Academy of Nutrition and Dietetics Methodology for Conducting Systematic Reviews for the Evidence Analysis Library

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EVIDENCE-BASED NUTRITION practice guidelines generated from systematic reviews are imperative for registered dietitian nutritionists to provide safe and effective care. These guidelines are the foundation on which practitioners base their patient care, third party payers compensate care, and public policymakers set standards for general care. Systematic reviews are at the core of evidence-based guidelines and are a "rigorous and transparent approach of synthesizing scientific evidence that minimizes bias."[1]

The Academy of Nutrition and Dietetics (Academy) has a commitment to evidence-based research that was fully realized in 2004 when the Evidence Analysis Library (EAL) (www.andeal.org) was launched. The EAL is a series of systematic reviews and nutrition practice guidelines for registered dietitian nutritionists and other members of health care teams. Meticulous methods are rigorously followed to ensure objectivity, transparency, and reproducibility of the process.

The objective of this article is to describe the current methodology of the Academy's systematic review process for the EAL.

A FIVE-STEP PROCESS

In creating the EAL, the Academy developed a process to conduct systematic reviews. The Academy reviewed several models during the development of its own customized process. Key models considered included those from the Center for Evidence-based Medicine; Agency for Healthcare Research and Quality; US Preventive Services Task Force; National Heart, Lung, and Blood Institute; Institute for Clinical Systems Improvement; American Diabetes Association; Cochrane Reviews; World Health Organization; and the US Dietary Guidelines. This critique of existing models helped to identify key systematic review components that led to the current five-step process (Figure 1) adopted by the Academy:

- Step 1—formulate the evidence analysis question;
- Step 2—gather and classify evidence (data collection);
- Step 3—critically appraise each article (risk of bias);
- Step 4—summarize the evidence; and
- Step 5—write and grade the conclusion statement.

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NUTRITION CARE PROCESS

Along with a rigorous five-step process, the Academy developed the Nutrition Care Process (https://ncpt.webauthor.com/nutrition-care-process),[2] which gives nutrition and dietetics practitioners a systematic structure to scientifically manage nutrition care and help patients meet health and nutrition goals. The four interrelated phases of the Nutrition Care Process include nutrition assessment, nutrition diagnosis, nutrition intervention, and nutrition monitoring and evaluation. These phases serve as the context to formulate the evidence analysis question.

SYSTEMATIC REVIEW TEAM AND PRELIMINARY WORK

Development of the Multidisciplinary Team

Each evidence analysis project consists of an Academy staff project manager, lead analyst, workgroup chair, 6 to 8 expert workgroup members, and 4 to 10 evidence analysts.

Oversight

The Evidence-Based Practice Committee serves as the oversight committee for the EAL and the Academy's methodology. They are responsible for determining systematic review topics, appointment of expert workgroup members, approval of evidence-based guidelines for publication, and EAL policies and procedures.

Expert Workgroup: Qualifications, Recruitment, and Appointment

Workgroup members are experts in the project topic. They develop and prioritize evidence analysis questions, approve the search plan and research articles, review and approve evidence summaries, and assign a grade to the conclusion statements based on the strength of the evidence. They must have a minimum of 5 years of experience in research and/or practice and an advanced degree (or 8 years experience in lieu of an advanced degree). Workgroup members do not receive any monetary compensation for their work on the systematic review. Workgroup candidates complete an online application and are carefully vetted. Approval by the Evidence-Based Practice Workgroup Selection Subcommittee is based on a scoring grid. All workgroup members are required to disclose any potential conflict of interest before their appointment and throughout their term on the project. Workgroup members receive orientation to the Academy's methodology and systematic review process. All of

