship between sodium intake and blood pressure in African Americans?*

Author, Year, Study Design, Class, Rating	Population/Sample	Intervention	Significant Outcomes
Appel LJ, Espeland MA, et al, 2001 Study Design: Randomized Controlled Trial Class: A Rating: +	681 subjects with HTN: Aged 60-79 years, 23% African Americans; SBP < 145 mm Hg and DBP < 85 Hg while taking 1 antihypertensive medication.	30 month intervention; Reduced sodium intervention group limited sodium intake to 100 mmol/d vs. usual lifestyle groups; Individual session for those in intervention group within 1 month, followed by weekly group meetings for 4 months, then biweekly group meetings for 3 months and then every 4th contact was individual session. After 3 months, medication was withdrawn. Endpoint (mean 27.8 mon) mean SBP ≥ 150 mm Hg or mean DBP ≥ 90 mm Hg or cardiovascular event.	Mean reduction in SBP was 4.3mmHg (P<0.0001) and in DBP was 2.0mmHg (P=0.001) Compared with control, mean urinary sodium excretion was 40mmol per day less in the reduced sodium intervention group (P < 0.001). NS difference by race. Significant reductions in urinary sodium occurred in subgroups defined by sex, race, age and obesity. Prior to medication withdrawal, mean reductions in SBP and DBPs from the reduced sodium intervention, net of control, were 4.3mm Hg (P<0.0001) and 2.0mm Hg (P=0.001). During follow-up, an end point occurred in 59% of reduced sodium and 73% of control group participants (relative hazard ratio=0.68, P<0.001). In African Americans, the corresponding relative hazard ratio was 0.56 (P=0.005)
Bray, Vollmer et al, 2004 Study Design: Randomized Crossover Trial Class: A Rating: ◑	N = 412 (131 African Americans without HTN, 103 African Americans with HTN)	Subgroup analysis of Dietary Approaches to Stop Hypertention (DASH) intervention	NS differences found by race. ↓ sodium intake consistently resulted in mean ↓ in SBP and DBP across all subgroups. With the control diet, BP changes from the higher to lower sodium level were all significant, and mean ↓ ranged from ~ 5 to 8 mm Hg for SBP and from 2 to 4 mm Hg for DBP; mean BP ↓ were about half as much for those who ate the DASH diet. There was approximately twice as much mean BP ↓ in going from the 2,300 mg sodium to the 1,150 mg sodium level as from the 3500 mg sodium level to the 2,300mg sodium level across the subgroups.
Chrysant SG, Weir MR et al, 1997 Study Design: Randomized Controlled Trial Class: A Rating: +	N = 624 (309 women, 315 men) Ethnicity: 367 Whites, 156 African Americans, 92 Hispanics, 8 Asians, 1 Native American; Age: 351 were ≤ 55 years; 273 were > 55 years; 195 had a BMI of ≤ 27; 429 had a BMI > 27	Patients experienced 3 weeks each (single-blind, placebo-controlled) of: ad lib salt intake, 100-200 mmol/d of sodium; 3 weeks of low-salt intake 50-80 mmol/d of sodium; 3 weeks of high-salt intake 200-250 mmol/d of sodium. Pts met with a dietitian to review a 3-day food record during each diet period.	Low-salt diet resulted in significant decrease in all blood pressure measurements in all ethnic groups (P<0.001). High-salt diet resulted in significant increase in all blood pressure measurements in all ethnic groups (P<0.001).

The DET Overview Table

Another benefit of the highly structured DET is the elimination of creating a separate overview table. The DET is custom-designed to extract relevant data and easily export the results in Excel tables.

Table 4.2 Example of DET Overview Table from Dietary and Metabolic Impact of Fruit Juice Consumption EAL® Project

Question: What is the association between intake of 100% fruit juice and weight status or adiposity (e.g., BMI percentile, weight gain, BMI Z-score and fat mass) in children?

Author and Year	Study Design	Quality Rating	Study Location	Final N	Sex	Race/Ethnicity	Age Group	Type of Juice	Factors Controlled (or Adjusted) For	Diet Intake Measured Using:	National Sample?	Diet Intake Measured By:	BMI Outcomes	Ponderal Index Outcomes
Alexy, Sichert-Hellert et al, 1999; PMID: 10468003	Prospective Cohort Study	Neutral	Dortmund, Germany	205	Both	White	Three to five years	NR	None	Three day diet record	No	Food weight or measurement	*BMI:* NS	
Berkey, Rockett et al, 2004; PMID: 15166298	Prospective Cohort Study	Positive	United States	4,620	Both	White, Black, Hispanic, Asian	Nine to 14 years	Apple	Sex, race/ethnicity, total EI, PA/sedentary behavior,Tanner stage and previous year intake	FFQ	Yes	Self-report	*BMI:* NS	
Danyliw, Vatanparast et al, 2012; PMID: 22694268	Cross-Sectional Study	Positive	Canada	10,038	Both	NR	Two to 18 years	NR	Sex, age, race/ethnicity, SES, total EI, PA/sedentary behavior	24-hour Food Recall	Yes	Self-report	*BMI:* NS	
Dennison, Rockwell et al, 1997: PMID: 8989331	Cross-Sectional Study	Neutral	Upstate New York (rural)	149	NR	White, Other	Two- and five-year-olds	NR	Sex, Age	Seven 24-hour Dietary Recalls; One Seven-Day Diet Record	No	Self-report	*BMI 75th percentile:* NS **BMI 90th percentile**	**Ponderal Index (two years, five years)**
Dennison, Rockwell et al, 1999; PMID: 12038478	Cross-Sectional Study	Neutral	Schoharie County, rural upstate New York	163	Both	White	Two- and five-year-olds	Apple, grape and "other" 100% fruit juice	Sex, total EI, maternal height	Seven 24-hour Dietary Recalls; One Seven-Day Diet Record	No	Self- report, researcher interview (researcher directed)	**BMI (apple juice)**	**Ponderal Index (apple juice)**

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.

SUMMARIZE THE FINDINGS OF EACH ARTICLE.

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?)

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.

Chapter

5

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 or DET 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 Worksheet*s 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 • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns, OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design, OR Consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published research studies	Relevant studies have not been done
Clinical impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of the effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

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/DET, quality criteria checklists, and search plan and results are published online on 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 must purchase a subscription 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 Project Team section of each project landing page.

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 EAL®. Nutrition Practice Guidelines published online include Adult Weight Management, Celiac Disease, Chronic Kidney Disease, COPD, Critical Illness, Diabetes, Prevention of Type 2 Diabetes, Disorders of Lipid Metabolism, Energy Expenditure, Gestational Diabetes, Heart Failure, HIV/AIDS, Hypertension, Oncology, Pediatric Weight Management, Spinal Cord Injury, Vegetarian Nutrition and Unintended Weight Loss in Older Adults.

Manuscripts

- 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*.

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.eatrightpro.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 Academy's website (www.eatrightstore.org) 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 Academy's website (www.eatrightstore.org) 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 Academy's website (www.eatrightstore.org) 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. The EAL is created by members of the Academy for members of the Academy. We are always looking for volunteers to be a part of this essential resource. Comprehensive training is provided to guide you in following the Academy's meticulous systematic process for identifying, analyzing and synthesizing food and nutrition research. Each evidence analysis project consists of an Academy staff project manager, lead analyst, workgroup chair, 6-8 expert workgroup members and 4-10 evidence analysts. Learn how you can get involved and contribute your expertise from http://www.andeal.org/get-involved.

.