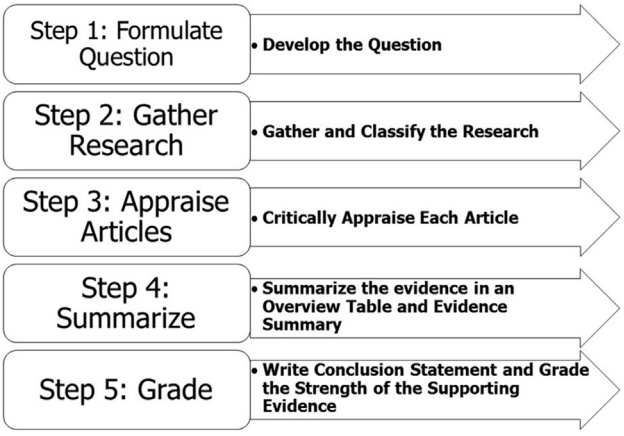

Figure 1. Academy of Nutrition and Dietetics five-step process for conducting a systematic review for the Evidence Analysis Library.

the work is conducted via teleconference calls and webinars.

Lead Analyst and Evidence Analyst

The role of the evidence analyst is to carefully read research articles determined to be relevant based on an extensive literature search. Evidence analysts are qualified members of the Academy and are required to have an advanced degree, research experience, and full knowledge of research methodology and statistics. They participate in a 2-day training program and receive mentoring throughout their tenure.

Lead analysts have a proven record as an evidence analyst but stronger and more relevant experience in recognizing study designs and bias and can interpret how bias is handled in a study. Strong writing and analytical skills are required to successfully develop evidence summaries and conclusion statements.

EVIDENCE ANALYSIS PROCESS

Topic Identification

The evidence analysis process begins with identifying the research needs within the dietetics field. Topic areas in the EAL include, but are not limited to, diseases/health conditions, nutrition screening and counseling, and food and nutrients. Research topics are suggested by Academy members, committees, and staff. Research needs are prioritized and approved by the Evidence-Based Practice Committee.

Developing the Scope of the Project

The scope of the project is developed by the lead analyst, project manager, and workgroup chair before commencing the systematic review. The scope describes the rationale and background of the topic and takes into consideration whether it is a new systematic review or an update to an existing systematic review. The scope contains objectives of the project, outcomes of interest, and the targeted population. A timeline is developed based on the breadth of the project scope. A preliminary search is conducted by the lead analyst to help guide the scope of the systematic review. On average, most EAL systematic reviews require 12 to 18 months to complete.

SYSTEMATIC REVIEW PROCESS

Step 1: Formulate the Evidence Analysis Question

The formulation of focused questions is critical to identify outcomes of interest established in the scope of the project. Three key items are used to generate good quality research questions: an analytic framework to identity links between these factors and outcomes; the population, intervention, comparison intervention, and outcome[3] format to appropriately compose research questions; and the Nutrition Care Process to serve as a framework for providing patient care. Use of these three items along with a well-defined project scope ensures that no bias is introduced during question development.

The workgroup identifies subtopic areas of interest within the research topic area and develops research questions. Research questions are developed in the PICO (population, intervention, comparison intervention, and outcome) format, which ensures specificity and relevance of the research questions to the intended goal of the project. The workgroup prioritizes research questions by considering the importance of the question to dietetics practice, potential influence on the patient or client, potential reduction in health care costs, potential reduction in controversy or confusion, variations in practice, assumptions to be verified with scientific evidence, and whether or not new research exists on that topic.

Step 2: Gather and Classify Evidence

Developing the Search Plan. The second step of the systematic review process is to develop a search plan that clearly defines the inclusion and exclusion criteria. The workgroup's goal is to find the best and most relevant research to answer the developed research questions.

Eligibility Criteria. The workgroup determines inclusion and exclusion criteria for the literature search and identifies search terms for each research question. The workgroup identifies specific eligibility criteria, including but not limited to population age, health status, setting, study design, size of study group, attrition rate, and year range of publication. Standard EAL protocol only includes peer-reviewed literature published in the English language using human participants. Non–English language articles, grey literature, and animal studies (because some of the systematic reviews may develop into evidence-based nutrition guidelines for humans) are not included in EAL systematic reviews.

Search Terms. During question development, the expert workgroup helps identify key terms and outcomes. These terms, along with identified outcomes, are used to conduct the literature search. When necessary, the workgroup will define search terms for further clarification.