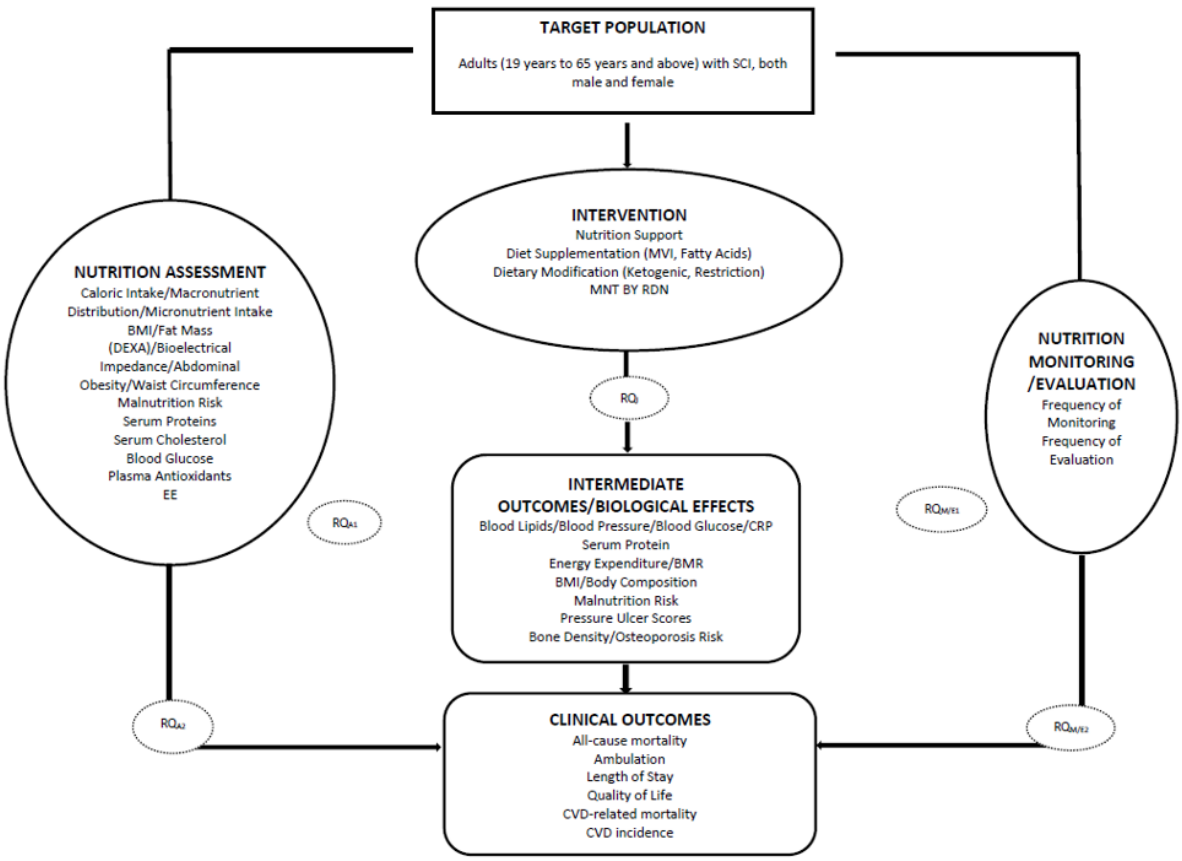
Appendices

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.



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? *Be specific.*	What is the main alternative to compare with the intervention? *Be specific.*	What could this intervention really affect? *Be specific.*

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

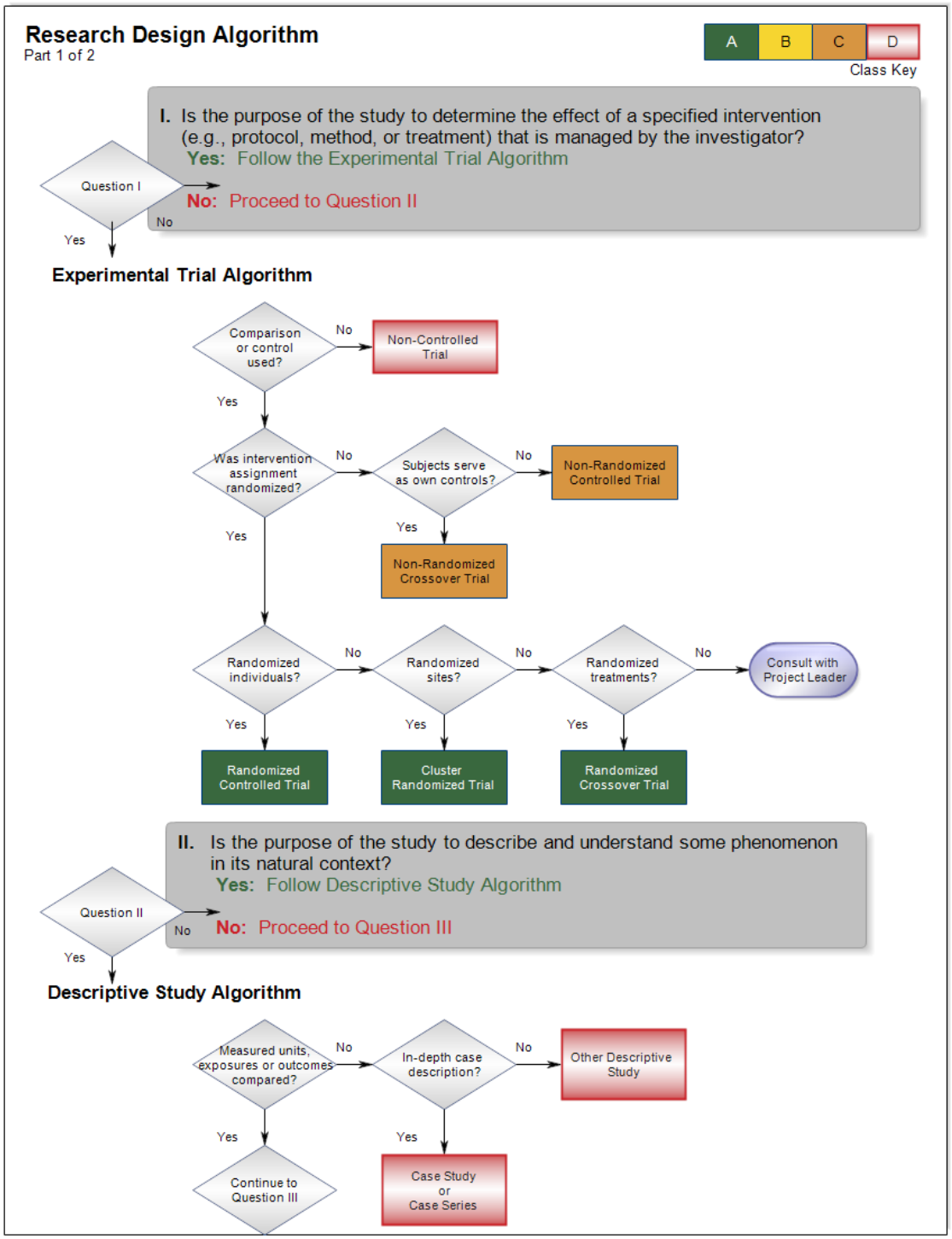
Question:	
Date of Literature Review:	
Inclusion Criteria:	• Age • Setting • Health Status • Nutrition-Related Problem or Condition • Study Design Preference • Size of Study Groups • Study Drop-Out Rate • Year Range • Authorship • Language
Exclusion Criteria:	• Age • Setting • Health Status • Nutrition-Related Problems or Condition • Study Design Preference • Size of Study Groups • Study Drop-Out Rate • Year Range