Perform Literature Search. A comprehensive literature search using the eligibility criteria defined by the workgroup using one or more databases is conducted. Common databases for nutrition research include Medline (ie, PubMed), Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, and Excerpta Medica Database. Secondary reports are separated from primary reports. The lead analyst reviews the reference list of relevant secondary reports for the potential identification of primary articles that meet search criteria. This second step ensures that a comprehensive search is conducted. The Academy employs a medical librarian who has earned an advanced degree in library science to assist with the searches. The end result is a list of articles to be abstracted and evaluated as well as a list of excluded articles along with reasons for exclusion. Each step is systematic, reproducible, and clearly documented for transparency (Figure 2).

Evaluate Search Results. The lead analyst assesses all citations and abstracts and filters out irrelevant articles per eligibility. Included abstracts are assigned to one or two workgroup members for further assessment per eligibility criteria. In cases where consensus cannot be reached, or if additional information is required, the full article is obtained for full assessment by the workgroup. A list of excluded articles with reason for exclusion is documented. All included articles are obtained and assigned to analysts and the lead analyst for data extraction and critical appraisal (risk of bias).

Documentation. All literature searches and results are documented in the search plan. The search plan includes the research question, month and year of the literature review, inclusion and exclusion criteria, and search terms. The report is based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart (PRISMA)[4] and includes information on articles identified through database search, additional articles identified via other sources, articles to screen after all duplicates are removed, articles excluded during the screening process, full-text articles assessed for eligibility, number of full-text articles excluded, and articles included in the quantitative synthesis.

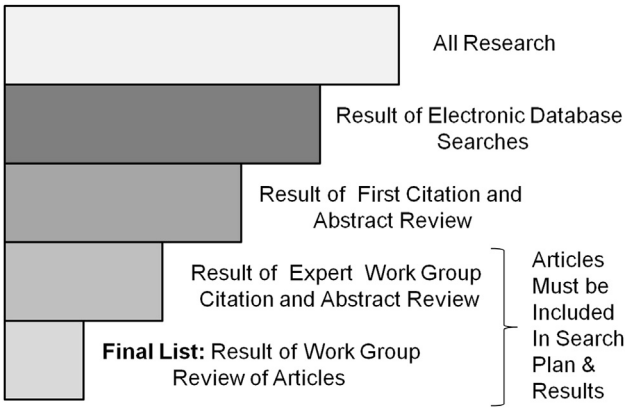

Figure 2. Illustration of steps to identify the best and most relevant research.

Step 3: Critically Appraise Each Article (Risk of Bias)

Once the individual studies that meet the inclusion criteria of the systematic review are identified, each article is carefully assessed for methodologic quality, outcomes of interest are extracted, the evidence is summarized, and finally the strength of evidence is assessed. The lead analyst and the analysts conduct the critical appraisal, also known as risk of bias, for each article. Online tools developed by the Academy are used to record the results and ensure consistency in the process and on the live site.

Each individual study is evaluated based on the appropriateness of the study design and the quality of how the study was conducted. The Academy uses an algorithm for classifying the research design of primary studies and study designs are organized into a hierarchy (Figure 3). The quality of the studies is assessed by two independent reviewers (two EAL analysts) using the Academy's risk of bias tool called the Quality Criteria Checklist (QCC) (Figure 4). The content of the QCC is

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	Nonrandomized controlled trial Nonrandomized crossover trial Case-control study Time series study Diagnostic, validity, or reliability study	R	Narrative review (review article) Consensus statement Consensus report
D	Noncontrolled trial Case study or case series Other descriptive study Cross-sectional study trend study Before—after study	X	Medical opinion

Figure 3. Hierarchy and classification table of research studies.