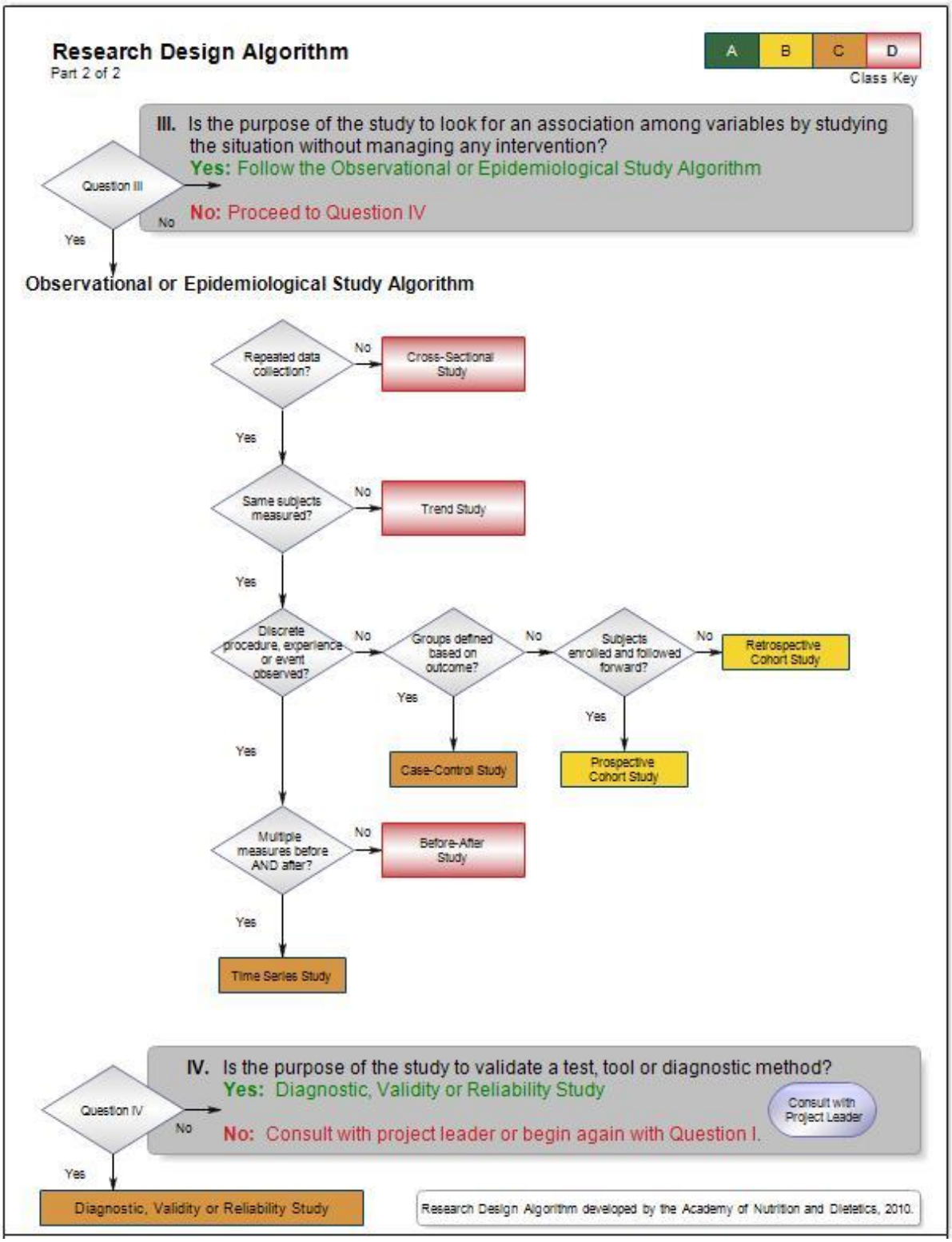
	• Authorship • Language
Search Terms: Search Vocabulary	
Electronic Databases:	• Database • Search Terms • Hits
Inclusion List:	
List of Articles Included from Handsearch or Other Means	
List of Excluded Articles with Reason:	
Summary of Articles Identified to Review	• Number of Included Primary Research 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




Research Design Algorithm
Part 2 of 2
A
B
C
D
Class Key
III. Is the purpose of the study to look for an association among variables by studying the situation without managing any intervention?
Yes: Follow the Observational or Epidemiological Study Algorithm
No: Proceed to Question IV
Question III
No
Yes
Observational or Epidemiological Study Algorithm
Repeated data collection?
No
Cross-Sectional Study
Yes
Same subjects measured?
No
Trend Study
Yes
Discrete procedure, experience or event observed?
No
Groups defined based on outcome?
No
Subjects enrolled and followed forward?
No
Retrospective Cohort Study
Yes
Case-Control Study
Yes
Prospective Cohort Study
Yes
Multiple measures before AND after?
No
Before-After Study
Yes
Time Series Study
IV. Is the purpose of the study to validate a test, tool or diagnostic method?
Yes: Diagnostic, Validity or Reliability Study
No: Consult with project leader or begin again with Question I.
Consult with Project Leader
Question IV
No
Yes
Diagnostic, Validity or Reliability Study
Research Design Algorithm developed by the Academy of Nutrition and Dietetics, 2010.