QCC domain	Primary research QCC
Research questions	1. **Was the research question clearly stated?** 1.1 Was the specific intervention(s) or procedure (independent variable[s]) identified? 1.2 Was the outcome(s) (dependent variable[s]) clearly indicated? 1.3 Were the target population and setting specified?
Subject selection	2. **Was the selection of study subjects/patients free from bias?** 2.1 Were inclusion/exclusion criteria specified (eg, risk, point in disease progression, and 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, demographic characteristics, and other characteristics of subjects described? 2.4 Were the subjects/patients a representative sample of the relevant population?
Comparable groups	3. **Were study groups comparable?** 3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if randomized controlled trial) 3.2 Were distribution of disease status, prognostic factors, and other factors (eg, demographic characteristics) 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 (eg, gold standard)?
Withdrawals	4. **Was method of handling withdrawals described?** 4.1 Were follow up methods described and the same for all groups? 4.2 Was the number, characteristics of withdrawals (ie, 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?
Blinding	5. **Was blinding used to prevent introduction of bias?** 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?

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Figure 4. The Quality Criteria Checklist (QCC; risk of bias tool) for critically appraising research articles.

QCC domain	Primary research QCC
Intervention/ exposure	6. **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?** 6.1 In a randomized controlled trial or other intervention trial, were protocols described for all regimens studied? 6.2 In observational study, were interventions, study settings, and clinicians/provider described? 6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? 6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured? 6.5 Were cointerventions (eg, ancillary treatments or 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?
Outcomes	7. **Were outcomes clearly defined and the measurements valid and reliable?** 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?
Analysis	8. **Was the statistical analysis appropriate for the study design and type of outcome indicators?** 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 (eg, 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 II error?
Conclusion support	9. **Are conclusions supported by results with biases and limitations taken into consideration?** 9.1 Is there a discussion of findings? 9.2 Are biases and study limitations identified and discussed?
Likelihood of bias	10. **Is bias due to study's funding or sponsorship unlikely?** 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 review should be designated with a minus (−) symbol on the Evidence Worksheet.

NEUTRAL (Ø)

If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a neutral (Ø) symbol on the Evidence Worksheet.

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 designed with a plus (+) symbol on the Evidence Worksheet

Figure 4. *(continued)* The Quality Criteria Checklist (QCC; risk of bias tool) for critically appraising research articles.

Strength of evidence elements	Grade				
	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 methodologic 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 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	Not available
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

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Figure 5. Criteria and definitions for grading the strength of the evidence for an Evidence Analysis Library Conclusion Statement.[10]

Strength of evidence elements	Grade				
	I Good/strong	II Fair	III Limited/weak	IV Expert opinion only	V Grade not assignable
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	Not available

Figure 5. *(continued)* Criteria and definitions for grading the strength of the evidence for an Evidence Analysis Library Conclusion Statement.[10]

based on the quality constructs and domains identified in the Agency for Healthcare Research and Quality report on Systems to Rate the Strength of Scientific Evidence.[5] The QCC is a component of the EAL web-based Data Extraction Tool (DET).

The QCC includes four questions on relevance that address applicability to practice and 10 validity questions that address scientific soundness. The relevance and validity questions are mainly focused on research question, study population, sampling (bias, randomization), intervention or exposure, outcomes measurements, statistical analysis, and interpretation of findings. Each of the 10 validity questions also contains several subquestions to help address specific study designs.

The detailed QCC (specific for different study designs) guides the analysts to recognize various threats that may undermine sound research and that could lead to invalid conclusions. Any discrepancies between the two reviewers is resolved by discussion and sometimes a third reviewer, when necessary. Based on the responses to these validity questions, each study is rated as positive, negative, or neutral. A full explanation of the rating system as it appears on the QCC is listed in Figure 4. The information from the QCC for each article is combined into a single report. All checklists that are applicable to the same evidence analysis question are compiled into a Quality Criteria Summary. This is generated electronically after the analysts have completed the QCC for each article.

Step 4: Summarize the Evidence

Data Extraction. The Academy's web-based DET is used for extracting and storing information from the research articles that meet the inclusion criteria. This tool facilitates structured data extraction that allows the analyst to generate detailed tables that summarize the study results for comparison by the workgroup. The DET has global fields that can apply to all EAL systematic reviews as well as other data entry fields that can be customized based on the scope of individual systematic reviews. Trained EAL analysts use the DET to extract the following data from each eligible research article: title, year and journal of publication, study design, intervention and control groups (if applicable), details of interventions (eg, type of intervention, who delivered the intervention, duration of intervention, and mode of intervention), and outcomes of interest (this part varies based on the research question). The lead analyst serves as the second reviewer and verifies the information extracted by the analyst for accuracy. If there is disagreement a third reviewer is consulted.

Synthesis of Evidence Summaries and Statistics. After completion of the data extraction and quality appraisal process, the lead analyst synthesizes results from studies pertaining to each research question into an evidence summary. Synthesizing evidence summaries involves combining relevant and valid information (presented in summary tables) into a brief, coherent, and easy-to-read summary. A summary table supports the information provided in the evidence summary and succinctly presents information regarding study characteristics and results from individual studies.

Statistical Analysis. When data are available, descriptive statistics and meta-analyses as appropriate are performed. Selection of the method of analysis (descriptive statistics, meta-analysis, or meta-regression) will depend on the nature of the data, appropriateness of combining studies, and how the results will be used. Meta-analysis will be performed in cases where data from independent studies demonstrate high levels of homogeneity. Heterogeneity between the studies will be assessed using the I^2 test and, if levels of heterogeneity (I^2>0.75%) exist, then meta-analyses will not be performed.[6] Also, possibility of publication bias is evaluated with a Begg's funnel plot and with Egger's test.[7,8] In situations where meta-analysis is not appropriate, the evidence will be provided in the form of narrative synthesis.

Step 5: Write and Grade the Conclusion

The fifth step in the evidence analysis process is writing the conclusion statement. The lead analyst drafts the conclusion statements for each research question, which are then reviewed and approved by the workgroup. The conclusion statement aggregates the

overall evidence presented by the summary tables and answers the research question. The conclusion needs to be clear, simple, and to the point. The workgroup members may accept the drafted conclusion statement, recommend minor changes, or request completely rewriting the material.

Grade the Strength of the Evidence for the Conclusion Statement. The conclusion statement grade reflects the quality of the studies, consistency and quantity of studies, and clinical influence and generalizability to the population of interest. Conclusion statements are graded either I (good/strong), II (fair), III (limited/weak), IV (expert opinion only), or V (not assignable).

The Academy adapted the Institute for Clinical Systems Improvement System grading approach (Figure 5).[9] In addition, Grade V was adopted in September 2004 because the workgroups and analysts found many situations where none of the original four grades were applicable resulting in the designation of "not assignable." The Institute for Clinical Systems Improvement System reviewed and modified their grading system and in November 2003 they adopted a "not assignable" grade.

FUNDING

The Academy is the primary source of funding of the EAL. External funding for the EAL has enabled the Academy to publish much more content than would have been possible through Academy funding only. External funders include government agencies, nonprofit foundations, collaborations with professional associations, and industry (evidence-based nutrition practice guideline projects are not open to industry funding). All sources of funding are fully disclosed on the EAL under "Project Team."

All externally funded projects are funded as unrestricted grants, meaning the funding entity has no input on the project, including the workgroup selection, question formulation, and outcome. In addition, all externally funded project topics must meet the EAL mission. Regardless of the funding sources, the Academy maintains full control over the content and process of all systematic reviews in the EAL. Only the expert workgroup members can formulate the evidence analysis questions, set the inclusion/exclusion criteria, review the articles and evaluate the research, approve the conclusion statements, and assign the final grade. Lastly, all funded EAL systematic reviews will be in compliance with Academy scientific integrity principles.[11]

CONCLUSIONS

This article summarizes the rigorous five-step process the Academy of Nutrition and Dietetics EAL follows when conducting systematic reviews on nutrient, food, or nutrition-related topics. The results of these systematic reviews are available on the EAL website.

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STATEMENT OF POTENTIAL CONFLICT OF INTEREST

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