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:	**Recruitment** **Design** **(These prompts assist you in determining** **Blinding used (if applicable)** **which information to abstract from research** **Intervention (if applicable)** **article.)** **Statistical Analysis**
Data Collection Summary:	**Timing of Measurements** **Dependent Variables** • Variable 1: brief description (how measured?) • Variable 2: brief description (how measured?) • etc. **Independent Variables** **Control Variables**
Description of Actual Data Sample:	**Initial N:** (e.g., 731 (298 males, 433 females)) **Attrition (final N):** **Age:** **Ethnicity:** **Other relevant demographics:** **Anthropometrics** (e.g., were groups same or different on important measures) **Location:**
Summary of Results:	**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			
Etc.			
Other Findings			

Author Conclusion:	
Review Comments:	*Italicize reviewer and expert panel comments.*
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
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1.	**Was the <u>research question</u> clearly stated?**	Yes No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?	
1.3	Were the target population and setting specified?	
2.	**Was the <u>selection</u> of study subjects/patients free from bias?**	Yes No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	
2.2	Were criteria applied equally to all study groups?	
2.3	Were health, demographics, and other characteristics of subjects described?	
2.4	Were the subjects/patients a representative sample of the relevant population?	
3.	**Were <u>study groups comparable</u>?**	Yes No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)	
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	
4.	**Was method of handling <u>withdrawals</u> described?**	Yes No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	

	4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.		**Was <u>blinding</u> used to prevent introduction of bias?**	Yes No Unclear N/A
	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.		**Were <u>intervention</u>/therapeutic regimens/exposure factor or procedure and any comparison(s) 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	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.		**Were <u>outcomes</u> clearly defined and the <u>measurements valid and reliable</u>?**	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 (-)			
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.			

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	
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)	Yes No Unclear N/A
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about?	Yes No Unclear N/A
3. Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A
4. Is the intervention, procedure or product feasible for application in dietetic practice?	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.	
VALIDITY QUESTIONS	
1. Was the <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?	Yes No Unclear N/A
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?	Yes No Unclear N/A
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.	Yes No Unclear N/A
4. Were methods of handling losses from the original sample (withdrawals) described?	Yes No Unclear N/A

	4.1	Were follow-up methods described and the same for all subjects/units of observation and groups?	
	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?	
	4.3	Were all enrolled subjects/units (in the original sample) accounted for?	
	4.4	Were reasons for withdrawal or loss similar across groups?	
	4.5	If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study?	
5.		**Was blinding used to prevent introduction of bias?**	Yes No Unclear N/A
	5.1	Were field and research staff and investigators blinded to treatment group, as appropriate?	
	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.)	
	5.3	In a 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, reliability or validity study, were test results blinded to unit of observation history and other test results??	
6.		**Was the intervention/treatment regimen/exposure factor, procedure, process or product of interest and any comparison(s) described in detail? Were intervening factors described?**	Yes No Unclear N/A
	6.1	Were protocols described for all alternatives studied?	
	6.2	Was the context (study setting, intervention or exposure details or process, involved personnel, etc) described?	
	6.3	Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured, and are data free from bias?	
	6.5	Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?	
	6.6	Were extra or unplanned interventions or environmental influences during the study period described?	
	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?	
	6.8	In diagnostic , validity or reliability study, were details of test administration and replication sufficiently described?	
7.		**Were outcomes or condition or status of interest clearly defined and the measurements valid and reliable?**	Yes No Unclear N/A
	7.1	Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?	
	7.2	Were nutrition-related outcomes measures, if included, appropriate to the study 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 outcomes or effect at an appropriate level of precision?	
	7.6	Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?	
	7.7	Were the measurements conducted consistently across units of observation, groups and time periods?	
8.		**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes No Unclear N/A
	8.1	Were statistical analyses adequately described and 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 there a clear description of subjects/units observed included in each analysis? If appropriate, was there 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 or pragmatic significance as well as statistical significance reported?	
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.)	
9.	**Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?**	Yes No Unclear N/A
9.1	Is there an adequate 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 (-)

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.

NEUTRAL (∅)

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 (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

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.

When a validity criteria question is NA

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 or "No" answers for a minus (-) rating.

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

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	2.1, 3.4, 4.2, 5.3, 6.3, 6.4, 7.1, 7.3, 7.4, 7.6, 8.5

		Large number of subjects tracked 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 Validity Study Reliability Study	C C C	Used to determine the sensitivity or specificity of a diagnostic or assessment method 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	1.3, 2.4, 3.6, 4.5, 6.8 5.5—Diagnostic Study only

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®.

Appendix13: Sample Tally Sheet from the EAL®

		Ash et al. 2003	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	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 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

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
Brown SA, Garcia AA et al, 2002 **Study Design: Prospective, randomly, repeated measures study** **Class: A** **Rating:**	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	**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/m^2 **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/m^2	52 hrs of intensive instruction in DM self-management, including: a) 3 mos of wkly 2-hr sessions on nutrition, glucose self-monitoring, exercise, and other self-care topics b) 6 mos of bi-wkly sessions c) 3 mos of monthly sessions Problem-solving and food preparation demos were included Culturally-competent interventions included utilization of bilingual nurses and RDs, were offered in Spanish, and focused on health recommendations consistent with Mexican-American preferences	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±2.36 treatment vs. 11.64±2.85 control, P=0.011), and DM knowledge (42.94±4.87% treatment vs. 40.92±4.87% control, P<0.001)	A culturally competent intervention resulted in improved outcomes measures for Mexican-American subjects with DM	Control group received DM education in the form of answers to questions during measurement visits, due to ethical considerations
Elder JP, Ayala GX et al, 2006 **Study Design: Randomized Control Trial** **Class: A** **Rating:**	To examine the 1-year impact of behavior change approaches to reduce dietary fat and ↑ fiber in Spanish-language dominant Latinas	357 Spanish-language dominant Latinas Mean age: 39.71±9.93yrs; 79% married 60% with income <$2000/mo; avg family size 5 persons 58.4% with educational level of middle school or less All participants were from the San Diego, CA area	Randomization to 1 of 3 groups for the 14-week study: 1) *"Promontoras,"* consisting of wkly dietary counseling via lay health advisors (*promontoras*) at home or telephone calls over a 14-wk period + 12 tailored newsletters with homework assignments delivered via mail to participant's home 2) "Tailored," consisting of 12 tailored print newsletters and homework assignments delivered via mail 3) "Control," consisting of 12 "off the shelf" materials targeted at Spanish speaking Latinos delivered via mail	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) The promotora group was SD from control group in intake of total energy and total CHO (P<0.05), and trended toward a SD in intake of total fat and sat fat (P<0.1)	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	The investigators did not provide information regarding the number of promotora visits completed in person vs. by phone
Ingram M, Gallegos G et al, 2005 **Study Design: Cross-sectional** **Class: D** **Rating:**	To assess the impact that DM self-management education and support have on the patients' control of their DM	A group of Hispanic patients with DM living in the area of the US-Mexico border. Patients were enrolled from 2 locations: **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 **Santa Cruz, AZ:** 406 enrolled, 33% [135] graduated, 30% [40] reached for F/U interview, 70% female, 50% >50 yrs, mean weight 184.6 lbs In both locations, a majority had not graduated from high school	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 Classes were held 1 x per week; 2 hrs per class Use of community health workers [CHW] ("promotores de salud") was central to the educational model	A significant ↓ in the avg random BG measurement among participants in both programs Both programs achieved a significant ↓ in DBP among participants In Yuma there was a significant ↓ in HbA1c from 9.4 to 8.7 among those who initiated the program with a HbA1c>8.9 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 80 - 88%, glucose monitoring 39-63%, P<0.001, P<0.01, n.s., respectively; **Yuma:** diet data incomplete, foot care 86-98%, glucose monitoring 51 - 96%, P=unknown, P<0.001, P< 0.001, respectively	Program participants achieved significant improvement in self-management behaviors, HbA1c, random BG levels and BP readings	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
Schillinger D, Hammer H et al, 2008 **Study Design: Randomized Trial** **Class: A** **Rating:**	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	339 patients with DM ≥17 yrs old, 59% female 19.8% insured by MediCal, 21.5% insured by Medicare, 50.2 uninsured, 8.6 other insurance 53.4% English-speaking, 35.7% Spanish-speaking, 10.9% Cantonese-speaking	Randomization to either standard care (N=115, no systematic SMS), automated telephone disease management (ATDM) or monthly medical group visits (MGV)	**ATDM:** 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 **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 (88.5%), 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	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 ATDM reached a greater proportion of the target population than GMV, and yielded higher rates of engagement for those with limited literacy and limited English proficiency	Small subgroup sample sizes

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 Worksheet*s or *DET* 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 • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns, OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design, OR Consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published research studies	Relevant studies have not been done
Clinical Impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of the effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA