EVIDENCE-BASED REVIEWS: HISTORY, UTILITY, AND APPLICATION

A Thesis

by

LINDSEY BRIGGS FIELD

Submitted to the Office of Graduate Studies of Texas A&M University in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

May 2011

Major Subject: Nutrition
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Approved by:

Chair of Committee, Committee Members, Intercollegiate Faculty Chair, Joanne R. Lupton Jenna D. Anding Peter S. Murano Joseph R. Sharkey Arnold Vedlitz Stephen B. Smith

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ABSTRACT

Evidence-Based Reviews: History, Utility, and Application. (May 2011)

Lindsey Briggs Field, B.S., Texas A&M University

Chair of Advisory Committee: Dr. Joanne R. Lupton

Performing evidence-based reviews (EBR) is a growing and important area of research, and more graduate students should be educated in this area. EBRs provide conclusions based on science and follow a specific methodology to decrease bias, consider all pertinent science on the topic, and have transparency. This thesis is two-fold and includes: 1) a faculty course manual on how to facilitate a college course on EBR and 2) an EBR manuscript on the utility of nutrition labeling to affect consumers’ ability to select more nutritious products and whether or not nutrition labeling can affect purchase and consumption of more nutritious products. This EBR is timely in that the US Food and Drug Administration (FDA) has called for a moratorium on Front-of-Pack labeling (FOP) until two Institute of Medicine Committees have produced their reports and FDA has interpreted those reports. The intention of the manuscript is that it will aid in this interpretation. Of 978 articles collected, 699 were excluded using exclusion/inclusion criteria, 253 were identified as secondary articles, and 26 were used for the EBR. Results: Ten studies answered question #1 on whether or not consumers can pick a more nutritious product by reading labels and 21 answered question #2 on whether consumers actually change their purchasing and/or eating behavior by using
labels. Studies ranged from simple cross-sectional studies that used survey data to more complex studies that collected sales data or performed in-store observations.

In conclusion, consumers are able to use food labels to pick more nutritious products. Preliminary evidence suggests that a subset of health conscious consumers will read food labels to select a healthier product within a product category. Less evidence exists that reading labels actually results in a change of food intake. More intervention rather than survey studies are required to address this issue. In addition, the next stages of investigation should include looking at the whole diet, rather than just individual foods, and finally what affect the whole diet may have on overall health.
DEDICATION

To my loving and faithful husband. Thank you for your support, patience, and “formatting dedication.” I love you.
ACKNOWLEDGEMENTS

I would like to thank my major professor, Dr. Joanne Lupton, for her tireless support and encouragement throughout the course of my work. I am very appreciative of the opportunities that have been awarded to me over the past three years as her graduate student.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>iii</td>
</tr>
<tr>
<td>DEDICATION</td>
<td>v</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>vi</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vii</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>x</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>What are systematic literature reviews and why are they important?</td>
<td>1</td>
</tr>
<tr>
<td>Data Quality Act, 2001</td>
<td>4</td>
</tr>
<tr>
<td>Who uses evidence-based systematic approaches?</td>
<td>4</td>
</tr>
<tr>
<td>MANUSCRIPT</td>
<td>11</td>
</tr>
<tr>
<td>METHODS</td>
<td>13</td>
</tr>
<tr>
<td>Literature search</td>
<td>13</td>
</tr>
<tr>
<td>Classification of studies as primary or secondary and assignment to questions</td>
<td>14</td>
</tr>
<tr>
<td>Categorizing studies as to study design and quality</td>
<td>14</td>
</tr>
<tr>
<td>Extracting data into spreadsheets</td>
<td>15</td>
</tr>
<tr>
<td>Coming to conclusions based on the strength of the evidence</td>
<td>16</td>
</tr>
<tr>
<td>RESULTS</td>
<td>17</td>
</tr>
<tr>
<td>Literature search</td>
<td>17</td>
</tr>
<tr>
<td>Question #1 Can consumers use FOP and standard back-of-pack labeling to select the more nutritious product?</td>
<td>19</td>
</tr>
<tr>
<td>Question #2 Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard back-of-pack nutrition labels?</td>
<td>31</td>
</tr>
<tr>
<td>CONCLUSIONS</td>
<td>54</td>
</tr>
<tr>
<td>Consumers are able to use food labels to identify the healthier food product</td>
<td>54</td>
</tr>
<tr>
<td>Label use influences consumer purchasing behavior</td>
<td>55</td>
</tr>
<tr>
<td>Label use influences consumer diet quality</td>
<td>56</td>
</tr>
</tbody>
</table>
COURSE MANUAL ................................................................................................... 59

Introduction ............................................................................................................. 59
Supplies/resources ................................................................................................ 61
Course description ................................................................................................ 61
Course objectives ................................................................................................. 62
Specific learning objectives .................................................................................. 63
Student prerequisites ............................................................................................ 63
Graduate student responsibilities .......................................................................... 63
Week 1..................................................................................................................... 64
Week 2..................................................................................................................... 65
  Team assignment #1 instructions – oral and written assignment ......................... 67
Week 3..................................................................................................................... 67
  Team assignment #1 – oral and written presentation ........................................... 67
  Take home activity #1 ......................................................................................... 69
  Team assignment #2 instructions – oral and written assignment ......................... 69
Week 4..................................................................................................................... 71
  Take home assignment #2 ................................................................................ 73
  Team assignment #2 – oral and written assignment ............................................. 73
  Team assignment #3 instructions – written assignment ...................................... 73
  Compressing an EndNote® library .................................................................... 74
  Converting EndNote® to Excel .......................................................................... 75
Week 5..................................................................................................................... 76
  Paper #1 oral and written presentation instructions ........................................... 77
  Invited guest lecturer from the statistic department ............................................ 77
  Lecture on quality rating .................................................................................... 78
  Team assignment #3 – written assignment ....................................................... 79
Week 6..................................................................................................................... 79
  Paper #1 oral and written presentations ........................................................... 80
Week 7..................................................................................................................... 80
Week 8..................................................................................................................... 81
Week 9..................................................................................................................... 82
  Paper #2 oral and written presentations ........................................................... 82
Week 10.................................................................................................................... 82
Week 11.................................................................................................................... 83
Week 12.................................................................................................................... 83
  Take home assignment #3 ................................................................................ 84
Week 13.................................................................................................................... 85
  Graduate student final presentation with the instructor ....................................... 85
  Final assignment instructions – oral presentation and written report ................. 86
Week 14.................................................................................................................... 87
  Peer group evaluations (due week 15) ............................................................... 87
Week 15............................................................................................................................. 87
Final assignment – oral presentation and written report ............................................. 88
REFERENCES .................................................................................................................. 89
APPENDIX A .............................................................................................................. 100
APPENDIX B.............................................................................................................. 113
APPENDIX C.............................................................................................................. 115
APPENDIX D .............................................................................................................. 163
APPENDIX E .............................................................................................................. 181
APPENDIX F .............................................................................................................. 191
APPENDIX G .............................................................................................................. 195
VITA ............................................................................................................................. 198
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>Study results that evaluate consumer ability to identify the more healthful food product using various nutrition labeling systems</td>
<td>21</td>
</tr>
<tr>
<td>Table 2</td>
<td>Study results that evaluate food label use on consumer purchasing and/or eating behavior</td>
<td>33</td>
</tr>
</tbody>
</table>
INTRODUCTION

What are systematic literature reviews and why are they important?

Systematic literature reviews (also known as evidence-based reviews) evaluate the totality of research for a specific research question using a systematic method including critically appraising each article based on quality of the research with the least amount of bias (1, 2). Evidence-based approaches to establish clinical guidelines for both nutrition and medical treatment have become the preferred method (3, 4). Since the 1980’s, healthcare professionals have paid more attention to the way research is evaluated and medical literature is meticulously evaluated more so than ever before (3, 4). In 2002, the Agency for Healthcare Research and Quality (AHRQ) identified the use of evidence-based systematic reviews as a highly potential emerging science used to identify disease risk factors and in the development of Community Guide recommendations (2).

Systematic literature reviews (SLR) differ from narrative reviews in that they are a transparent method of systematically appraising, collecting, and reproducing the search and evaluation of articles (2). According to some, groups conducting SLR as the foundation for the development of guidelines and treatments are “likely to be in the best position to evaluate the strength of the evidence they are assembling and analyzing” (5).

This thesis follows the style of Journal of the American Dietetic Association.
Evidence-based reviews (EBR) are particularly important and useful for physicians, clinicians, dietitians, and policy makers. Healthcare professionals and government officials do not have time to gather and review the entire body of scientific literature and then form unbiased conclusions based on high quality studies. Therefore, SLR/EBR provide conclusions based on science with the least amount of bias and follow a specific methodology to decrease bias, consider all pertinent science on the topic, and have transparency (6).

Like many organizations currently using SLR to form the basis of their recommendations, the former way of developing conclusions was too simplistic and there was concern that the entire body of scientific literature was not captured and design type not considered (7). Therefore in 1996 the Institute for Clinical Systems Improvement (ICSI) for example, adopted an evidence based grading system (8). Likewise, many other organizations (9-14) have similar rationales for adopting evidence-based grading systems. Conducting a SLR demonstrates to the user that the evidence has been appraised and there is a higher level of certainty that the conclusions are based on design type and quality (8). When conducted correctly, SLR can identify particular areas of research that are lacking, rationalize the inability to form conclusions, and identify emerging areas of science (6).

Typically, a set of analysts or evidence-based centers are assigned to conduct the literature searches on a particular topic. The advantage is having a consistent group of people who become “experts” in an area and are familiar with the totality of the science and consistency of results. Analysts are better able to form unbiased conclusions based
more on higher rather than lower quality studies (8). Some organizations such as the Cochrane Reviews, 2010 Dietary Guidelines for Americans Committee (DGAC), and the American Dietetic Association Evidence Analysis Library (ADA EAL) seek volunteers to attend their workshops to become evidence analysts for the organization (9, 12, 14).

As mentioned above, it has become more and more apparent over the past 30 years that there is a need for evidence-based approaches when evaluating the science and coming to conclusions as the foundation for recommendations (3, 4). For example, the Dietary Guidelines for Americans (DGA) offer nutritional guidance for healthy Americans ages two and older to reduce the risk of chronic disease and promote overall health (15). The DGA is jointly updated by the Departments of Agriculture (USDA) and Health and Human Services (HHS) every 5 years (15). In 2003, a paper was published that supported the need for an evidenced-based approach for the 2005 DGA and thereafter (4). Prior to the 2005 DGA, each Dietary Guidelines Advisory Committee (DGAC) often gathered and interpreted the scientific literature reviewed previously by other DGACs when it came time to update the forthcoming Guidelines (4). However, if an evidence-based system were used by every DGAC, the current Committee would collect the new scientific literature since the previous DGA was issued and add to the body of evidence (4). Systematically evaluating the literature for the 2005 DGA would increase the credibility of Committee recommendations. This is achieved through the use of a transparent process in which recommendations can be defended and interpreted easily (3, 4).
Data Quality Act, 2001

On October 1, 2001 the Data Quality Act (DQA) came into effect and mandated that all government agencies disseminate and use information accurately by ensuring quality, objectivity, utility, and integrity (16). As outlined in section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (16), the Office of Management and Budget (OMB) would “issue government-wide guidelines that provide policy and procedural guidance to Federal agencies” (17). The Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies describe in detail the 4 terms federal agencies must maximize when developing information to be disseminated according to the DQA: 1) Quality includes objectivity, utility, and integrity; 2) Objectivity focuses on presentation and substance of the disseminated information. The information must be presented in an unbiased method that is also clear, accurate, and complete while the substantive aspect should be unbiased, accurate, and reliable; 3) Utility is “usefulness of the information to the intended user”; and 4) Integrity is the “protection of the information from unauthorized access or revision” (17).

Who uses evidence-based systematic approaches?

In 2005 as a means to abide by the DQA, the USDA and HHS adopted a systematic review methodology for the development of the 2010 DGA. Many agencies including the American Dietetic Association (ADA), the AHRQ, and U.S. Cochrane Collaboration, assisted with the development of the USDA Nutrition Evidence Library
(NEL) systematic review process used by the Committee (13). The NEL was useful with
the synthesis of evidence for the DGAC Report (12).

Likewise, the Institute of Medicine (IOM) established an IOM Roundtable on
Evidence-Based Medicine in 2006 to “provide a neutral forum for discussion and
collective action by healthcare stakeholders to help transform the way evidence on
clinical effectiveness is generated and used to improve health and health care” (18). The
Roundtable’s first formal report, *Learning Healthcare Systems*, promotes the use of
evidence-based medicine in practice and strives for a learning healthcare system that
“draws on the best evidence to provide the care most appropriate to each patient,
emphasizes prevention and health promotion, delivers the most value, adds to learning
throughout the delivery of care, and leads to improvements in the nation’s health” (10).

In addition, conferences have been organized by the National Institute of Health (NIH)
Consensus Development Program since 1977. The conferences “produce evidence-based
consensus statements addressing controversial issues important to healthcare providers,
policymakers, patients, researchers, and the general public” (11). Before each conference
a systematic literature review is conducted by one of the AHRQ Evidence-based practice
centers. Conference proceedings include panelist evaluation of the SLR, presentations
from experts in the field, and finally a draft report (11). Finally, in January of 2009 (first
draft issued in 2007), the Food and Drug Administration (FDA) issued a guidance letter
to industry describing the evidence-based review system the Agency intends to use when
evaluating the significant scientific agreement (SSA) health claims and qualified health
claims “on the relationship between a substance and a disease or health-related condition” (19).

As mentioned previously, many organizations have sought and developed formal methods of evidence-based grading systems to evaluate research. A concise list of the prominent and well known systems include: US Preventive Services Task Force (supported by AHRQ) (2); Cochrane Reviews (14); Institute for Clinical Systems Improvement (ICSI): Evidence Grading System (8); American Dietetic Association Evidence Analysis Library (ADA EAL) (9); USDA Nutrition Evidence Library (13); and Agency for Healthcare Research and Quality (AHRQ) (2).

Although there are many different evidence-based systems, there are far more similarities between the systems than differences. For example, the majority of the Systems follow the PICO format to develop strong research questions (6, 9, 14). PICO format stands for: P = primary problem or participants, I = intervention, procedure, or exposure, C = control or how alternatives compare, O = outcome. In addition the primary components of developing a SLR are similar: a) posing the question; b) conducting the literature search; c) extracting the information; d) characterizing the type of study; e) rating the study quality; and f) developing a conclusion based on the evidence.

Each step must be meticulously followed according to the system to avoid bias and correctly and consistently rate the quality of the studies. However, some differences do occur among the evidence-based Systems. For example, some systems use primarily intervention studies only (14) while others use both intervention and observational
studies (9, 20) to develop conclusions. Likewise, some systems consider randomized controlled trials (RCTs) as the gold standard, highest quality studies while others do not (9). Yet, due to the nature of nutrition and public health research and the limited number of RCTs on dietary intervention, RCTs may not be the preferred type of study for all SLR (4, 6, 21). Furthermore, some systems (9, 13) have developed a checklist of questions to evaluate the quality of the studies while others have not (20).

The scope of this thesis is two-fold and therefore contains two aspects of an evidence-based review. It includes the completion of a systematic literature review suitable for publication and the development of a course manual to assist faculty on how to successfully teach an evidence-based review class following the ADA Evidence Analysis Process (EAP) (9).

First, the completion of a SLR serves as an example of a completed evidence-based review following ADAs EAP. The ADA EAP is selected as the evidence-based system of choice to conduct a systematic literature review for a number of reasons: 1) the American Dietetic Association is the professional organization for registered dietitians including the author of this thesis; 2) it is the process that was taught to the author by an ADA analyst and Chair of the graduate committee and the process that the author has used for over two years; and 3) the evidence-based process is respected among the nutrition community, so much so that the USDA developed their own Nutrition Evidence Library (NEL) using ADAs EAL as a model for the 2010 DGAC Report, as mentioned above (13). In addition, USDA adopted ADAs EAL Checklist as their Implementation Checklist to assess the quality of primary articles (22, 23).
Conducting a SLR is an important form of research and more people need the skills to scientifically and critically appraise the quality of studies to come to a consensus conclusion. The SLR focuses on the area of front-of-pack (FOP) nutrition labeling, more specifically, point-of-purchase (P-O-P) nutrition labeling. This is a very timely and important issue. In October 2009, the USDA issued a letter to industry regarding improper use of FOP nutrition labels (24) and USDAs intent to work with the IOM “to develop an optimal, common approach to nutrition-related FOP and shelf labeling that all Americans can trust and use to build better diets and improve their health” (24). In October 2010, the IOM issued the first of two phases in their report: Examination of front-of-package nutrition rating systems and symbols: Phase 1 report. The report highlights the strengths and limitations of various FOP labeling systems and the IOMs intent to consider consumer use and understanding of these labels during a second phase to be unveiled during the Fall of 2011 (25). As a result of the Letter (24) and the IOM report (25), two research questions have been studied and researched for the SLR manuscript: 1) Can consumers use both FOP and standard back-of-pack nutrition labels to select the more nutritious product? and 2) Do consumers change their purchasing and/or eating behavior because of the use of FOP standard back-of-pack nutrition labels? Through the intensive assessment and synthesis of the scientific literature the author has become knowledgeable in this area and has identified gaps in the research. The intent and hope is that this research will provide the USDA and FDA with the information necessary to come to a conclusion regarding the FOP label that consumers are best able to use to identify the healthier food product to ultimately
decrease obesity rates among Americans.

Second, a course manual was developed as a guide for faculty on how to teach a 15-week college course for undergraduate and graduate students on conducting EBRs in a nutrition, food science, or public policy/health class following the ADA EAP (9). The goal is that instructors will feel comfortable and confident following the outline of this course as displayed in the manual from an experienced facilitator who shares her knowledge and experience conducting such a course at a major university. The course manual is intended to assist faculty at Texas A&M University (TAMU) and equivalent universities or colleges with step-by-step instruction to successfully conduct a 15-week course on EBR. Students will focus on one topic area during the entire semester and will obtain the skills to scientifically and critically appraise the quality of studies to come to a consensus conclusion. As students review the scientific literature in one area they will become qualified in that area to recognize research gaps (26).

Students will learn a number of useful and marketable skills necessary to successfully complete an EBR during the course of the class including: 1) formulating the research question; 2) conducting the literature review to answer the research question(s); 3) learning to critically appraise each relevant article based on quality rating and to decrease the likelihood of bias; 4) summarizing the evidence; and 5) drawing conclusions based primarily on higher quality studies. Likewise, graduate students will learn to lead a group of undergraduate students and set realistic goals, assign duties, and develop manage skills. The course manual is designed in a week-by-week fashion and provides detailed instructions and assignments for each class period. The manual
includes all reproducible resources: weekly class instruction for a succession of 15 weeks, lectures in the form of Power Point® presentations, an example of a course syllabus including assignments and point system, class handouts, grading evaluation forms, oral presentation templates, written assignment samples, and more. It also provides course objectives and student learning objectives.
Sixty-five to 80% of the average consumer’s purchasing decisions are unplanned and made in-store, an indication that the supermarket is an ideal setting to impact healthy eating habits (27). A number of Point-of-Purchase (P-O-P) labeling systems, more specifically Front-of-Pack (FOP) nutrition labels have been developed in response to this opportunity to help direct consumers to “better for you” products: The UK’s Traffic Light System (28); the European Food Safety Agency’s Guideline Daily Amounts (29); the Smart Choices Program (30); Hannaford’s Guiding Stars (31); the Nutrient Rich Foods Index (32) and the NuVal system (33) to name a few. For the purposes of this paper FOP nutrition labels are defined as front-label nutrition icons (34) excluding health claims, nutrient content claims, and structure/function claims. Although the US Food and Drug Administration (FDA) is generally supportive of FOP labeling systems, there is concern that multiple systems, with differing nutrition criteria, may be more confusing than helpful to consumers (35). In October, 2009, FDA issued a Guidance Letter to Industry regarding FOP labeling (36). In the letter, FDA states that FOP labeling can be helpful in encouraging consumers to select healthier diets but states its intent to provide “standardized, science-based criteria on which FOP nutrition labeling must be based” (36). To that end and in response to a congressional directive, the Centers for Disease Control and Prevention and the FDA asked the Institute of Medicine “to undertake a review of front-of-package nutrition rating systems and symbols” (34). In October 2010, the IOM issued the first of two phases in their report (25). The report highlights the strengths and limitations of various FOP labeling systems and the IOMs
intent to consider consumer use and understanding of these labels during a second phase to be unveiled during the Fall of 2011 (25).

The purpose of this paper is to systematically review consumer research on use of food labeling systems asking two specific questions in order to apply these “lessons learned” to the decision making process for developing a unified FOP system. 1) Can consumers use both FOP and standard back-of-pack nutrition labels to select the more nutritious product? 2) Do consumers change their purchasing and/or eating behavior because of the use of FOP and standard back-of-pack labels? Collectively this information should help to contribute to best practice guidelines for designing a FOP system.
METHODS

Literature search

A systematic review of the studies pertinent to each of the two questions noted above was conducted. Peer-reviewed articles published from January 1980 (in order to capture consumer research prior to the Nutrition Facts Panel) to December 2010 were located electronically using the databases Agricola, PubMed, CAB Abstracts, OVID Medline, and PsycINFO. Key words included: “nutrition facts panel,” “nutrition label,” “food label,” “label,” “front of pack label,” “signposting,” “qualifying criteria,” “nutrient profil*,” “food choices,” “food intake,” and “consumer behavior” used in various combinations. Primary literature included peer-reviewed original research while meta-analyses and reviews were considered secondary literature. Reference lists from secondary literature although not used for the systematic reviews were manually back-referenced for inclusion of primary studies. The search was limited to human studies and those written in the English language. Articles were excluded from the review process if they focused exclusively on specific nutrient deficiencies or diseases or other aspects of food labels such as ingredient labeling. Results of the literature searches were extracted into an EndNote X3® Library to eliminate duplicates and to aid in the review process. Studies were assigned to reviewers for evaluation against inclusion/exclusion criteria. Where uncertainties arose, articles were presented by the original reviewer to the rest of the group and consensus was achieved as to whether or not the article should be included. All literature searches were conducted in the months of October and November of 2009 and updated in December 2010.
Classification of studies as primary or secondary and assignment to questions

All studies meeting inclusion/exclusion criteria were further divided into two categories: primary research (original studies) and secondary research (e.g., reviews, meta-analyses). The primary studies were then assigned to each of the two questions. Our *modus operandi* for distinguishing among the questions was as follows. *Question 1* required individuals to actually select a healthy product and *Question 2* had the highest level of consumer involvement as it asked if people would actually use the label information to purchase and/or consume a “better for you” product. All authors participated in the assignment of manuscripts to the questions and there was 100% agreement as to this assignment.

Categorizing studies as to study design and quality

Included documents were categorized as to study design using criteria defined by the American Dietetic Association (ADA) Evidence Analysis Manual (37). The senior author was trained by ADA in the use of their evidence-based analysis system and teaches a course in all aspects of doing evidence-based reviews. The other authors were students in this class who then stayed on for additional semesters to write the manuscript. All primary research studies were categorized by study design: randomized control trials (A), cohort studies (B), nonrandomized trials including case-control studies and historical or concurrent controls (C), cross-sectional studies, trend studies, and before and after studies (D). The four types of studies mentioned above (A, B, C, or D) are organized in a descending fashion based on the potential for bias. For example, a randomized control trial is awarded an “A” because it has the least potential for bias.
whereas a cross-sectional or “D” study is more likely to have bias.

After assigning the study design classification score to each paper it was reviewed for the quality of the study. Each paper received a quality score of negative, neutral, or positive for relevance and validity using the 10 questions outlined in the ADA Primary Research Quality Criteria Checklist (38). Each rating was verified and confirmed by at least two reviewers. If the two reviewers disagreed as to the score a third reviewer scored the paper and the predominant value was used. Reviewers applied all ten validity questions to the 26 papers for the evidence based review and answered “yes”, “no” or “unclear” to all questions. High quality or positive papers answered “yes” to four specific questions and at least one other question. Positive studies were identified on the spreadsheet as a “+” or plus symbol. Articles were designated as low quality or negative if they received a score of “no” to six or more of the validity questions. They were identified on the spreadsheet with a “-” or minus symbol. Articles were designated as neutral if “unclear” was answered for four specific questions. These articles were identified on the spreadsheet as a “Ø” or null symbol (38).

**Extracting data into spreadsheets**

Information from primary research reports was extracted into a worksheet for each of the two questions. The categories in the worksheets were modeled after ADAs Evidence Worksheet (section 3.1) (38). Review articles were summarized separately and used for background information as appropriate. Information abstracted from each primary article included the citation, the ranking of study design and a quality assessment for the manuscript, population studied, purpose, subject eligibility, study
design and methods. Results of the study were included if supported by data from the tables and figures. Study limitations and reviewer comments/conclusions were also included.

**Coming to conclusions based on the strength of the evidence**

All articles for the evidence-based review were categorized according to the two research questions. Some articles overlapped and were used in more than one category (which is noted in the Tables). The final step of the process was to form conclusions on the two research questions based on the study design and quality rating of the articles. When interpreting the data, higher quality studies with the least amount of bias contributed more to the conclusions than other studies. In addition, the number of articles and consistency of results contribute to the overall conclusion.
RESULTS

Literature search

Using the search strategies shown above we located 978 articles (Figure 1). Of these, 699 were excluded after reading the abstract and/or the entire article using the exclusion criteria also noted above. Of the remaining 279 articles, 253 were secondary studies (reviews, meta-analyses) and were used for back-referencing and background information only. The remaining 26 articles were used for the evidence-based review. Five of these articles overlapped and contained information and data pertinent to more than one of the two questions and thus were used more than once. On occasion, some of these articles earned different quality ratings or study designs due to the nature of the task or study that answered the particular question, therefore variation exists (refer to the tables on pp. 21 and 33). As shown in the Figure 26 total articles answered question one and two. Of the 26 articles used for the evidence-based review, keeping in mind that some overlapping studies earned different quality ratings and study designs, four were “A” type studies, one was a “B” type study, 0 were “C” type studies, and 26 were “D” type studies. Due to the nature of this systematic review, it was expected that fewer “A” type studies and more “D” type studies would be conducted in this area.
Documents retrieved from electronic literature database: 978

Documents retained in full text for detailed examination based on inclusion criteria: 279

Documents excluded based on abstract and full text (if necessary): 699

Final peer-reviewed articles (primary research) retained: 26

Secondary articles used for background information: 253

Question #1 Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product? 10*

Question #2 Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard BOP nutrition labels? 21*

Figure 1. Flowchart presenting the search results from electronic databases and back-referencing. Articles included in the systematic literature review addressed the two research areas: #1 Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product? and #2 Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard BOP nutrition labels?

*Overlapping articles exist among the 2 categories for the systematic literature review.
**Question #1 Can consumers use FOP and standard back-of-pack labeling to select the more nutritious product?**

The question at hand is “Can consumers actually use FOP and BOP nutrition labels to select or identify the healthier food product”. Studies have attempted to answer this question in a number of ways from asking subjects to determine the healthfulness of one food category (e.g., crackers), select the healthier food from product pairs, or comparing fictitious labels. All of the studies discussed below compare consumer ability to identify the healthier food product through the use of FOP labels alone, BOP labels alone, and a limited number of studies that compare them both. As presented below, the studies build on each other from testing consumer use of a single nutrition label to studies that use multiple nutrition labels.

Ten studies address question #1, *Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product?* Of these, two were classified as “A” studies and the remaining eight were “D” studies. Both (39, 40) of the “A” studies were positive quality while five (41-45) of the “D” studies were rated as neutral quality and three (46-48) were positive quality.

Only one study (43) compared consumer use of one FOP label, guideline daily amounts (GDA). In the study, participants were recruited from grocery stores in the UK, France, Germany, Hungary, Poland, and Sweden after having been observed using nutrition labels before selecting the food product. Participants agreed to participate in an in-store interview and complete a survey at home that was mailed back to the researchers. The self-administered take-home questionnaire measured consumer
understanding of GDA labels, nutrition knowledge, and collected background information. More importantly, their ability to identify the healthier food product using GDAs was measured through four performance tasks (Table 1). Respondents performed four tasks with the GDA label only and identified the healthiest and least healthy product labels (tasks 1-3) and ranked frozen “ready meals” (with the GDA plus a standard BOP label) in terms of healthiness (task 4). Task one products had a dominant healthier alternative while products from task two and three had no clear dominant alternative. To accommodate French consumers who do not use GDA labels, a FOP label currently used in France was displayed that did not list information on saturated fat. Swedish consumers were also accommodated for task four and used the keyhole logo on the front of the package instead of GDAs. Most respondents from all six countries correctly identified the healthiest food product using GDA labels alone (task 1). For task 3, respondents’ rankings were more distributed as they had the most difficulty differentiating between 2 products; 1 high in salt and the other high in saturates. This large distribution was seen especially among French respondents who ranked the label higher in saturates as healthier than the label high in salt. The likely explanation for the large variation is because French respondents were using a French appropriate FOP label that does not list saturates as the GDA label does. Interestingly, among Swedish respondents for task four, identifying the healthiest of the three food products simply required looking for the presence of the keyhole logo but only 57% of the Swedish people correctly ranked the label with the logo as the healthiest. According to the author,
<table>
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<th>Primary author(s), y (ref no.)</th>
<th>Study type</th>
<th>Quality rating</th>
<th>Population</th>
<th>Objective</th>
<th>Overall study design</th>
<th>Labeling format(s)</th>
<th>Methods</th>
<th>Results</th>
<th>Comments</th>
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<tr>
<td>Balasubramanian S, et al., 2002* (39)</td>
<td>A +</td>
<td>n=190 college students; United States.</td>
<td>Determine if pre or post-NLEAw labels help consumers identify the healthier food product among breakfast cereals.</td>
<td>Computerized shopping lab experiment; 2 (knowledge) X 2 (motivation) X 2 (label format) between-subjects design. Manipulations: knowledge - half of the participants were randomly given a nutrition information brochure; motivation (high-motivation or low-motivation) - groups depended on if they were provided with physician-specified attributes of a cereal (low in fat, sodium, and cholesterol; high-motivation) or no instruction was given (low-motivation).</td>
<td>Pre-NLEAw label and post-NLEAw label.</td>
<td>12 breakfast cereals were displayed on a computer. Participants were assigned to 1 of the 2 labeling conditions and selected a cereal. Participant search activities were collected from computer records.</td>
<td>Highly-motivated participants assessed a higher percentage of the 3 physician-specified attributes compared to low-motivation participants (p&lt;0.01).</td>
<td>High-motivation consumers are able to identify the healthier food product (breakfast cereal) when provided with instruction compared to consumers who receive none.</td>
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<td>Borgmeier I, et al., 2009* (40)</td>
<td>A +</td>
<td>n=420 adult participants; Hamburg, Germany.</td>
<td>Determine which of 5 labeling conditions best predicts for selecting the healthier food product.</td>
<td>Each participant exposed to 1 of 5 labeling conditions for 28 food pairs. Flashcards included the picture of the food, the FOP label, and portion size. No FOP label was associated with the &quot;no label&quot; condition.</td>
<td>Five experimental conditions: Simple tick; Multiple Traffic Light (MTL); Monochrome Guideline Daily Amount (GDA); a Colored GDA label (CGDA); and &quot;no label&quot; condition.</td>
<td>28 food pairs were photographed and displayed on flashcards. Participants selected the healthier food among each product pair.</td>
<td>Participants using the MTL were best able to identify the healthier product (24.8 out of 28 pairs; (p&lt;0.001). &quot;No label&quot; was associated with the worst average to identify the healthier product. No significant difference between the average number of correct choices between the GDAs and CGDA.</td>
<td>Simple FOP food labels (MTL systems) help consumers identify the more healthy food product compared to more complex labeling formats (GDAs). FOP labels are better differentiators between healthier and less healthy food products than &quot;no label.&quot;</td>
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<td>Feunekes, GI, et al., 2008* (41)</td>
<td>D Ø</td>
<td>n=1630 adults; United Kingdom, Germany, Italy, the Netherlands.</td>
<td>Determine which of 6 labeling conditions best predicts for selecting the healthier food product.</td>
<td>Online consumer survey; 6 label conditions; 3 product categories. Participants randomly assigned to 3 out of 6 label conditions; exposed to 9 pairs of food pictures (1 healthy &amp; 1 less healthy variant); all 3 food categories were associated with the 3 assigned label conditions.</td>
<td>Health Promotion Factor (HPF), Healthier Choice Tick (HCT), Smileys², Stars, Multiple Traffic Light (MTL), Wheel of Health (WHO)</td>
<td>Labels were associated with 3 product categories (spreads, ice-cream, dairy drink) were displayed online. Participant ability to identify the healthier food product was calculated.</td>
<td>Consumers are best able to differentiate between the healthier and less healthy food product using the Stars and Smileys (Mdiff of 1.0) labeling format and least likely using the HPF² (Mdiff of 0.6, p&lt;0.01).</td>
<td>Simple FOP labeling formats (Smileys² and Stars) are the best differentiator between healthy and less healthy food products.</td>
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<td>D</td>
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<td>n=1525 grocery shoppers; New Zealand.</td>
<td>Determine which of 4 labeling conditions best predicts for selecting the healthiest food product among participants from 4 main ethnic groups in Auckland.</td>
<td>Supermarket survey; 1 product category (cracker); 4 label conditions.</td>
<td>MTLn; Simple Traffic Light (STL)(^b), Nutrition Information Panel (NIP)(^p); and Percentage of Daily Intake (%DI)(^q).</td>
<td>Each participant observed the sample food cracker with the 4 label conditions and determined if the product was &quot;healthy&quot;, &quot;not healthy&quot;, or &quot;don't know&quot;.</td>
<td>Participants are best able to determine if the product was healthy (83% participants (95% CI 81, 86%)) with the STL(^b) followed by the MTLn(^b) (80% (95% CI, 77, 82%)). Consumers are less able to determine the healthiness of a food product using the NIP(^p) (54% (95% CI, 51, 57%)) and %DI(^q) (49% (95% CI, 46, 53%)).</td>
<td>The traffic light systems are the best predictors for identifying the healthier food product across ethnic and income groups.</td>
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<td>n=929 grocery shoppers who returned the take-home questionnaire (from the UK); n=841 (France); n=826 (Germany); n=704 (Hungary); n=1,484 (Poland); n=1,208 (Sweden).</td>
<td>Determine consumer ability to identify the healthiest of 2 and 3 products using GDA FOP labels alone and GDA plus standard back-of-pack labels combined.</td>
<td>1 (label condition) X (1 product category) X 2 (product pair): respondents were presented with 2 fictitious labels for half a frozen pizza (task 1); 1 (label condition) X (1 product category) X 3 (products): respondents were given 3 fictitious labels for half of a frozen pizza (Hungary) or &quot;ready meal&quot; (task 2 &amp; 3); 2 (label conditions) X (1 product category) X 3 (products): respondents were presented with 3 fictitious labels for a ready meal with GDA(^c) and back-of-pack labels (task 4).</td>
<td>GDA(^c) and standard back-of-pack labels. The French retailer Auchan logo was used for task 1-3 instead of the GDA label (French respondents only). The Keyhole logo was used for task 4 (Swedish respondents only).</td>
<td>Respondents performed 4 tasks and identified the healthiest and least healthy product labels (tasks 1-3) and ranked the &quot;ready meals&quot; in terms of healthiness (task 4). Task 1 products had a dominant healthier alternative while products from task 2 &amp; 3 had no clear dominant alternative.</td>
<td>Most respondents from all 6 countries were able to identify the healthiest food product using GDA(^c) labels alone (task 1). For task 3, respondents had the most difficulty differentiating between 2 products: 1 high in salt and the other in saturates in terms of healthiness.</td>
<td>Most respondents correctly identified the more nutritious product among 2 and 3 fictitious labels using GDA(^c) labels alone or GDA and back-of-pack labels together. Participants seem to have little difficulty with intra-category comparisons using GDA(^c) labels to select the healthier product. Some country differences were observed: the UK performed the best across all tasks.</td>
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<tr>
<td>D</td>
<td>+</td>
<td>n=921 grocery shoppers; United Kingdom.</td>
<td>Determine consumer understanding of 3 labeling conditions that best predicts for selecting the healthiest product from an in-home questionnaire.</td>
<td>3 (label conditions) X 1 (product category). Participants were presented with 3 labeling conditions 1 at a time for 2 or 3 fictitious frozen ready meals. They ranked the healthiness of the products by completing 3 different tasks.</td>
<td>GDA(^c), TL(^o), hybrid label (TL color-coded GDA with high, medium, and low).</td>
<td>3 tasks displayed on paper using fictitious labels (ready meals) to rank product healthfulness (repeated with all 3 labeling conditions): Task 1) 1 label condition to compare 2 products; Task 2) 1 label condition to compare 3 products; Task 3) 1 label condition plus back-of-pack information to compare 3 products and answer specific nutrient related questions per label.</td>
<td>Participants were best able to identify the healthiest product using GDA(^c) (87.5% of respondents) followed by TL(^o) (83.7%), and the hybrid label (82.8%). Most participants reported basing their judgments of product healthfulness on 1) fat content; 2) calories; 3) salt; 4) saturated fat; and 5) sugar.</td>
<td>Consumers have a high level of proficiency when using FOP labels. Consumers had a slightly better percentage of identifying the healthier food product with GDA(^c) compared to the TL(^o). This may be from consumer over interpretation of amber and red colors.</td>
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<td>Jones G, et al., 2007 (47)</td>
<td>D Ø</td>
<td>n=92 staff/students from the University of Derby, England</td>
<td>Determine if the presence of a TL\textsuperscript{n} labeling system effects consumer healthiness ratings compared to nutrition labels that display only a standard set of 8 nutrients.</td>
<td>2 (label type) X 9 (nutrition types) repeated measures design. 2 label conditions; participants viewed 18 fictitious labels created for label types A and B at varying nutrient levels and order. Each participant judged the label for healthiness.</td>
<td>Label Type A: displayed 8 nutrients: energy (per 100 grams and per serving), protein, carbohydrates, sugar, fat, saturates, sodium, and fiber; Label Type B: label type A in addition to fat, saturates, salt, and sugars displayed according to the TL\textsuperscript{n} symbols (high, medium, or low)</td>
<td>Eighteen fictitious labels displayed on a computer screen: 9 displayed as type A and 9 as type B labels.</td>
<td>Participants were more closely able to rate the healthiness of the labels according to the SSAg/1 system when the TL\textsuperscript{n} label is present than without. The mean error for label A was significantly higher (2.22) than for label type B (1.77; p&lt;0.01).</td>
<td>Participants accurately rated the labels more often when the TL\textsuperscript{n} label was present than without. When TL\textsuperscript{n} labels are present, consumers pay most of their attention on the nutrients associated with the system\textsuperscript{n} than when it is not present.</td>
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<td>Kelly B, et al., 2009 (44)</td>
<td>D Ø</td>
<td>n=790 primary grocery store shoppers; New South Wales, Australia</td>
<td>Determine which of 4 labeling conditions best predicts for selecting the healthier food product.</td>
<td>Supermarket intercept study: 3 food product categories; 4 label conditions. Each participant exposed to 2 product categories and 1 label condition; asked to select the healthier food among each product pair. Two-dimensional mock food packages (breakfast cereals, savory snacks [crispbread], frozen meals [lasagna] were used.</td>
<td>Traffic Light System (TL\textsuperscript{n}); Traffic Light + Overall Rating (TL\textsuperscript{*}); Monochrome %DI (M-%DI); Color-Coded %DI (CC-%DI)</td>
<td>Participant performance of each FOP label was measured by multinomial logistic regression.</td>
<td>TL\textsuperscript{n} system (81% of participants accurately identified the healthier product) and TL\textsuperscript{*} (78%) (not a significant difference); CC-%DI system (70%); M-%DI system (64%)</td>
<td>Across all socioeconomic areas, the TL\textsuperscript{n} system is best able to help consumers identify the more healthful product.</td>
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<td>Levy AS et al., 1992 (45)</td>
<td>D Ø</td>
<td>n=1,460 primary grocery shoppers; United States</td>
<td>Determine which of 5 labeling conditions best predicts for selecting the more nutritious food product.</td>
<td>Shopping mall-intercept study: 5 food product categories; 5 labeling conditions; 5 different food pairs.</td>
<td>Control (similar to the NFP); Control/DRV: adds the DRVs for 6 nutrients in g or mg per day; Adjectival (similar to the TL\textsuperscript{n} concept in that the nutrition profile information is listed in verbal form: high, medium, low); Numeric: information is displayed as a percentage of the RDI or DRV; Bar Graph: identical to the Numeric format plus a bar graph illustrating the percentages of RDI or DRV.</td>
<td>Each participant was exposed to all 5 labeling conditions for 5 food pairs and asked to select the healthier food among each product pair. Scores were collected for performance on Judgment (identification of the more nutritious product).</td>
<td>Consumers were best able to use the Control format and the worst using the Bar Graph format. Yet the Control, Control/DRV, and Adjectival formats were not significantly different from each other.</td>
<td>Consumers scored the best using the Control format and the worst using the Bar Graph format. Yet the Control, Control/DRV, and Adjectival formats were not significantly different from each other.</td>
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### Table 1 continued

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<td>Levy AS et al., 1996 (48)</td>
<td>D</td>
<td>+</td>
<td>n=1,216 adults who did at least half of the household food shopping; United States.</td>
<td>Determine which of 4 labeling conditions best predicts for correctly identifying the correct and incorrect nutrition statements on the front-of-the-package.</td>
<td>Shopping mail-interrupt study; 4 product categories; 4 labeling conditions. Each subject exposed to 4 different labeling conditions and 4 different product categories.</td>
<td>Control/DRV; Grouping (group nutrients based on nutrients to limit or encourage); Percent; Adjectival (identify nutrients as high, medium, or low)</td>
<td>4 single-product label-use tasks. Consumers rated the healthiness of each product with (task 1) and without (task 2) the 4 nutrition labels. All food products were associated with 5 front-panel statements, one of which was incorrect (nutrition claim, health claim, percentage of fat-free claim). The impact of nutrition label use on subject product evaluation was measured by the difference in ratings.</td>
<td>Subjects were equally able to rate the healthiness of the 4 products with the Control/DRV, Grouping, and Percent groups (not significantly difference from each other) and least able to rate the healthiness using the Adjectival format.</td>
<td>Subjects have the most difficulty using nutrition labels to rate the healthiness of foods with formats that deviate from the standard format (e.g., BOP label) such as the inclusion of multiple columns, provided additional information, or verbal descriptors such as the Adjectival format.</td>
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*This article divided into more than 1 study or task; this table reflects only 1 study/task pertinent to question #1.*

*Simple tick: Single logo displayed on foods that qualify as green based on the multiple traffic light grading system criteria for fat, saturated fat, sugar, and sodium. *

*MTC=Multiple Traffic Light; illustrates a low (green), moderate (amber), or high (red) color code system based on the amount of 4 nutrients (fat, saturated fat, sugar, and sodium) per 100 g or per 100 ml in a food product. *

*GDA=Guideline Daily Amounts; the amount (in grams) of 5 key nutrients (calories, fat, saturated fat, sugar, and salt) per portion of food and as a percentage of an individuals guideline daily amount (note: Borgmeier specified that the GDA's were specific for a women whereas Feunekes did not specify) *

*CGDA=Colored Guideline Daily Amounts; 5 nutrients displayed as a GDA label are color coded according to the TL system criteria as green, amber, or red. *

*HPI= Health protection factor; modeled after the labeling format of sunscreen lotion. Food products receive a numeric rate of 1 to 7; higher numbers indicate a healthier product. *

*HCT=Healthy Choice Tick; displayed on food products considered "healthy" as a single tick according to undefined rating system. *

*Smiley: A graded nutrient labeling format; 1 to 3 smiley faces are awarded to individual food products based on an undefined rating system. More smileys indicate a healthier product. *

*Stars: Rating system for hotels and restaurants; 1 to 5 starts are awarded to individual food products based on an undefined rating system. More stars indicate a healthier product. *

*WOH=Wheel of Health; lists the exact amount of the 5 key nutrients (energy, total fat, saturated fat, salt, and sugar) in a pie chart. Depending on the nutrient score, each nutrient is color coded; low (green), moderate (amber), high (red). *


*Mdiff=Mean difference; determined for each label format as the difference between the healthier and less healthy product. *

*MCT=Multiple Choice Tick; food products were given zero to 3 ticks; the more ticks on the product indicated a healthier product. *

*The difference between intended usage (times per year) at baseline and intended usage after exposure to label formats. *

*MTL=Multiple Traffic Light; illustrates a low (green), moderate (amber), or high (red) color code system based on the amount of 4 nutrients (fat, saturated fat, sugar, and sodium) per 100 g in a food product. *

*SML=Simple Traffic Light; the entire food is rated on healthfulness and subsequently assigned a green (low), amber (moderate), or red (high) color code based on healthiness. *

*NIP=Nutrition Information Panel (similar to the U.S. Nutrition Facts Panel) is the standard food labeling format required on food packages; developed by Food Standards Australia and New Zealand *

*MNI=Percentage of Daily Intake of nutrients for the diet of an average adult in one day. *


*TL+=Traffic Light + Overall Rating illustrates a low (green), moderate (amber), or high (red) color code system based on the amount of 4 nutrients (fat, saturated fat, sugar, and sodium) individually plus the overall rating of the entire food based on the nutrient profile criteria according to the FSANZ. *

*MDM=Monochrone Percent Daily Intake indicates the contribution of energy, protein, total fat, saturated fat, carbohydrates, total sugars, fiber, and sodium per 100g per a 70 kg adult with an estimated 8700 KJ energy requirement (Food Standards Australia New Zealand, 2008). *

*CC-%DI=Color-Coded Percent Daily Intake is identical to M-%DI plus assigns the relevant color code, green (low), amber (moderate), or red (high), for total fat, saturated fat, total sugars, and sodium. *

*NLEA=Nutrition Labeling and Education Act (1990); regulated information displayed on the Nutrition Facts Panel, health claims, serving size, and descriptor terms (e.g., "low fat") on food packages. *

*TOP=Front-of-pack nutrition label found on the front of a food package. *
this suggests that this population of participants look for other nutrition information besides the single keyhole label. Although UK respondents performed the best overall, most respondents were able to identify the healthier food product among 2 and 3 fictitious labels using GDA labels alone or GDA and back-of-pack labels together. Participants had little difficulty with intra-category comparisons using GDA labels to select the healthier product (43).

Although valuable information can be gained from consumer differences across multiple countries and their ability to identify the healthier food product using only one FOP label, the studies that compare more than one nutrition label provide more information. For example, Balasubramanian et al. (2002) used a laboratory experiment to manipulate three factors: knowledge about nutrition information, motivation to process this information, and the nutrition label format, pre and post-NLEA to create different levels of motivation and knowledge in consumers (39). Consumers were asked to shop for cereal with either the old or the new labels. Because the computer recorded the specific information that consumers inspected during a shopping task, they could examine whether the post-NLEA labels changed the type of information their subjects used. One half of the subjects (high-knowledge condition) studied an informative brochure on the topic. High-motivation subjects were instructed to follow a physician’s recommendations to select a cereal that is low in fat, sodium, and cholesterol while the low motivation subjects did not receive this instruction. It was found that participants in the high-motivated group who were instructed to select a breakfast cereal with specific attributes were able to identify the healthier cereal using post-NLEA labels (39).
Likewise, Jones et al. (2007) studied the effect of traffic light (TL) labels on consumer ability to rate the healthiness of food products (47). Researchers tested consumer use of 18 fictitious food labels; half of the labels with the TL label and half without the TL label (illustrating a standard BOP label only) (Table 1). Unique to this study is the use of eye tracking equipment to assess areas of the nutrition label consumers use to determine the healthiness of the label, particularly specific nutrients. All 8 nutrients (energy per 100 grams and per serving, protein, carbohydrates, carbohydrates of which are sugar, fat, fat of which are saturates, fiber, and sodium) were designated as high, medium, or low for each nutrient based on GDA definitions of “a little” (3.3% or less) and “a lot” (20% or more) for the 18 label combinations (49). Participants rated each label in terms of healthiness on a scale of 1-10 (1 being less healthy and 10 being more healthy). The SSAg/1 system of calculating healthiness was used to determine the health scores for each label (49). Scores range from 0-8 as the mean perceived healthiness ratings; scores tending toward zero were considered more healthy and those tending toward eight were considered less healthy (according to the SSAg/1 scores). It was found that participants accurately rated the labels more often when the TL label was present than without. For the labels without the TL label, the mean error is significantly higher (2.22, standard deviation (SD) 0.77) than for the labels with the TL label (1.77, SD 0.76; p<0.01). The eye tracking equipment results concluded that when TL labels are present, consumers pay most of their attention to the nutrients associated with the TL than when it is not present (47).
Although the studies mentioned above provide useful information about the presence or absence of one specific nutrition label or consumer change in ability to use a “new” vs. an “old” label (i.e., pre and post-NLEA nutrition labels), it is still unclear if presented with multiple nutrition labels if consumers are still able to select the healthier product. Building on the studies above but expanding the knowledge learned, the next level of studies test consumer ability to identify the healthier product using three different nutrition labels. Similar to Grunert et al. (2010a), consumers from the UK were observed at grocery stores reading nutrition labels before making a product selection (43, 46). Participants took a self-administered questionnaire home that measured understanding of FOP nutrition labels and nutrition knowledge. In addition, their ability to identify the healthier food product using three FOP labels (GDA, TL, and hybrid label) was measured (Table 1). Participants performed 3 tasks to determine their ability to identify the healthiest and least healthy product labels (task 1-2) and ranked 3 “ready meals” in terms of healthiness with the FOP label plus standard BOP label (task 3). Just as with Grunert et al. (2010a), one healthier alternative food label was clearly the healthier option for task 1 only. Eighty-eight percent of participants were best able to identify the healthiest product using GDAs followed closely by 83% of respondents’ ability to correctly use the TL for task two. The authors suggest consumers’ greater ability to identify the healthier food label with the GDA over the TL may be from consumer over interpretation of amber and red colors. However, this suggests that regardless of label format, participants are proficient in the use of nutrition information. For the food label comparison task (task 1), 78% to 88% of respondents were able to
identify the healthier food label among all 3 label formats. Overall, results suggest consumers have a high level of proficiency when using FOP labels (46).

Unlike the majority of studies that compare consumers’ ability to identify the healthier food from among product pairs within the same food category (e.g., cereal A and cereal B); two studies compared consumer use of a single product with multiple nutrition labels (42, 48). For example, Gorton et al. (2009) used four different labeling conditions: simple traffic light (STL), multiple traffic light (MTL), Nutrition Information Panel (NIP), and percentage of daily intake (%DI) to observe which condition consumers are best able to decide if a snack cracker was “healthy,” “not healthy,” or “don’t know” (Table 1) (42). All four crackers ranged in healthiness and were presented to the participants one at a time with a different FOP label. Results determined that 83% of participants are best able to determine if the product was healthy with the STL followed by the MTL label (80% of participants). Only 54% and 49% of participants were correctly able to identify the healthier cracker using the NIP and %DI label, respectively. This study concluded that TL systems are the best predictors for identifying the healthier food product among single foods (42). Although different from other study designs in this area, Levy et al. (1996) tested consumer accuracy in judging the healthfulness of four single food products (macaroni and cheese, canned condensed soup, frozen dessert, and cake) by determining the labeling condition that consumers were best able to differentiate between correct and incorrect statements on the front of the package (48) (Table 1). The four nutrition labels that were variations of a standard BOP label (Control/DRV, Adjectival, Grouping, and Percent) were each associated with
the food products. Most of the statements were nutrition claims and at least one was a percentage of fat-free claim (e.g., 25% fat-free) or disease-specific health claim and at least one of the 5 claims was incorrect. On a 10-point scale, subjects rated the healthiness of each of the four foods with the claims alone, then re-rate the healthiness of the food in the presence of one of the four nutrition labels (Table 1). The difference between the two ratings was measured to indicate the nutrition label impact on participant product evaluations. Participants were equally able to rate the healthiness of the four products with the Control/DRV, Grouping, and Percent groups (not significantly different from each other) and least able to rate the healthfulness using the Adjectival format. The authors concluded that participants do not perform well using labels that deviate from the standard BOP format (e.g., post-NLEA) include multiple columns, provide additional information, or verbal descriptors such as the Adjectival format (nutrients displayed as having high, medium, or low levels) (48).

Forty percent of all articles that answer question #1 test consumer ability to identify the healthier food from among product pairs using four or more different nutrition labels and provide the most information. These articles help to determine which label, among multiple different labels, best helps consumers identify the healthier food product. For example, Levy et al. (1992) examined consumer ability to use five different BOP labeling conditions (Control, Control/DRV, Adjectival, Numeric, and Bar Graph) among five food pairs (45) (Table 1). The healthier food label was defined as having the most positive nutrient profile, was lower in fat, energy, sodium, or cholesterol or higher in vitamin C, calcium, carbohydrate, or fiber. Consumers were exposed to one product
pair and one labeling condition at a time and scores were collected on performance to identify the healthier product. The overarching conclusion was that consumers were best able to use the Control format (similar to the NFP and included quantitative amounts for macronutrients per serving and micronutrients listed as percentage of Reference Daily Intake) to identify the healthier product compared to the Bar Graph format that scored the worst (p<0.01).

Among three similar studies (40, 41, 44), all asked participants to identify the healthier food product from a pair of products using FOP labeling conditions. For example, Kelly et al. (2009) exposed participants to one of four labeling conditions: TL, TL + Overall Rating (TL+), monochrome percentage daily intake (M-%DI), and Color-Coded percentage daily intake (CC-%DI) and two out of three food products (44) (Table 1). Performance was measured by their ability to correctly select the more nutritious food from among the product pairs. Participants were best able to identify the more nutritious food using the TL and TL+ conditions (81% and 78%, respectively) followed by the CC-%DI system (70%) and M-%DI system (64%). After controlling for household income, educational level, gender, and age, participants were five times and three times more likely to identify the more nutritious food product using the TL systems compared to the M-%DI and the CC-%DI, respectively; however, the difference between the TL and TL+ systems were not statistically significantly (44). Likewise, Borgmeier et al. (2009) assigned participants to one of five FOP labeling conditions: simple tick, multiple traffic Light (MTL), monochrome Guideline Daily Amount (GDA), colored GDA label (CGDA), and "no label" condition (40). Participants were asked to select the
healthier food product among 28 food pairs displayed on picture cards. Overall, the MTL label yielded the highest percentage of correct choices (24.8 ± 2.4 out of 28 pairs; p<0.001) followed closely by the CGDA and GDA (22.8 ± 3.2 and 23.1 ± 3.2, respectively). The average of the correct choices for the “no label” condition yielded the worst average (20.2 of 28 pairs) (40). In the same way, Feunekes et al. (2008) tested consumer ability to use six FOP labeling conditions (stars, smileys, healthier choice tick, health protection factor, MTL, and wheel of health) to identify the healthier food product out of nine pairs (41). Among three different food categories tested, participants were best able to differentiate between the healthier and less healthy product using the stars and smileys labeling conditions and least likely to use the health protection factor format (Table 1). Authors concluded that simpler FOP labeling conditions such as stars and smileys are the labels most appropriate to help consumers select healthier products (41).

**Question #2** Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard back-of-pack nutrition labels?

Question #1 has shown that consumers are able to choose the healthier product when given a choice between foods in the same category (e.g. cereals, crackers, etc.). The question then becomes, do consumers, on their own, actually purchase healthier foods because of label use and incorporate those foods into their diet.

Twenty-one studies address question #2, *Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard back-of-pack nutrition labels?* Of these, two were classified as “A” studies, one was classified as a “B”, and the remaining 18 were “D” studies. Both (40, 50) of the “A” studies were neutral quality, the
one (39) “B” study was positive quality, while the “D” studies ranged from positive quality (9 studies) (43, 46, 51-57) and neutral quality (9 studies) (41, 58-65).

A wide range of studies address this issue from the simplest cross sectional data asking if consumers read labels, and if they choose a healthy diet. Although survey data suggest an association between reading labels and choosing a healthy diet the question remains: “Are the people who are health conscience the same people who read food labels.” In other words, these studies do not show a cause and effect relationship between label use and eating healthy foods. No external validation is used to determine if label use influences consumer change in purchasing or diet quality. For example, Wiles et al. (2009) recruited participants outside of a fat spreads aisle after they had made their selection (65) (Table 2). They completed a self-reported questionnaire about fat spreads and about their purchase of the spreads. Among the study sample, 55% reported using nutrition information to influence their purchase of the fat spread but whether or not this was a healthier product than other choices was not evaluated (65). Similarly, Drichoutis et al (2005) collected self-reported survey data from grocery shoppers at 15 supermarkets (60). The survey data was used to measure the impact label use has on diet quality by way of an econometric approach. It was found that 54% of the respondents self-reported using food labels and are most likely to use nutrition information concerning vitamins/minerals, fat, and ingredients to influence purchasing behavior (60). Barreiro-Hurle et al. (2010b) collected consumer self-reported data to determine the type of nutrition information (nutrition labels vs. nutrition/health claims) used by consumers and if labels promote healthier food choices (58) (Table 2). An
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<th>Results</th>
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<tr>
<td>Antonuk B, et al., 2006 (57)</td>
<td>D</td>
<td>+</td>
<td>n=112 undergraduate students; United States</td>
<td>Determine if dual-vs. single-column labels influence eating behavior among dieters and nondieters.</td>
<td>Between-subjects experimental design: 2 (labels: single vs. dual) X 2 (dieter vs. nondieter); assess eating behavior change and label type on consumption of M&amp;M’s candy.</td>
<td>Standard back-of-pack nutrition label (Nutrition Facts Panel): single and dual-column. Single-column labels provides nutrient content per serving only and dual-column labels provide 1 label with nutrient content per serving plus a second column with information for the entire package.</td>
<td>Participants were provided with a 1.5 oz bag of M&amp;M’s (50 pieces or 1.5 servings) with 1 label condition; ate ad libitum. The change in M&amp;M’s intake was determined by subtracting the remaining M&amp;M’s from 50 to determine the change in eating behavior.</td>
<td>No significant difference between the amount of M&amp;Ms consumed in either the single- (mean=21.83) or dual-column (25.52) label type among dieters. Nondieters consumed more candy with the single-column label (mean=33.03) and less with the dual-column label (mean=20.81, p&lt;0.05).</td>
<td>The presence of dual-column labels reduces the consumption of snack foods among nondieters. Label type did not significantly change eating behavior among dieters.</td>
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<td>Balasubramanian S, et al., 2002 (39)*</td>
<td>B</td>
<td>*</td>
<td>Sales data from several grocery stores in a large city’s major grocery store chain; United States</td>
<td>Determine if pre and post-NLEA food labels influence consumers’ decisions by purchasing healthier foods through the analysis of sales transactions from grocery stores.</td>
<td>Longitudinal scanner data analysis; UPCs representing healthy levels of each nutrients were compiled for each food category.</td>
<td>Pre-NLEA label and post-NLEA label.</td>
<td>A regression model was estimated for each category/descriptor (positive or negative nutrient) combination. E.g., vitamin C and calcium (positive); fat-healthy and sodium-healthy (negative).</td>
<td>Post-NLEA: decline or no change in consumer purchasing of products with positive descriptors; increase in products purchased with negative descriptor sets displaying negative nutrients. Although a negative descriptor, consumers purchase fewer foods with calorie-healthy descriptors compared to fat-healthy descriptors post-NLEA*.</td>
<td>Consumers’ purchasing behavior changed post-NLEA* as they began to focus more on negative nutrients than positive nutrients. Post-NLEA* consumers prefer to purchase fat-healthy products compared to calorie-healthy ones.</td>
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<td>Barreiro-Hurlé J, et al., 2010a (51)</td>
<td>D</td>
<td>+</td>
<td>n=800 main household food shoppers; Cordova and Zaragoza, Spain</td>
<td>Determine the relationship between nutrition and health information labels, and the way information is displayed (claims or facts) with the type of information (health or nutrition) on consumer purchasing behavior.</td>
<td>Survey/interview and. 2 food products: pork sausages (less healthy option) and plain yogurt (healthy option). 4 labeling conditions. 80 pairs of profiles were collected.</td>
<td>4 labeling conditions: European nutrition facts panel (basic panel with 4 nutrients and detailed panel with additional information), nutritional claim, health claim, price per package.</td>
<td>Participants completed a self-reported questionnaire regarding food label use and participated in a Choice Experiment: participants were given 3 mock food packages for each food product (e.g., yogurt A, yogurt B and a no purchase option). All 4 labels were presented in isolation and in combinations. Multiple statistical models were used to determine label utility on purchasing behavior.</td>
<td>Sausage: positive utility when the nutrition claims and detailed facts panel are both present. Negative utility with the joint presence of nutrition claims and health claims. Yogurt: negative utility when the nutrition facts panel and health claims are both present. Overall, labels in isolation have a higher utility among consumers. The addition of a second label to a food package results in negative utility for most consumers.</td>
<td>Consumers value and utilize nutrition claims and the European nutrition facts panel more for unhealthy foods (sausage) compared to healthier foods (yogurt). Combinations of label information (claims) when the European nutrition facts panel is already present may drive consumers to derive negative utility among products perceived as healthy.</td>
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Table 2: Study results that evaluate food label use on consumer purchasing and/or eating behavior.
Table 2 continued

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<tr>
<td>Barreiro-Hurle J, et al., 2010b (58)</td>
<td>D Ø</td>
<td>n=800 primary food buyers; Cordova and Zaragoza, Spain.</td>
<td>Determine the type of nutrition information (nutrition labels vs. nutrition/health claims) used by consumers and if labels promote healthier food choices/diet quality.</td>
<td>Survey/face-to-face interviews conducted at the grocery store regarding consumer food label use. Self-reported data.</td>
<td>Nutrition facts panel and nutrition/health claims in Spain.</td>
<td>A 3-equation multivariate probit model was used. To measure nutrition label use, 2 variables reflected frequency of the use of nutrition facts panels and claims to examine a change in diet quality.</td>
<td>There is a direct association between self-reported purchase of healthier foods and consumers' use of either label. There is a stronger effect of consumer label use on healthy food choices for the nutrition facts panel. Yet, an even higher intention of making healthier food choices was observed when both types of labels were present.</td>
<td>The presence of both labels or 1 label in isolation present on a food product will positively influence consumer intention to make healthier food choices.</td>
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<td>Borgmeier I, et al., 2009* (40)</td>
<td>A Ø</td>
<td>n=420 adult consumers; Hamburg, Germany.</td>
<td>Assess potential associations between the use of food labels and change in eating behavior.</td>
<td>A simulated shopping situation was created using pictures of 78 food; 5 FOP labeling conditions, and 7 food categories. Each participant was exposed to only 1 labeling condition.</td>
<td>Five experimental conditions: Healthy Choice Tick (HCT); Multiple Traffic Light (MTL); Monochrome Guideline Daily Amount (GDA); a Colored GDA label (CGDA); and &quot;no label&quot; condition.</td>
<td>Participants arranged a hypothetical breakfast, lunch, dinner, and snack for the next day. The nutrient density and energy of each shopping cart was analyzed.</td>
<td>Among all experimental groups levels of certain nutrients (fat, saturated fat, sodium and sugar) was above the recommended daily intake. No significant difference was observed for the labeling conditions for intake of energy, nutrients as percentage of energy, or nutrients in grams.</td>
<td>No influence was observed among different label conditions and their effect on food consumption or diet quality. Energy intake nor energy density varied significantly between the 5 labeling conditions.</td>
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<td>Byrd-Bredbenner C et al., 2000 (59)</td>
<td>D Ø</td>
<td>n=60 females, household primary food purchaser; United Kingdom.</td>
<td>Determine consumer ability to locate nutrition labeling information and the frequency with which labels impact food purchasing behavior.</td>
<td>Survey/face-to-face interviews. 2 label conditions (US Nutrition Facts labels and those prepared in accordance with the EU Directive)</td>
<td>2 standard back-of-pack nutrition labels (1 from the U.S. and others from the EU)</td>
<td>Participants completed self-reported questionnaires regarding food label use that determined purchasing behavior change.</td>
<td>92% of consumers reported that nutrition labels affect their food purchasing decisions 'always' or 'sometimes'.</td>
<td>According to the majority of consumer interviewed, reading nutrition labels indicates that labels influence the foods they purchase.</td>
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<td>Drichoutis AC, et al., 2005 (60)</td>
<td>D Ø</td>
<td>n=320 grocery shoppers; Greece.</td>
<td>Survey/questionnaire: Consumers were randomly approached in the grocery store to answer questions about label use; data determined nutrition knowledge and nutrient content use.</td>
<td>Standard nutrition label used in Greece.</td>
<td>Empirical models were used to estimate label use, nutrient content use, and nutrition knowledge. All based on self-reported data.</td>
<td>54% of respondents self-reported using food labels, yet it was not mentioned if they feel label use with influence their purchasing and/or eating behavior. Consumers with higher nutrition knowledge report using information concerning vitamins/minerals, fat, and ingredients.</td>
<td>Nutrition label and nutrient content usage (concerning vitamins/minerals, fat, and ingredients) to influence purchasing behavior can be improved with increased nutrition knowledge. Therefore there is a strong link between label use and knowledge.</td>
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<td>Feunekes GI, et al., 2008* (41)</td>
<td>D Ø</td>
<td>n=776 adults; United Kingdom &amp; Italy.</td>
<td>Simulated shopping situation (online consumer survey); 4 label conditions; 5 product categories (foods consumed as snacks and 2 filler products). Participants randomly exposed to 12 food product pairs and 2 out of 4 label conditions (GDA label format was shown on each product separately).</td>
<td>HCT; Stars; Multiple Choice Tick (MCT); GDA</td>
<td>Baseline measurements first determined perceived healthiness and usage frequency of 12 food products without labels. Participants were then exposed to 2 collages of food pictures containing less healthy and healthier food products. After exposure to the labeling conditions consumer intended usage frequency was measured.</td>
<td>Participants intention to consume healthier products only slightly increased, while their intended consumption of less healthy products decreased for all 4 labeling conditions. No significant differences were found between the 4 labeling formats.</td>
<td>All 4 label formats slightly improved perceived healthiness and intended usage* among healthier products and decreased healthiness and intended usage* of less healthy products.</td>
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<td>Fitzgerald N et al., 2008 (61)</td>
<td>D Ø</td>
<td>n=201 Latina adults with and without type 2 diabetes; United States.</td>
<td>Survey/questionnaire completed in a convenience sample plus an 18-item food frequency questionnaire.</td>
<td>Nutrition Facts Panel</td>
<td>Researchers evaluated food label use by a simple question: “How often do you use food labels to select foods that are better for your health?” Diet quality was determined by the food frequency questionnaire to determine if label use influences eating behavior.</td>
<td>67.5% of people with diabetes were more likely to use food labels to purchase foods low in sugar compared to 34.1% of those without diabetes (p=0.001) Among all food labels users in both groups, label use improved diet quality. People with diabetes have a decreased likelihood to consumer sweets, salty snacks, and regular soft drinks frequently, and more likely to consumer fruits and vegetables.</td>
<td>Food label users are 62% less likely to consumer salty snacks, consume sweets (49%), and are about 3 times more likely to consumer fruits and vegetables frequently, after adjusting for potential confounders.</td>
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<td>Grunert et al., 2010a* (43)</td>
<td>D</td>
<td>+</td>
<td>n=2,019 grocery shoppers (from the UK); n=1,858 (Sweden); n=2,337 (France); n=1,963 (Germany); n=1,800 (Poland); n=1,804 (Hungary).</td>
<td>Observe consumer use of nutrition labels to influence purchasing decisions and diet quality.</td>
<td>In-store observations and interviews. 3 (retailers) X 3 (locations) X 6 (product categories) for the UK and Sweden; 2 (retailers) X 3 (locations) X 6 (product categories) for France, Germany, Poland, and Hungary. Researchers observed consumer purchasing behavior in 1 of 6 grocery aisles (breakfast cereals, &quot;ready meals,&quot; confectionary, carbonated soft drinks, salty snacks, and yogurts).</td>
<td>All areas of the food product were observed (including the GDA label)</td>
<td>Researchers recorded if consumers looked at the food label before selection, where they looked on the package, and for how long. During the interview consumers were asked if they had looked for nutrition information; if yes they were asked to show where they looked on the package.</td>
<td>62.6% of respondents looked on the front of the package (GDA’); of these only 6% reported selecting the product for health/nutrition reasons. Shoppers are more likely to use nutrition information to influence their purchase of yogurt and breakfast cereals and least likely for carbonated soft drinks, confectionaries, and salty snacks.</td>
<td>A small percentage of shoppers observed in the grocery store let nutrition labeling influence their food purchases. However, shoppers tend to use nutrition labeling more for foods with a healthier profile (e.g., yogurt) compared to less healthy foods (e.g., confectionary).</td>
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<tr>
<td>Grunert et al., 2010b* (46)</td>
<td>D</td>
<td>+</td>
<td>n=2,019 grocery shoppers; United Kingdom.</td>
<td>Observe consumer use of nutrition labels to influence purchasing decisions and diet quality.</td>
<td>In-store observations and interviews. 3 (retailers) X 3 (locations) X 6 (product categories) for the UK only. Researchers observed consumer purchasing behavior in 1 of 6 grocery aisles (breakfast cereals, &quot;ready meals,&quot; confectionary, carbonated soft drinks, salty snacks, and yogurts).</td>
<td>All areas of the food product were observed</td>
<td>Researchers recorded if consumers looked on the front of the package, looked somewhere else on the package, or did not spend time looking at the package before making a selection. During the interview consumers were asked if they had looked for nutrition information; if yes they were asked to show where they looked on the package.</td>
<td>Observation: the front of the package was evaluated by 65.6% of participants before selecting the product, 11.6% looked elsewhere, and 31.8% did not spend time looking at the package for the first product selected. Interview: 47% of respondents answered “usually” or “regularly” when asked if they generally use nutrition information before purchasing items from the same category.</td>
<td>Usage of nutrition information in the grocery store is dependent on the product category and consumer interest in healthy eating. Consumers over report using nutrition information when making product selections by about 50% when self-reported data is considered along with observational measures.</td>
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<td>Guthrie J. et al., 1995 (52)</td>
<td>D</td>
<td>+</td>
<td>n=2,214 CSFII households and n=1,906 DHKS respondents (88% of the CSFII households); United States</td>
<td>Determine consumer nutrition label use and its influence on diet quality.</td>
<td>Survey data from the USDA’s 1989 Continuing Survey of Food Intakes by Individuals (CSFII) and Diet and Health Knowledge Survey (DHKS). Includes two 24-hour diet recalls.</td>
<td>Standard U.S. nutrition labels in 1989.</td>
<td>A regression analysis was conducted for 26 nutrients and food components to determine the effects of label use on nutrient density. Some control variables: race, education; nutrition knowledge; ratings of the importance of the product attributes nutrition; taste; income; nutrients/food components to avoid and those to seek.</td>
<td>Label use influenced consumer consumption of foods with a higher nutrient density of vitamin C and lower density of cholesterol (p&lt;0.05 for both). No other significant effects were seen for the other 24 nutrients/food components evaluated.</td>
<td>Limited impact of nutrition label use on improving overall diet quality. Label use significantly improves diet quality for vitamin C and cholesterol only.</td>
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<td>Kim et al., 2000 (53)</td>
<td>D</td>
<td>+</td>
<td>n=5,203 adult; United States.</td>
<td>Determine associations between consumer food label use and nutrient level intakes on diet quality.</td>
<td>Survey data from the USDA’s 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) and Diet and Health Knowledge Survey (DHKS). Includes two 24-hour diet recalls.</td>
<td>Standard U.S. nutrition labels in 1994-1996.</td>
<td>Endogenous switching regression models to control for self-selectivity for diet intake and label use decisions.</td>
<td>Average daily caloric intake from total fat and saturated fat decreased due to consumer label use by 6.90 and 2.10 percentage points, respectively; and the average daily cholesterol and sodium intakes by 67.60 mg and 29.58 mg, respectively. The average daily fiber intake increased with label use by 7.51 g.</td>
<td>Consumer use of nutrition labels influences eating behavior. In general, label use decreased the intake of calories from total and saturated fat, cholesterol and sodium, while it increased the intake of dietary fiber.</td>
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<tr>
<td>Kim et al., 2001 (54)</td>
<td>D</td>
<td>+</td>
<td>Not specified; United States</td>
<td>Determine consumer food label use and impact on overall diet quality using the Healthy Eating Index (HEI).</td>
<td>Survey data from the USDA’s 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) used for the Healthy Eating Index (HEI) variable and Diet and Health Knowledge Survey (DHKS). Includes two 24-hour diet recalls.</td>
<td>5 components of the food label: 1) nutrient content claims; 2) list of ingredients; 3) nutrition panel; 4) information regarding serving size; 5) health claims.</td>
<td>Endogenous switching regression models to control for self-selectivity for diet intake and label use decisions.</td>
<td>Consumer use of the nutrition panel improves diet quality (HEI) by an average of 4.509 percentage points; this follows health claims (6.138 points) and nutrient content claims (5.398 points).</td>
<td>Overall diet quality improves with all 5 types of nutrition information as measured by the HEI. HEI range from health claims with 6.1 points to the list of ingredients with 3.5 points.</td>
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<td>Lewis JE, et al., 2009 (55)</td>
<td>D</td>
<td>+</td>
<td>n=5603 adults participants; United States</td>
<td>Determine nutrition information use and eating behavioral change among people with at least 1 of 5 chronic disease states.</td>
<td>Data collection from the 2005-2006 NHANES - 17 items related to label use behavior in regards to the NFP; knowledge of federal nutrition information programs; two-24 hr dietary recalls.</td>
<td>Nutrition Facts Panel; according to the guidelines for each of the macronutrients, participants were categorized as adhering or not adhering to the guidelines.</td>
<td>3 scales were computed from the 17 label factor analysis and participants’ intake of total energy and protein, and grams of fat, saturated fat, carbohydrates, and fiber determined associations between label use or nonuse, presence or absence of chronic disease, and change in eating behavior/diet quality.</td>
<td>Among heart disease participants who are adherent to the macronutrient guidelines and reported using the NFP or serving size information, this group is most likely to meet the recommendations for fiber (p=0.000), total fat (p=0.009) and saturated fat (p=0.013).</td>
<td>Participants with chronic disease reported better label use of the NFP compared to those without chronic disease. Food label use does influence diet quality, especially among those with heart disease.</td>
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<td>Miller D et al., 1998 (50)</td>
<td>A</td>
<td>Ø</td>
<td>n=85 staff, students, and community members from Penn State University; United States</td>
<td>Determine participant consumption of snack chips with and without the presence of nutrition label information to determine eating behavior change.</td>
<td>Crossover design: 4 (participant groups) X 2 (chip types) X 2 (condition groups). Participants were divided into 4 groups: unrestrained or restrained group; male or female. 2 potato chip types: fat-free and regular. 2 condition groups: no-information (received no nutrition information and were blinded to the chip type consumed) and information (provided with nutrition information label and the chip type was known).</td>
<td>Nutrition facts label and the labeling of the chip type (fat-free or regular) for the information group or no labeling information for the no-information group.</td>
<td>Each participant consumed both chip types: 1 chip type for 2 weeks; 1 week washout; the opposite chip type for another 2 weeks. The provided chips were consumed ad libitum. The remaining chips were weighed to determine the net amount consumed and change in eating behavior.</td>
<td>Participants in the no-information condition consumed significantly more regular potato chips (60 +/- 4 g) compared to the fat-free (55 +/- 5 g). Unrestrained participants in the information condition ate similar amounts of both chips while restrained participants consumed significantly more of the “healthier” fat-free chips compared to regular (60 +/- 7 g and 50 +/- 17 g, respectively).</td>
<td>When nutrition information is present and snack chips are clearly labeled on the front of the pack, participant eating behavior is influenced and consumers in the information group will eat more of the “healthier” fat-free potato chips.</td>
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<td>Reid RD et al., 2004 (82)</td>
<td>D</td>
<td>Ø</td>
<td>n=200 adult grocery shoppers; Canada.</td>
<td>Determine consumer use of the Health Check® (HC) logo on food products to influence purchasing behavior and diet quality.</td>
<td>Survey/questionnaire and sales receipt data regarding use of the HC® logo.</td>
<td>Health Check® Participants completed a self-reported questionnaire regarding reported use of the logo, provided their shopping receipts, and completed a food frequency questionnaire. Data was used to examine consumers’ intended and actual use of the HC logo and eating behavior change.</td>
<td>On the day of the survey, 92% of shoppers reported not using the HC® logo to help guide their purchasing decisions compared to 6% who did. Shoppers who were aware of the logo reported using it when comparing products to purchase the healthier option. 25% of respondents purchased food products with the logo (1.6 +/- 0.5 products).</td>
<td>Although the majority of shoppers reported not using the HC® logo, among those who do are more likely to use the logo to purchase healthier foods and have a diet lower in fat compared to those who do not use the logo (30.4% vs. 33.9% calories from fat; p&lt;0.05).</td>
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<tr>
<td>Sacks G, et al., 2009 (56)</td>
<td>D</td>
<td>*</td>
<td>Point-of-sales data from over 1000 supermarket stores; United Kingdom</td>
<td>Determine the initial impact on product sales (purchasing behavior change) from adding the MTL® label to 2 food categories with the presence of the standard nutrition labels.</td>
<td>Supermarket sales data collection. 2 food categories: fresh pre-packaged sandwiches and chilled pre-packaged meals. Data collection 4 weeks before and after the introduction of the MTL®</td>
<td>Multiple Traffic Light (MTL®) Examined total weekly select product sales 4 weeks before and after the MTL introduction using linear mixed models. Product healthiness was determined by a point system: red (3 points); amber (2 points); green (1 point); thus a score of 4 points is deemed the healthiest and 12 points is least healthy.</td>
<td>Sales of ready meal products increased by 2.4% (p=0.03) 4 weeks after the introduction of the MTL® weekly sales of the pre-packaged sandwiches did not change significantly.</td>
<td>No association was found between the change of sales and consumer purchasing of the healthier products among the 2 food categories after the introduction of the MTL®.</td>
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<td>Primary author, y (ref no.)</td>
<td>Study type</td>
<td>Quality rating</td>
<td>Population</td>
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<td>Overall study design</td>
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<td>Varyam JN, 2008 (63)</td>
<td>D</td>
<td>Ø</td>
<td>n=5,439 adults; United States</td>
<td>Determine if the NFP impacts consumer diets quality.</td>
<td>Survey data from the USDA’s 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) and Diet and Health Knowledge Survey’ (DHKS). Includes two 24-hour diet recalls.</td>
<td>Nutrition Facts Panel¹</td>
<td>Nutrition labeling positively influences label users intake of fiber and iron rich foods compared to label nonusers. Label users’ intake increased by 0.69 g (p&lt;0.05) and 0.65 g (p&lt;0.01) for fiber and iron, respectively.</td>
<td>The NFP has a positive benefit on dietary intake among label users. Consumers who reported using labels consumed diets higher in fiber and iron compared to nonlabel users.</td>
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<td>Vyth EL et al., 2010 (64)</td>
<td>D</td>
<td>Ø</td>
<td>n=404 adult grocery shoppers; The Netherlands.</td>
<td>Determine consumer use of the Netherlands Choices® logo on consumer purchasing behavior.</td>
<td>Survey/questionnaire and the recording of food products purchased with and without the Choices® logo were calculated.</td>
<td>Choices logo²</td>
<td>Among shoppers who reported using the logo to guide their purchasing decisions (n=72), 23.65% (p&lt;0.01) of their products purchased carried the logo. Shoppers who reported not intentionally purchasing products with the logo (n=172), 17.19% of their purchases carried the logo (not significant). Shoppers who intentionally use the Choices® logo to select healthier foods purchase these products more than those who do not use the logo. Yet, a high percentage of shoppers (71%) unintentionally purchase products with the logo.</td>
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<td>Wiles NL et al., 2009 (65)</td>
<td>D</td>
<td>Ø</td>
<td>n=150 female grocery store shoppers; Pietermaritzburg, South Africa</td>
<td>Determine consumer use of nutrition information on fat spreads to influence purchasing behavior.</td>
<td>Completion of a survey/questionnaire guided interview at the grocery store after consumers were observed purchasing a selected fat spread.</td>
<td>Nutrition information on food labels - standard back-of-pack</td>
<td>55% (n=82) of the study sample reported using nutrition information to influence their purchase of fat spreads. n=74 (54%) out of n=136 (92%) participants who claimed to be the primary shopper reported using nutrition information to influence their purchase of fat spreads. 62% out of 126 respondents reported trying to choose the healthiest option (lower in fat) also reported using nutrition information to influence their purchase of fat spreads.</td>
<td>More than half of all participants reported using nutrition information on food labels to influence their purchase of fat spreads. The likelihood of using this information increased as consumer concern for health increased. Shoppers who have higher education, live in households of 4 or more, and have more money are most likely to use nutrition labels to select fat spreads.</td>
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Table 2  continued

*This article divided into more than 1 study or task; this table reflects only 1 study/task pertinent to question #2.

HCT=Healthy Choice Tick; displayed on food products considered "healthy" as a single tick according to undefined rating system.

MTL=Multiple Traffic Light; illustrates a low (green), moderate (amber), or high (red) color code system based on the amount of 4 nutrients (fat, saturated fat, sugar, and sodium) and energy per 100 g or per 100 ml in a food product.

GDA=Guideline Daily Amounts; the amount (in grams) of 5 key nutrients (calories, fat, saturates, sugar, and salt) per portion of food and as a percentage of an individuals guideline daily amount.

CGDA=Colored Guideline Daily Amounts; 5 nutrients displayed as a GDA label are color coded according to the TL system criteria as green, amber, or red.

Choice: Single FOP logo that appears on food products that have increased levels of fiber and lower levels of saturated fat, trans fatty acids, sodium, added sugar, and energy compared to their counterpart within the same product category.

HC=Health Check; single on-pack logo sponsored by the Heart and Stroke Foundation of Canada since 1999 to identify nutrient dense foods that meet nutrient criteria.

T0=First questionnaire completed 4 months after the Choices logo was introduced.

T1 = Second questionnaire completed 1 year after the Choices logo was introduced.

NHANES=National Health and Nutrition Examination Survey

NFP=Nutrition Facts Panel

NIP=Nutrition Information Panel; specified by Food Standards Australia New Zealand (FSANZ) in the Food Standards Code.

NLEA=Nutrition Labeling and Education Act (1990); regulated information displayed on the Nutrition Facts Panel, health claims, serving size, and descriptor terms (e.g., "low fat") on food packages.

CSFII=Continuing Survey of Food Intake by Individual; provides data on nutrient and food consumption.

DHKS=Diet and Health Knowledge Survey; provides data on nutrition- and food-related attitudes and knowledge. This data can be combined with data obtained from the CSFII to explore relationships of practices, attitudes, and knowledge.
equation for nutrition label use was created for the nutrition/health claims and nutrition facts panel. The data found a statistically significant link between label use and consumer self-reported selection of healthy foods. This link is stronger with the presence of the nutrition facts panel but is also considered strong with both types of labels suggesting the positive intent to follow a healthy diet (58). Through similar data measurements as the studies discussed above, Byrd-Bredbenner et al. (2000) concluded that 92% of study participants reported that food label use does influence their purchasing decisions always or sometimes (59).

Similar to the studies above, Fitzgerald et al. (2008) collected self-reported survey data in a convenience sample but also had respondents complete an 18-item food frequency questionnaire (FFQ) (61) (Table 2). Among Latinas, respondents were equally divided into two groups: 1) those with type two diabetes and 2) those without type two diabetes. The researchers evaluated food label use by a simple question: “How often do you use food labels to select foods that are better for your health?” (61). It was found among all food label users that label use is associated with improved diet quality as assessed by the food frequency questionnaire among those with and without diabetes. More specifically, they are less likely to consume sweets, salty snacks, and regular soft drinks frequently, and more likely to consume fruits and vegetables. Furthermore, 67.5% of people with diabetes were more likely to use food labels to purchase foods low in sugar compared to 34.1% of those without diabetes (p<0.001) (61).

The studies mentioned above provide useful information using simple survey and associative data, yet studies that evaluate label use and food purchasing behavior using
different instruments lend more information regarding actual label use impact on diet quality. For example, a number of studies used data from the USDA’s Continuing Survey of Food Intakes by Individuals (CSFII) and its companion Diet and Health Knowledge Survey (DHKS) (52-54, 63). The CSFII collected food and nutrient intake from over 9,000 American households between 1989-1991, 1994-1996, and in 1998 through in-person interviews using a 24-hour diet recall plus the collection of sociodemographic information. Individual intakes of macronutrients, vitamins, and minerals were produced from these data. As a follow-up to the CSFII, DHKS called individuals from the CSFII at random and obtained information on nutrition attitudes, knowledge, dietary habits, and nutrition label use. Researchers often use both sets of data since information from CSFII on food intake can be linked to dietary intakes and label use habits from DHKS.

Among the studies that used an external validation for label use and change in diet quality, four studies used data from the CSFII and DHKS (two survey instruments) while 1 study used data from the National Health and Nutrition Examination Survey (NHANES) (one survey instrument). Lewis et al. (2009) used the 2005-2006 NHANES data that included 17 questions regarding respondents’ knowledge of federal nutrition information programs and food label usage in addition to two 24-hour diet recalls (55) (Table 2). Therefore, information was obtained on respondents’ intake of total energy and protein, and grams of fat, saturated fat, carbohydrates, and fiber. The purpose of the study was to determine associations between label use or nonuse, presence or absence of chronic disease, and change in eating behavior/diet quality. It was found that participants
with heart disease who reported using nutrition information was the group most likely to meet the recommendations for total fat, saturated fat, and fiber. This implies that people with chronic disease, especially heart disease, use nutrition labels and their diet is improved because of it (55). Guthrie et al. (1995) used the 1989 CSFII and DHKS data to determine the impact of label use on 26 food components through separate regression analysis (52) (Table 2). This study concluded that labels do influence the consumption of foods with a nutrient density high in vitamin C and a lower density of cholesterol. However, these were the only significant effects found among the 26 nutrients and food components. Overall this study found a limited impact of nutrition label use and overall diet quality (52). It should be noted that these data were collected before the introduction of the 1990 Nutrition Labeling and Education Act (NLEA) in the U.S. that mandated nutrition information such as the presence of the NFP on all packaged foods. Respondents may have found the pre-NLEA nutrition labels confusing or unavailable since at the time nutrition labels were not required to appear on all packaged foods and health claims were likely not consistent. Two similar studies conducted by Kim et al. in subsequent years assessed the association between food label use and nutrient intake using the 1994-1996 CSFII and DHKS data (53, 54). In 2001, Kim et al. incorporated the healthy eating index (HEI) as a measure of diet quality to evaluate label use effectiveness in addition to using the CSFII and DHKS data (54) (Table 2). Both studies used endogenous switching regression models. These models correct for self-selectivity bias by separating out label users from nonlabel users in order to obtain accurate estimates of label use and independent variables on diet quality. It was found that label
use positively improves diet quality as measured by the HEI (54) and significantly
decreases the average calories from total fat and saturated fat, average daily cholesterol
and sodium intake, and increases the average daily fiber intake (53). Variyam (2008)
also used the 1994-1996 CSFII and DHKS data to determine if the nutrition information
found on the NFP impacts diet quality but took a slightly different approach (63). The
researcher used empirical modeling to reduce potential bias of foods consumed away
from home (FAFH) that do not have nutrition labels (e.g., restaurants, fast food places).
Thirty-two percent of daily caloric intake is consumed from FAFH locations (66).
Although most food consumption survey instruments do not require subjects to report
food consumed away from home, an equation was estimated to account for food
consumed at home that have nutrition labels and FAFH intakes that do not have nutrition
labels. This was done to reduce potential bias that may be associated with label use.
Nutrition labeling was found to positively influence label users’ intake of fiber and iron
rich foods compared to label nonusers (63).

Although the studies above provide a higher level of evidence that consumers
who read labels purchase and consume healthier products because there are multiple
probes to answer that question, nevertheless the data are still associative only. The next
level of studies document a change in consumers’ purchasing behavior based on food
labels using an external validation for purchasing behavior but not diet quality. For
example, Barreiro-Hurle et al. (2010a) collected data through self-reported
questionnaires on nutrition knowledge, health, food label use, and participants intake of
pork Frankfurter sausages and yogurt (51) (Table 2). The purpose of the study was to
examine the relationship between many nutrition and health information labels, and the 
way in which information is displayed (claims or facts) with the type of information 
(health or nutrition) on consumer purchasing behavior. Participants were presented with 
3 mock packages for sausage and yogurt (e.g., yogurt A, yogurt B, and no-purchase 
label). Each package included either a nutrition claim, nutrition facts label, or health 
claim or two pieces of nutrition information were present on the food package (e.g., a 
nutrition facts label and nutrition claim together on one package). This was to see 
whether consumers’ food choices are influenced by different labels and label 
combinations associated with food products that have different healthiness attributes. 
Only two significant findings with the presence of multiple labels were found: 1) study 
participants were less likely to use the health claim and nutrition facts panel to influence 
their purchasing decision of yogurts and 2) study participants were more likely to use the 
nutrition claim and nutrition facts panel to influence their purchase of sausage. 
Furthermore, participants were more likely to use labels in isolation (only one label 
present on the food package) to influence their purchasing decisions compared to the 
addition of a second label expect for the case of sausage mentioned above. The results 
indicated that consumers use the European nutrition facts panel label and nutrient claims 
more when deciding to purchase unhealthy foods (e.g., sausage) compared to healthier 
foods like yogurt (51). In addition, combinations of label information (claims) when the 
NFP is already present may drive consumers to avoid using multiple labels to impact 
their purchase of products perceived as healthy. Therefore, a change in food purchasing
behavior depends on the type of label and amount of nutrition information present on the label (51).

Four studies used grocery store sales data or shopper receipts to determine purchasing behavior as a result of label use (39, 56, 62, 64). A before and after study conducted by Balasubramanian et al. (2002) used longitudinal sales data to analyze change between pre- and post-NLEA labels (39) (Table 2). Food bar codes were scanned in several different categories with descriptors that were of interest such as “low fat,” “light,” “low sodium,” or for positive nutrients “vitamin C added” or “calcium added.” Results showed that the products that carried descriptors of “positive nutrients” were purchased less often after NLEA, whereas products carrying “negative nutrient” descriptors were purchased more often. Interestingly, products characterized as lower in calories did not register as increased in sales. The authors explain this seeming anomaly as consumers focusing on decreasing fat intake to lose weight, rather than focusing on calories (39). This indicates that consumers’ food selection is influenced by post-NLEA labels and they purchase more foods with descriptors for negative nutrients (except calories) than positive. A similar study performed by Sacks et al. (2009) examined total weekly product sales for fresh pre-packaged sandwiches and chilled pre-packaged meals that commonly display multiple traffic light (MTL) labels (56) (Table 2). Researchers conducted a before-and-after study by collecting sales data four weeks before and after the introduction of the MTL label. A point system was created to determine product healthiness: 3 points for red; 2 for amber; and 1 for green; a score of 4 points is deemed the healthiest (the maximum number of green “lights” possible) and 12 points is least
healthy (the maximum number of red “lights” possible). Sales of “ready meal” products increased 2.4% (p=0.03) four weeks after the introduction of the MTL while weekly sales of the pre-packaged sandwiches decreased 0.43%, although this was not significant. Among the six “ready meals” the healthiness rankings ranged from 5 (most healthy) to 10 (least healthy). As a measure of the percentage of category sales for the “ready meals” and the sandwiches, no associations were found between change in purchasing of the healthier products and sales. However, it is worth mentioning that the healthiest “ready meal” experienced a 148% increase in sales after the MTL label was introduced. Overall, no associations were found among the change of sales and consumer purchasing of healthier products four weeks after the introduction of the MTL. This suggests that among this population of subjects were not using FOP nutrition information to influence their purchasing decisions through the use of sales data collection (56). Vyth et al. (2010) interviewed grocery shoppers after check out and had them complete a survey (64). The questionnaire regarded food choice motivation and included questions about familiarity with the Netherlands FOP Choices logo, if products were intentionally purchased with the logo, and how often they intentionally purchase products with the logo (Table 2). Actual logo use was determined by counting the products purchased with the logo. Among grocery shoppers who reported using the logo to guide their purchasing decisions, 24% (p<0.01) of the total products purchased carried the logo. Yet, even among shoppers who did not intentionally purchase products with the logo, representing 71% of the total study participants, 17% of their purchases carried the
logo (64). This suggests that the presence of FOP labels influences shoppers to purchase healthier foods; however, they can also purchase these foods unintentionally.

Unlike the studies mentioned above that document a change in consumers’ purchasing behavior based on food labels using an external validation for purchasing behavior but not diet quality, Reid et al. (2004) includes a FFQ to validate diet quality (62). Food shoppers completed a survey regarding attitude towards the purchase of healthy foods, use of the FOP Health Check (HC) logo, and use of food package information. Participants also provided their shopping receipts (Table 2). Similar to Vyth et al. (2010), researchers examined consumers’ intention and actual use of the HC logo (62, 64). Even though the majority (92%) of shoppers reported not using the logo when making their purchasing selections, those did were more likely to use the logo to purchase healthier foods and have a diet lower in fat compared to those who did not use the logo. In addition, shoppers who were aware of the HC logo reported using the logo when comparing products to purchase the healthier option (62).

Although the studies mentioned above provide even more valuable information regarding actual consumer purchase of food products, we still know little about label use and the influence on diet quality or eating behavior change. Studies that document label use and diet quality independently from purchasing behavior and actually require individuals to plan a one-days meal provide even more information regarding actual label use impact on eating behavior. For example, two studies create simulated shopping situations, in other words, presenting consumers with a preselected set of food pictures and participants identified the foods they would typically eat (40, 41). Borgmeier et al.
(2009) displayed 78 food pictures each labeled with portion size and one of five FOP labels (Healthy Choice Tick (HCT); Multiple Traffic Light (MTL), Monochrome Guideline Daily Amount (GDA); a Colored GDA label (CGDA); and "no label" condition) (40) (Table 2). Participants simulated a shopping experience and chose the foods and drinks typically consumed for breakfast, lunch, dinner, and one snack. The intake of all of the nutrients they would have potentially consumed were calculated. Fat, saturated fat, sugar, and sodium were the nutrients generally above the recommended intake. The study found no influence among any of the five FOP labeling conditions on diet quality or food consumption (40). Similarly, Feunekes et al. (2008) took baseline measurements by exposing participants to 12 products without the four tested FOP labels (41) (Table 2). They completed a number of questions on health behavior, nutrition knowledge, and intended usage frequency of the products. Then participants were presented with pictures of less healthy and healthier food products. Participants completed a questionnaire on intended usage frequency for both types of food products. After exposure to the FOP labels, intended usage frequency of each food product was measured by the question “Having seen this product with the health indicator, how often do you intend to use this product?” (41). The difference between baseline and intended usage frequency after exposure to the labeling format determined the intended change in usage frequency. Findings revealed only a slight improvement in intended usage of all four FOP labels. A slight increase was observed among participant intention to consume healthier food products, while they intended to consume less of the less healthy food.
products (41). Overall, between the 4 labeling formats, no significant differences were found.

Similar to the simulated shopping situations yet even a better determinant of consumer actual change in eating behavior, Antonuk et al. (2006) and Miller et al. (1998) reported on intervention studies that observe the consumption of selected foods (50, 57) (Table 2). Antonuk et al. (2006) grouped American undergraduate students as to whether they were dieters or non-dieters and observed their consumption of a bag of M&Ms (1.5 servings) during separate occasions with a single-column label (provides nutrient content per serving) or a dual-column label (provides nutrient content per serving and a second column lists the nutrient content for the entire package) (57). The goal of the study was to test if people eat less when nutrition information is presented for the total package instead of one serving, and also to see if this outcome is different if the person is dieting. When the participants were allowed to eat the M&Ms ad libitum the dieters always ate less than the non-dieters (p<0.05). Interestingly, when the dual-column label is present compared to the single label, non-dieters ate less (p<0.05), but the dual-column label had no effect on food intake with the dieters. This suggests that non-dieters would benefit from packages with a dual label for foods that can be consumed in one eating occasion yet contain more than one serving. It also suggests that people who pay close attention to the NFP because they are dieting may not need extra prompts to trigger them to stay within a lower calorie range (57). In the same way, Miller et al. (1998) grouped participants as to whether they were restricted or non-restricted eaters and assigned them to an information group or a no-information group
(50). The information group was provided with a bag of chips that included the nutrition facts label and had the name of the type of potato chip (regular or fat-free) on the front of the package while the no-information group received a bag of chips without any nutrition information and were blinded to the potato chip they were provided (Table 2). Participants visited the laboratory for two 2-week periods. During the first 2-week period, participants were given the same chip type each day followed by a second 2-week period in which the opposite chip was given. Differences were observed among participants who restrict their food intake as a concern for body weight (restricted) compared to participants who do not (unrestricted). Unrestricted participants in the information group ate approximately the same amount of fat-free and regular potato chips. However, restricted participants in the information group consumed more “healthier” fat-free chips made with a better-for-you fat (olestra) compared to regular chips. Results suggest that consumers are more likely to use nutrition labels to consume an overall diet of foods perceived to be healthy if they are concerned with their body weight (50). Results from both studies (50, 57) suggest that dieters provided with labeling format act according to their dietary restrictions either consuming approximately equal amounts regardless of label type or consume more foods that are perceived as healthier while consuming less if it is perceived as less healthy. On the other hand, non-dieters are influenced by label format consuming less if the label provides more information or consuming the same amount if the food is perceived to be healthy or less healthy.
Different from the studies mentioned above, actual consumer purchasing behavior is observed at the point-of-purchase. For example, two studies performed by the same author used in-store observations to determine consumer label use before deciding to select the product (43, 46). Both studies used three components: 1) in-store observation; 2) in-store interview; and 3) in-home questionnaire. Six aisles were preselected in the grocery store and shoppers were monitored in the aisles that corresponded to 6 product categories: “ready meals,” breakfast cereals, yogurts, confectionary, salty snacks, and carbonated soft drinks (Table 2). The product categories were selected because these products usually have FOP and BOP labels, have a wide range in healthiness, and the retailers have the labels on their foods. During the in-store observation, Grunert et al. (2010b) found that 65.6% of participants looked at the front of the package before selecting the product, 11.6% looked elsewhere, and 31.8% did not spend time looking at the package before making a selection for the first product selected on the aisle in which they were observed (46). During the interview, 47% of respondents answered “usually” or “regularly” when asked if they “generally” use nutrition information before purchasing items from the same category (46). Similarly, Grunert et al. (2010a) observed 62.6% of respondents looking on the front of the package (GDA label); of these only 8% reported selecting the product for health/nutrition reasons (43). Furthermore, shoppers are more likely to use nutrition information to influence their purchase of yogurt and breakfast cereals and least likely for carbonated soft drinks, confectionaries, and salty snacks. A small percentage of shoppers observed in the grocery store let nutrition labeling influence their food
purchases (43). Both studies concluded that consumers do use food labels to influence their purchases and therefore diet quality yet; usage of nutrition information in the grocery store is largely dependent on the product category and consumer interest in healthy eating. For example, shoppers tend to use nutrition labeling more for foods with a healthier profile (e.g., yogurt) compared to less healthy foods (e.g., confectionary) (43, 46).
CONCLUSIONS

To our knowledge, no other systematic literature review has been conducted to determine consumer ability to use nutrition labeling (both FOP and BOP) to identify the healthier food product or determine consumer use of labels to change diet quality or purchasing and/or eating behavior. This research has produced 3 major findings for question #1 *Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product?* and question #2: *Do consumers change their purchasing and/or eating behavior because of the use of the FOP or standard back-of-pack nutrition labels?*

**Consumers are able to use food labels to identify the healthier food product**

Research supports that both FOP and BOP nutrition labels can be used by consumers to select the healthier food product (39-41, 43-46, 48) and/or more nearly rate the healthiness of the product using a standard (47). This result is further supported by one study that included a “no label” option as consumers were least likely to identify the healthier product in the absence of a food label (40).

Although some studies only tested consumer ability to identify the healthier food product by using only one single label condition (43), a “new” vs. an “old” label (39), the presence or absence of one labeling condition (46), or one food product category (e.g., cracker) (42), all studies resulted in consumers being able to identify the healthier food product. Likewise, other studies that presented consumers with product pairs and were asked to select the healthier product the consumers were able to so (40, 41, 44-46).
However, the research is not fully conclusive since the majority of the studies are limited to product pairs – foods from the same product category and do not directly imitate a realistic shopping experience when consumers are faced with multiple food items in a grocery store.

Future research is needed in this area to determine consumer ability to identify the healthier food product from multiple different products and not simply from the same product category. In addition, the environment in which these studies must be performed should imitate a typical shopping experience. Furthermore, to best assist the FDA in the decision making process to determine which FOP labeling format best helps consumers identify the healthier product, more research is needed especially among people from differing sociodemographic areas.

**Label use influences consumer purchasing behavior**

Many studies have researched the association between label use and a change in purchasing behavior (39, 43, 46, 51, 56, 58-60, 62, 64, 65). Cross-sectional data that used simple survey data and no external validation for label use or consumer purchasing behavior did show a relationship between label use and purchasing; however, as mentioned above, this is associative data and does not necessarily mean label use is what caused the change in purchasing. However, findings from studies that used an external validation for purchasing such as the collection of sales data or sales receipts when assessing individuals use of labels were consistent with the cross sectional data. The majority of studies (39, 51, 62, 64) that used these external validation instruments found a positive change in purchasing behavior due to label use while one study found no
association (56). The positively rated study in which grocery store sales data were collected found no association between change of sales and consumer purchasing of healthier food products from 4 weeks before or after the multiple traffic light (MTL) front-of-pack nutrition label was introduced. It is possible that the short time-frame (4 weeks) since the introduction of the label was insufficient for consumers to adjust to it and use it for their purchases (56).

Finally, among the highest quality intervention studies that performed in-store observations to determine consumer actual use of nutrition labels and their impact on product selection at the point-of-purchase and diet quality, both studies found positive associations (43, 46). Although there is good evidence consumers use nutrition labels to influence their purchasing decisions, the evidence is not conclusive and is limited to more studies that use associative data than intervention studies. More research is needed in this area to perform intervention studies that observe food shoppers at the point-of-purchase and less survey data.

**Label use influences consumer diet quality**

Similar to the above stated comments, cross-sectional data have shown a positive association between label use and change in eating behavior using an external validation for diet quality (52-55, 61-63). All of these studies except for one (52) found a positive association between consumer label use and diet quality. Guthrie et al. (1995) found that participants met the recommended intake of only 2 out of 26 nutrients tested and suggested a limited impact of nutrition label use on overall diet quality. It should be noted that the Guthrie et al. (1995) study used data from pre-NLEA from the 1989 CSFII
and DHKS (52). At the time of the study, CSFII and DHKS surveys had been conducted in 1989, 1990, and 1991. The 1989 survey was the only one that included specific questions on nutrition label use. In addition, it is possible that consumers found labels in 1989 to be complex and not easily interpreted. Perhaps they would have found post-NLEA labels easier to understand and would therefore have used them to select healthier foods and thus improve their diets.

Yet, again, these findings are based on associations and do not indicate that label use does in fact cause consumers to have a healthier diet. Intervention studies that actually have consumers use labels to plan a one-day meal (40, 41), observe their actual consumption of a given food (50, 57), or perform in-store observations (43, 46) provide more insight to actual changes in eating behavior due to label use. All of these studies found a positive association except for one neutral quality study (40). Borgmeier et al. (2009) instructed participants to create a one-day meal plan from a select, yet limited number of food pictures that were associated with a variety of nutrition labels in a simulated shopping situation (40). The majority of participants created a meal that exceeded the daily recommendations for fat, saturated fat, sugar, and sodium. This leads us to consider that the way in which these studies are performed can have an influence on the results. In other words, the way in which information is processed (various nutrition labels on picture cards) may be different in an experimental setting compared to more realistic settings in a grocery store (41). However, when reviewing higher quality studies such as those that actually observe consumer intake of a given food or perform
in-store observations; we learn that consumer label use does positively influence their diet quality.

Although we present good evidence that label users have a higher quality diet, due to variations among the studies and limited intervention data, it is difficult to definitely conclude that label use impacts consumers’ overall diet. More intervention studies are needed in this area. The next step in research should be to look at the entire diet of participants instead of individual foods and finally, what effect the whole diet may have on overall health such as decreasing the risk of disease.

In the future, more nutrition education programs are needed to motivate consumers to follow a balanced diet for overall health. Educational programs should aim to teach consumers about the importance of following a healthy diet, understand the format of nutrition labels and how to use them to make the best selections, and understand the nutritional recommendations from the most recent Dietary Guidelines for Americans. More specifically, education programs for front-of-pack nutrition labels should teach consumers about the nutrient profiling system behind the label, and whether the information is intended to be product category specific or across the board. It may also be necessary to develop education programs targeted to specific populations such as men vs. women and various educational levels.
COURSE MANUAL

Introduction

This course manual is intended to assist faculty at Texas A&M University (TAMU) and equivalent universities or colleges with step-by-step instruction to successfully conduct a 15-week course on evidence-based reviews (EBR). Students will focus on one topic area during the entire semester. Conducting an EBR (also known as a systematic literature review or SLR) is an important form of research and students will obtain the skills to scientifically and critically appraise the quality of studies to come to a consensus conclusion. As students review the scientific literature in one area they will become an expert in that area to recognize research gaps and become well-versed (26).

This course follows the steps of conducting an EBR as outlined by the American Dietetic Association Evidence Analysis Library (ADA EAL). This evidence analysis system was selected for two reasons: 1) the majority of students enrolled in the course are generally nutrition students, some of which plan to become Registered Dietitians and the ADA is their professional organization and 2) the evidence-based process is respected among the nutrition community, so much so that the USDA developed their own Nutrition Evidence Library (NEL) using ADAs EAL as a model for the 2010 DGAC Report (13). In addition, USDA adopted ADAs EAL Primary Research Quality Criteria Checklist as their Implementation Checklist to assess the quality of primary articles (22, 23).

Students will learn a number of useful and marketable skills necessary to successfully complete an EBR during the course of the class including: 1) formulating
the research question; 2) conducting the literature review to answer the research
question(s); 3) learning to critically appraise each relevant article based on quality rating
and to decrease the likelihood of bias; 4) summarize the evidence; and 5) draw
conclusions based more so on higher quality studies. Likewise, graduate students will
learn to lead a group of undergraduate students and set realistic goals, assign duties, and
manage students. For the best learning experience it is recommended to keep the class
relatively small. This course manual is designed for a class of 12-16 students.

It is important for the instructor or the instructors department to be a member of
the American Dietetic Association to access the ADA EAL website
(http://www.adaevidencelibrary.com/) for this course. If the instructor is not a member,
access to the EAL can be purchased annually from the website. Class assignments and
lectures are based on information located from the Library website and therefore the
instructor will need to have immediate access.

The organization of the manual is designed to assist faculty to successfully teach
and direct students to complete all steps to produce an EBR on a nutrition or food
science topic in a 15 week semester. The manual includes all reproducible resources:
weekly class instruction for a succession of 15 weeks, lectures in the form of Power
Point® presentations, an example of a course syllabus including assignments and point
system, class handouts, grading evaluation forms, oral presentation templates, written
assignment sample and more.

This course has been approved at TAMU by the TAMU Office of Graduate
Studies and Faculty Senate. The course content is based on resources available to
TAMU faculty, staff, and students as a model but can be modified to meet the needs of most colleges and universities.

Supplies/resources

1. Internet and computer access
2. Projector
3. Student and faculty email access
5. Access to university electronic databases and journals (www.library.tamu.edu)
6. EndNote® Library (https://software.tamu.edu)
7. USB Flashdrive
8. Wireless presenter with laser pointer
9. Classroom with internet access, computer with Microsoft Office®, and projector
10. Printer/copier

Course description

This course is designed to develop a critical approach to evaluating the quality of the scientific literature in areas specific to nutrition and food science. Students will learn how to develop search terms and search the scientific literature, how to categorize papers into types of studies, how to evaluate the quality of an individual study, and how to produce an EBR of the complete literature on a specific topic that is suitable for publication.

The instructor has two options when assigning research questions to the class: option 1) the instructor may choose to assign one overall research question to the class
and assign sub-questions to each group; or option 2) the instructor may assign an overall research question to each team. Through experience option 1 works better than option 2 because during class presentations the students are engaged in the research regardless if it is presented by a different group who has a slightly different, but similar research question that focuses on the same topic.

Course objectives

With successful completion of the course, students will have achieved:

1. An understanding of how to pose an appropriate question for evaluation by an evidence-based review of an important issue in nutrition and develop search terms and strategies to uncover all relevant literature.

2. An understanding of the different types of studies in nutrition (randomized clinical trials, prospective epidemiological studies, case control studies, etc.) and the issues of bias associated with each type of study.

3. An understanding of what makes an excellent scientific study and what detracts from a study being categorized as excellent (appropriate controls, statistics, length of study, how the intervention might affect the rest of the diet, etc.)

4. Knowledge of how to pull together all of the evaluated research studies into one evidence-based review and come to a conclusion as to the strength of the science behind the posed question.

5. Experience in presenting and defending your evaluations and conclusions.
Specific learning objectives

Students should know and be able to communicate verbally and in writing with specific examples:

1. How to conduct a formal evidence-based literature search and find all appropriate publications.
2. How to categorize a study as to the type of study and evaluate study type with respect to bias.
3. How to evaluate the quality of an individual study and rate it as excellent, good, or poor.
4. How to come to a conclusion based on the totality of the studies reviewed.
5. How to report the findings once the evidence-based review is complete.
6. How to present and defend their decisions.
7. How to work with others in a synergistic manner.

Student prerequisites

Students are required to take a basic introductory nutrition course (Nutr 202 or 203) and a college level statistics course (Stat 302) to succeed in this class. A fundamental knowledge of nutrition, statistics, and technical writing is expected of all students to understand technical papers and form accurate conclusions. Eligible students are classified as a junior or senior undergraduate or graduate students.

Graduate student responsibilities

Graduate students will act as team leaders for each of the EBR teams. They will manage their team and make sure the group functions cohesively. The graduate student
will be responsible for taking each segment of completed work from the team and writing it up in manuscript form. It will be the responsibility of the graduate student (with help from the rest of the team) to prepare the final manuscript for publication.

**Week 1**

The first day of class pass out and review the student syllabi (Appendix A). Since graduate students are required to have more responsibility than undergraduate students separate syllabi have been created. Both syllabi include point distribution and a weekly outline. Note: the point distribution is a guide and should be modified as appropriate using instructor discretion. The instructor should administer Appendix B, *Graduate student responsibilities as team leaders*, to all graduate students since their primary responsibility as a graduate student is to be the team leader for the undergraduate students in their group.

The first day of class present an introduction to the course, *Nutrition and Food Sciences 489/689 Evidence based reviews: A critical evaluation of the nutrition/food science literature* (Appendix C). This presentation introduces the course to the students, learning objectives, how they can use the skills learned in the class, requirements and grading scale.

The next class period students will be introduced to what an EBR is, the importance of this type of review paper, and the steps necessary to complete an EBR. Refer to the instructor lecture *How to do an evidence-based review* (Appendix C). Provide students with a copy of a recent EBR paper. An example is: Guadalupe X. Ayala, Barbara Baquero, Sylvia Klinger. A systematic review of the relationship
between acculturation and diet among Latinos in the United States: Implications for future research. *J Am Diet Assoc.* 2008;108:1330-1344. Have the students read the paper and ask questions as necessary during the next class.

During this week of class students should be encouraged to purchase EndNote® at no cost from the TAMU Software Licensing Library (https://software.tamu.edu).

**Week 2**

Students should attend a special EndNote® training with one of the librarian’s on campus. There are two EndNote® librarians at TAMU: Robin Sewell (Medical Science Library); phone: 979-845-0650; Email: rsewell@medlib.tamu.edu; John Paul Fullerton (Evans Library); phone: 979-458-1393; Email: j-fullerton@tamu.edu. The training should be held during regularly scheduled class time and the librarian should be contacted before the semester begins.

Note: Refworks® is another equally appropriate citation manager. The class and professor as a whole need to agree on the citation manager for the class. For simplicity this manual will refer to EndNote® as the citation manager.

Before the EndNote® training begins the instructor will take 10 minutes to announce student groups that he or she selected. Each group will have 1 graduate student per team who will act as the leader. Junior and senior undergraduate students should be divided equally among the groups. If the instructor chooses, he/she may select a research question and sub-questions based on his/her knowledge and ability to identify gaps or issues in an area of practice where scientific evidence is needed. The overall research question will be presented to the class at this time providing each team with one sub-
question. It is necessary for the instructor or teaching assistant (TA) to conduct an initial online search to determine if adequate research has been conducted in the chosen area before assigning the research question to the class.

During the next class period invite a research librarian to offer practical advice and tips to search their topic from TAMU’s library website (www.library.tamu.edu), identify appropriate online databases, describe the P.I.C.O. method etc. The instructor should provide the overall research question and sub-questions with the librarian prior to the class date to incorporate specific search suggestions on the topic. Refer to Appendix D, *Tips for conducting an online search* that will provide students with the foundation to conduct a thorough search.

Margaret Foster, assistant professor, is an expert librarian in the area of EBRs. If Ms. Foster is not available Nancy Duran is equally capable to walk the students through the steps to successfully search their topic. Ms. Duran is the library liaison for the College of Agriculture and Life Sciences (COALS). Margaret Foster (Evans Library); phone: 979-862-1893; Email: margaretfoster@library.tamu.edu. Nancy Duran (Medical Sciences Library); 979-862-1050; Email: nduran@library.tamu.edu.

The search process is a crucial part of identifying the most appropriate search terms to collect the most relevant peer-reviewed articles to answer the research question and sub-questions. It is advisable to invite Margaret Foster, an expert in the area of conducting systematic searches and the author on numerous systematic literature reviews to attend two class periods to assist the students in their search process. If this is not possible, each group should be required to meet with her outside of class.
At the end of this week students should begin doing an initial search to
development one set of key terms. The group should proactively contact a research
librarian to assist them in their search to fine-tune search terms and identify appropriate
databases.

*Team assignment #1 instructions – oral and written assignment*

The first team assignment is due the following week (week 3). One member of
each team will present the group’s search terms, databases searched, and
inclusion/exclusion criteria in a Power Point® presentation. See Appendix E for a
template of the oral and written presentations. The following class period the same or a
different group member (the decision is up to the group) will submit the materials and
methods section for the paper listing the search terms, databases searched,
inclusion/exclusion criteria, results, lessons learned, plus any changes the group will
make since receiving feedback from their peers and the instructor after the oral
presentation (see Appendix E for detailed instructions).

**Week 3**

*Team assignment #1 – oral and written presentation*

Team assignment #1 is due at the beginning of this week. Students will take 10
minutes to present the group’s search terms, databases searched, and inclusion/exclusion
criteria in a Power Point® presentation. The following class period the materials and
methods section is due. The person who presents the Power Point® presentation can
receive a maximum 10 points toward the total 100 points. The person who writes up this
presentation as a “Materials and Methods” section, due the following class period, can
receive a maximum 20 points (see Appendix E for detailed instructions). See Appendix F for the instructors oral evaluation form.

After the group presentations the instructor will lecture on *Where we are now and next steps* (Appendix C). This lecture will provide the class with a more clear understanding of the 13 steps to complete an EBR.

At the beginning of the next class period, recap and answer questions from the *Where we are now and next steps* presentation. Also allow time for questions regarding the search process. One student from each group will turn in the Materials and Methods section at the beginning of class.

The instructor will lecture on how to classify studies as A, B, C, and D based on experimental design from the *Type of study design* presentation. Refer to Appendix C for a copy of the slides and notes pages. Articles included in the EBR will be categorized according to the ADA Evidence Analysis Manual (9). All primary articles applicable to answer at least one of the research questions will be categorized by study design: randomized control trials (A), cohort studies (B), nonrandomized trials with concurrent or historical controls, case-control studies (C), cross-sectional studies, trend studies, case series, case reports, and before and after studies (D). The four types of studies mentioned above (A, B, C, or D) are organized in a descending fashion based on the potential for bias. For example, a randomized control trial is awarded an “A” because it has the least potential for bias whereas a cross-sectional or “D” study is more likely to have bias.

Randomized control trials (“A” studies) are ideal and the gold standard studies.

Suggested handouts: Refer to the ADA Evidence Analysis Manual (9) at

_Take home activity #1_

Provide students with 4-5 papers and require them to identify the study design for week 4. It is best if the instructor selects papers relevant to the class research question. The instructor may provide hard copies, send the pdfs via email, or provide the full citation and have the students look up the pdfs for practice. At the beginning of week 4 discuss how the students categorized the studies and why. Clear up confusion as necessary. See appendix G for a sample set of citations, _Take-home activity #1: Identifying the study design._

_Team assignment #2 instructions – oral and written assignment_

The second team assignment is due the following week (week 4). One member of each team will present the group’s search terms, databases searched, inclusion/exclusion criteria, and a flow chart of results in a Power Point® presentation. See Appendix E for a template of the oral and written presentations. The following class period the same or a different group member (the decision is up to the group) will submit the materials and methods section for the paper listing the search terms, databases searched, inclusion/exclusion criteria, results, lessons learned, a flow chart of results, and a full list of primary articles that will be used in the evidence-based review (see Appendix E for detailed instructions). The instructor should also pass out instructions for organizing student EndNote® libraries (Appendix D) and a sample flow chart (Appendix D).
After this week students will continue to refine search terms, determine exclusion/inclusion criteria, and schedule a meeting(s) with a research librarian. Students need to have a firm set of search terms and exclusion/inclusion criteria before week 4 and have equally divided all articles captured among the group members. Students will review the title, abstract and if necessary the entire text to exclude or include the article based on exclusion/inclusion criteria. The graduate student will need to make one EndNote® library to eliminate duplicates. It is suggested the graduate student upload all references into a free database such as Google Groups® (see Appendix D, Tips for conducting an online search). Multiple students can access and work on the spreadsheet at the same time and updates are viewed as soon as changes are made. The graduate student will create columns and equally assign articles to each group member to decide if the article answers the research question and meets exclusion/inclusion criteria. Refer to Appendix D, How to organize your articles and assign reviewers as an example on how to organize a spreadsheet. The graduate student will need to monitor the groups work and ask questions or assign himself or herself as a second reviewer if they question the study design or rational for an articles exclusion or inclusion. If the primary and secondary reviewers disagree the decision will be adjudicated by the entire team. It is important during this time to make sure all group members understand the research question and it is helpful if the graduate student or instructor provide examples of articles that would be included or excluded and why.

The graduate student for each group will need to keep all search terms for each database in a safe location. During the writing of the manuscript (weeks 12 through 14),
one final search will need to be performed to capture articles that have been published since the initial search. This information will be sent electronically to the instructor and/or TA.

**Week 4**

During the beginning of class review the 4 or 5 papers assigned during week 3 to identify the study design. Discuss each study one at a time and why it is an A, B, C, or D study. Allow 10-15 minutes for questions and discussion.

After class discussion regarding the take home assignment, the instructor will lecture on how to abstract articles following the ADA Evidence Analysis Process (9) (see Appendix C, *Abstracting Primary Articles lecture*). The slideshow presentation is very informative and detailed and should be provided to the students to follow along. A copy of the abstraction worksheet can be located from the ADA EAL website by downloading the ADA Evidence Analysis Manual, Appendix 7 (9). An interactive, Excel spreadsheet of the abstraction worksheet has been modified for the class and should be distributed as a hard copy and electronically (Appendix D). Each primary article that is critically reviewed and abstracted should be entered into the worksheet.

The information entered into the abstraction worksheet will be used to come to conclusions regarding the research question(s). It is also a useful tool to abstract key information, organize the information gathered in a consistent manor, collect author conclusions, and locate reviewer comments. All abstraction worksheets should be uploaded to EndNote® along with the pdf of the article if not already attached.
During the abstraction process students should follow the steps below and also those found in the abstraction worksheet (Appendix D):

Step 1: Read the entire article to determine the study population and purpose.

Step 2: Methods section: List details about the study design. What are the participant eligibility requirements? What is the study protocol and variables measured?

Step 3: Results section: This information can be found from the text and tables. How does the author interpret the findings? List how the author describes study limitations.

Step 4: Conclusion section: How does the author describe conclusions of the study?

Step 5: Transfer the above information and other relevant information to the abstraction worksheet.

In class, pass out the abstraction worksheet (Appendix D). The lecture, Abstracting Primary Articles will proceed down the entire worksheet explaining each cell and the type of information that needs to be abstracted from the article. The final few slides review the ADA recommended style when entering information. For example, correct spacing, appropriate symbols, and punctuation. The slides also cover common mistakes made by actual ADA analysts, such as writing “data is” instead of the correct, plural format, “data are.”

For more information and examples on ADAs instructions to abstract articles refer to Step 3 of the ADA Evidence Analysis Manual (9).
Take home assignment #2

Visit the ADA EAL website (http://www.adaevidencelibrary.com/) and select a topic and example paper similar to the topic for the class that has been abstracted by an analyst. Pass out the paper after the lecture on Abstracting Primary Articles and have the class read it before the next class period this week. In class go over the abstraction worksheet that was completed for the paper and answer questions and explain why certain information is appropriate for each cell.

Team assignment #2 – oral and written assignment

Team assignment #2 is due at the end of this week. Students will take 10 minutes to present the group’s search terms, databases searched, inclusion/exclusion criteria, and create a flow chart of search results in a Power Point® presentation. The following class period the materials and methods section is due. The person who presents the Power Point® presentation can receive a maximum 10 points toward the total 100 points. The person who writes up this presentation as a “Materials and Methods” section, due the following class period, can receive a maximum 20 points (see Appendix E for detailed instructions). See Appendix F for the instructors oral evaluation form.

Team assignment #3 instructions – written assignment

The third team assignment is due at the end of week 5. This assignment will include only the materials and methods for each team. This assignment is similar to assignment #2 except students will update this section and include an updated flow chart. Students should be encouraged to search for or be provided with a published systematic literature review to follow their materials and methods section. This
assignment should include the databases searched, search terms, inclusion/exclusion
criteria, and a flow chart of results (see Appendix E for detailed instructions). The group
member who writes the “Materials and Methods” section can receive a maximum 20
points.

Each group’s EndNote® library should be emailed to the instructor or TA by the
end of this week. The instructor should receive only one library per group. All secondary
articles need to be in a separate group folder titled “secondary articles.” PDFs of all
articles need to be attached to the appropriate article. The EndNote® library will need to
be compressed before emailed and should be titled by the group’s letter and date. For
example, group A will title their library as, “Group A 09_21_10”.

_Compressing an EndNote® library_

To compress an EndNote® library go to file ➔ _compressed library_ ➔ make
sure create, all references, and with file attachments are all selected. Click next and save
the file. Then attach the compressed library to an email or save it to a disk or flash drive.
It is advisable for the instructor to review the articles captured in the group searches to
double check the class is on the right track.

The instructor or TA will need to make one class EndNote® library to eliminate
duplicate articles captured in multiple group searches. He or she will then need to
equally assign all students an equal number of articles to abstract. This is to avoid one
group doing more work than another because more articles were located that answer
their research question. As often as possible, students should be assigned articles that
were originally found by their group. If this takes too much time, the instructor may
instruct the graduate student to randomly assign group members to an equal number of articles. This list can be used as a basis when assigning the entire class articles.

Secondary articles are also important to read and determine their usefulness for the introduction of the paper or for back-referencing. Secondary articles should be equally divided among group members by the graduate student. A suggested way to organize an entire list of class citations is to create an Excel spreadsheet from the class EndNote® library.

*Converting EndNote® to Excel*

The easiest way to convert an EndNote® Library to an Excel spreadsheet is to select all citations in EndNote®, go to *Edit ➔ Copy Formatted* and paste into a new Word Document. Select all citations in the word document and copy and paste it into an Excel file. The user will need to adjust the cells as appropriate. Column A will include the students name, column B will list the group(s) that found the citation to avoid confusion if a student from a different group is assigned the paper, and column C will list the full citation.

Email the Excel spreadsheet to the class and also make copies to distribute during the next class period. The graduate student is responsible for uploading new citations not found by his/her group but assigned to group members. He or she will also need to assign a secondary reviewer to all articles. The graduate student leader should consider uploading the assigned list of primary articles for their group to a free online database such as such as Google Groups® to always provide current access to citations and closely follow the status of group member progress. As mentioned under week 3, refer to
Appendix D, *How to organize your articles and assign reviewers* as an example on how to organize such a spreadsheet.

All students should keep their individual EndNote® library and attach a pdf of all assigned articles. During the abstracting phase students should be encouraged to back-reference articles while always referring back to the class Excel spreadsheet to avoid duplicate work. If students find more relevant articles not captured in the original searches for their question or another group’s question, he or she will need to forward the citation(s) to the graduate student leader of their group who will either forward the citation(s) to the graduate student of the appropriate team or equally distribute the articles among his or her group to abstract.

**Week 5**

At the beginning of this week distribute the primary papers (list of full citations) assigned to each student for abstraction. Encourage each student to choose 1 paper to abstract and come to class at the beginning of week 6 with questions about the paper. Provide the students with the handout, *Organizing your EndNote® Library* (Appendix D) if you have not already done so and remind them that they will be responsible for making sure their citations are correctly entered into EndNote®.

Pass around a signup sheet for students to present paper #1 and #2 that they have chosen to abstract from their list of assigned primary articles. It is recommended no more than four – 15 minute presentations per day. Presentations for paper #1 will begin at the end of week 6 and conclude on week 8. Paper #2 presentations will be between week 9 and week 11.
Pass around a second signup sheet for students to choose a 30 minute time slot to meet with the instructor or TA outside of class between weeks 7 and 10. This time will be used to ensure each student is completing the abstraction worksheet correctly, determining the study design and quality rating appropriately and they are correctly abstracting primary articles. Students should bring in at least 2 completed abstraction worksheets and use the time to ask questions.

*Paper #1 oral and written presentation instructions*

Provide students with the slides template (Appendix C) outlining the requirements for their Paper #1 and #2 Power Point® presentations. The written report of the paper is due the following class period after the oral presentation has been presented. Students should follow the same format for the slide presentation as for the written report. The written report should use subheadings similar to those used for the abstraction worksheet. This assignment will begin during week 6 and conclude during week 8.

*Invited guest lecturer from the statistic department*

During the beginning of this week the instructor should invite a lecturer or professor from the statistics department to come and do a statistic refresher presentation. The instructor should focus on various statistical methods common among food, nutrition, and public policy studies, appropriate times when to use them, and interpreting data. Students are required to interpret data and clearly complete this section on the abstraction worksheet and should be comfortable in this area.
Lecture on quality rating

The instructor will lecture on how to assign a quality rating to each primary article using ADAs *Primary Research Quality Criteria Checklist* (22). After assigning the study design classification score to each primary paper the studies quality will be evaluated. All primary papers will receive a quality score of positive, neutral, or negative for relevance and validity using the 10 questions outlined in the *Checklist* (22). Each rating will be determined by the primary reviewer and verified by a second reviewer who will be assigned by the graduate student to ensure accuracy. Disagreement between the primary and secondary reviewers will be settled by the entire group. If the final paper is to be submitted for publication, before submittal the instructor should be a third reviewer of all primary articles included in the EBR.

All ten validity questions will be applied to the collection of papers for the EBR and will answer “yes”, “no” or “unclear” to all questions. To remain organized throughout the entire process comments will be entered into a spreadsheet and all “yes” articles for the EBR will be clearly marked according to the assigned quality rating. All positive articles that earn a positive rating will be identified by a “+” or positive symbol; negative articles with a “−” or negative symbol, and neutral articles with a “Ø” or null/neutral symbol.

Suggested handouts: Refer to the ADA Evidence Analysis Manual (9) at http://www.adaevidencelibrary.com/. During the lecture, the instructor should help students locate the *Checklist* from ADAs website and from the Manual. The *Checklist* is
Table 3.3. *Quality Criteria Checklist: Primary Research* in the ADA Evidence Analysis Manual (9) and the instructor should go through each question with the class.

The instructor should explain the criteria for an article to be rated as a positive, neutral, or negative:

- Positive/Plus (+) articles must answer “yes” to questions number two, three, six, seven, and at least one additional “yes.”
- Neutral/Null (Ø) articles are unable to indicate that the study is strong when answering questions two, three, six, and seven.
- Negative/Minus (-) articles answer “no” to six or more validity questions.

**Team assignment #3 – written assignment**

One student from each group will turn in the materials and methods section for their group at the end of this week. At the end of this week the class should agree on a deadline to have all primary research articles abstracted. As a good rule of thumb, students should expect to abstract between two and four articles a week. At first, reading and abstracting articles can take 2 or more hours. As students become more comfortable with the process this time will decrease. The class should strive to have all assigned primary articles abstracted by week 11.

**Week 6**

At the beginning of this week one class period should be dedicated to helping students abstract their paper #1 to be presented during week 6 through week 8. Questions about study design and quality rating can also be addressed during this time.
Paper #1 oral and written presentations

Three to four students will present a 10-15 minute oral presentation on a primary article they were assigned to abstract. Students should have received a template of the expectations for the Power Point® presentations during week 5 (Appendix C, Organizing your slides for paper #1 and #2 oral presentation). Students should email the pdf of their paper to the entire class at least 2 days before their presentation. Each student can receive a maximum 50 points toward their total 150 points for individual oral presentations. See Appendix F for the instructors oral evaluation form.

Following each oral presentation it is suggested to provide the students in the audience an opportunity to ask questions about the presentation or the study presented. Next, one or two students should have an opportunity to say one or two positive characteristics about the presenters speaking style or something they did well. Finally, one or two students in the audience should say one or two things that the presenter could improve on. This will help the presenter identify areas for improvement in the future. The written report of the paper is due the following class period after the oral presentation has been presented. Each student can receive a maximum 50 points toward their total 150 points for individually written reports. The abstracting worksheet and quality criteria checklist for paper #1 should be attached to the report.

Week 7

Students will continue their presentations over a paper they were assigned to abstract. No more than three or four – 10 to 15 minutes presentations per day. The
instructor should follow the same format mentioned for week 6. The instructor oral evaluation form can be located from Appendix F.

If time allows after the presentations the instructor should make him/her available to help students with the abstraction process. This can be done individually or as a class; one student could ask a question and the instructor could answer the question for the entire class to hear. Alternatively, any time allowed after the presentations is a good opportunity for each group to meet as a team.

**Week 8**

Students will continue their presentations over a paper they were assigned to abstract. No more than three or four – 10 to 15 minutes presentations per day. The instructor should follow the same format mentioned for week 6. The instructor oral evaluation form can be located from Appendix F.

Just as the previous week, if time allows after the student presentations use this time to answer student questions about abstracting, determining quality rating, etc. This may also be a good time to remind students the difference between primary and secondary articles and that one abstraction form will need to be completed for each primary article they were assigned to abstract. Since some students were assigned articles not found by their group all students should regularly be reminded of the primary research question and sub-questions for the entire class, not just their group. Also, it is important to remind the students of the importance of back-referencing their assigned primary articles and checking the class Excel spreadsheet of articles found that was distributed during week 5 to make sure they have been located. If they have not the full
citation should be sent to the lead graduate student of their group and he or she will decide who will abstract the article.

**Week 9**

The final students who presented at the end of week 8 will turn in their written reports along with the abstracting worksheet and quality criteria checklist for paper #1 at the beginning of this week.

The instructor should remind students when they will be presenting their second paper. The same instructor evaluation form can be used for this oral presentation as for the paper #1 presentations (Appendix F). The same slide template (Appendix C) and points system applies to the oral and written presentations for paper #2 (maximum of 50 points each for the oral presentation and written report).

*Paper #2 oral and written presentations*

Three to four – 10 to 15 minute oral presentations on paper #2. As time allows clarify abstracting details as necessary; e.g. independent and dependent variables, study design, quality criteria ratings, etc.

**Week 10**

Students will continue their presentations over a second paper they were assigned to abstract. No more than three or four – 10 to 15 minutes presentations per day. The instructor should follow the same format mentioned for week 6. The instructor oral evaluation form can be located from Appendix F.
Allow time to answer questions and provide support to students each class day.

Remind students of the deadline previously agreed upon during week 11 to have all primary articles abstracted and to turn in to the instructor/TA.

**Week 11**

Finish up the final few oral presentations on paper #2 during this week.

At the end of this week students should submit the abstraction forms for each primary article they were assigned, one EndNote® library per group, and a pdf of articles. It is best if each group submits one EndNote® library that includes the citations the entire group was assigned to abstract. Each pdf and Excel abstraction worksheet should be attached to the citation in EndNote®. If the pdf is unable to be saved and a url can be provided it should be located under the “URL” heading in EndNote®. All documents should be saved with the last name of the author, publication year, an abbreviated journal name, and volume to distinguish multiple articles by the same author from each other (e.g., Smith 2008 JADA, 92).

Students should follow the instructions to compress their EndNote® library to email to the instructor or TA as stated above under week 4. If the library is too big to email than it should be saved on a disk or a flash drive.

**Week 12**

Students should come prepared with their abstraction forms and articles to class each day during the remainder of the semester. During this week and week 13 the instructor will lead the class in a discussion to identify various themes they noticed in their papers. The entire week will be dedicated to agreeing on a final set of sub-
questions, for example discussing if the articles found directly answer the original sub-questions or if sub-questions need to be modified. Each should have a chance to comment. Provide one or two students the opportunity to type the information discussed and the sub-categories/questions agreed upon during class for class participation points. The instructor or TA will email this list of research questions to the class.

*Take home assignment #3*

In preparation for week 13 students will begin to summarize the evidence within an Excel spreadsheet that captures information for each question. A new spreadsheet should be created on Google Groups® or an equivalent free online database by the instructor or TA. One spreadsheet per research sub-question should be created. Separate cells should be created to include: 1) full citation; 2) publication year; 3) study design; 4) quality rating; 5) purpose of the study; 6) study population; 7) intervention; 8) outcome(s); 9) study limitation(s); and 10) name of the student reviewer. Students should be reminded that many articles will likely answer more than one sub-question and they will need to list the appropriate information from the article in the appropriate sub-question spreadsheet (for an example refer to Appendix D from week 3, *How to organize your articles and assign reviewers*). Organizing study findings in this fashion will assist the class in identifying patterns and relevant findings among the studies included in the EBR.

Students are responsible for looking at the online spreadsheets and making an attempt to identify patterns among the research by week 13. The instructor or TA should
re-organize the articles by high quality to lower quality studies (positive, null, then negative studies).

**Week 13**

*Graduate student final presentation with the instructor*

Graduate students will need to schedule 30 minutes outside of class with the instructor for their final oral presentation during week 14 or 15. The presentation is worth 50 points. The graduate student must be able to orally demonstrate their performance as a team leader in the following areas:

- Provide examples on how the graduate student motivated their group;
- What the student would change about the way they managed their group;
- How the student will use what they learned from the course for job applications or future research projects;
- Strategies used to keep the group on task;
- Strategies used to organize a large set of data;
- Personal strengths and weaknesses with managing a group of people;
- What grade does the student think he/she deserves

The instructor or TA will pass out hard copies of the online spreadsheets created by the students. The Google Groups® spreadsheets will need to be projected onto a screen during class. The instructor will instruct the students to discuss their primary articles one at a time as they answer the first question, then the second question, and so on. This will help the entire class understand each study and identify patterns of agreement or disagreement. The class will also identify sets of articles that focus on specific subtopics.
All of week 13 and part of week 14 will be devoted to identifying trends among the primary studies for the EBR.

*Final assignment instructions – oral presentation and written report*

Assign students to groups for the final oral presentation and written manuscript due during week 15. The final written report will be a draft of the paper as if it were submitted for publication. Pass out Appendix E, *Final assignment instructions* to the class.

The instructor will assign students to one of three groups: *introduction, materials and methods, and results*. A *conclusion* group may be possible but since the groups will work independently of each other it may be difficult to have such a group. During week 14 a final conclusion statement will be created and the statement can be inserted into this section. The results group will be further divided into sub-groups for each sub-question. The instructor should try and specifically place students who have multiple articles that answer one sub-question into this group due to their familiarity with the studies.

One graduate student will be the team leader for each group and has the primary responsibility of writing the report. Yet, each undergraduate student is responsible for a portion of the written report (as agreed upon by the group) and is required to equally present their findings during the oral presentation. The graduate student will divide up responsibilities as they see fit. Students can earn a maximum 50 points each for the oral presentation and the written report. See Appendix E, *Final assignment* for full instructions and an outline of requirements for the written report.
**Week 14**

During this week continue discussing articles for each sub-question and determine patterns and themes. During the final class period of this week, the class will develop a conclusion statement. The conclusion(s) should be based more so on the higher quality primary articles used in the EBR.

*Peer group evaluations (due week 15)*

At the end of class pass out student survey’s asking students to make comments and grade their individual group members’ performance for the sub-question group they were assigned at the beginning of the semester (not groups for the final). See Appendix G, *Peer group evaluations*. This will determine individual group involvement and will assess their total awarded points (maximum 100 points). This grade will reflect their individual contribution as evaluated by the group. Each student will need to receive the number of surveys per number of group members in their group. Surveys are due at the beginning of week 15 during the final exam time.

Assure the students that any comments made about another student will be kept strictly confidential and will only be read by the instructor and the TA. Afterwards the surveys will be shredded.

**Week 15**

Before final presentations begin, have students turn in their peer group evaluations in a confidential envelope.
**Final assignment – oral presentation and written report**

Students are required to electronically submit their group’s portion of the manuscript to the instructor or TA by 5 pm the day before the final exam time. The TA will organize the paper by section and pass out hardcopies at the beginning of class. Students in each group will equally present their group findings during the oral portion of the presentations. The instructor will evaluate the completeness of the oral presentations based on the individual groups’ ability to capture the required information as outlined in Appendix E, *Final assignment*. After each group presentation allow 5-10 minutes for class discussion and questions.

Before the end of class the instructor should make sure he or she has the most updated contact information for students and make a mental note of the “stars” in the class. The following semester the instructor may wish to finalize the paper and submit for publication. These students may be interested in writing the final manuscript for publication after the semester has concluded.
REFERENCES


67. Foster MJ. Searching systematically Power Point® presentation. Paper presented at: Writing for publication in education and human development research course 2010; TX A&M University, College Station, Texas.


APPENDIX A

GRADUATE AND UNDERGRADUATE STUDENT SYLLABI
Nutrition 689
(Cross listed with FSTC 689; Stacked with NUTR 489 and FSTC 489)
Critical Evaluation of Nutrition & Food Science Literature: Evidence based reviews
Course Syllabus, semester, year

Instructor: Name; office; email

Teaching Assistants: Name; email

Time/Location: Day; time
Location

Textbook: There is no textbook for the class. All readings will be based on current literature.

Course Description:
This course is designed to develop a critical approach to evaluating the quality of the scientific literature in areas specific to nutrition and food science. The goal is to actually produce an evidence-based review by the class which could be submitted for publication. Students will learn how to develop search terms and search the scientific literature, how to categorize papers into types of studies, how to evaluate the quality of an individual study, and how to produce an evidence based review of the complete literature on a specific topic that is suitable for publication.

Prerequisites: Nutrition 202 or 203 and Stat 302
The following knowledge base is expected of all students entering this class: A fundamental knowledge of nutrition, statistics, and technical writing.

Course Objectives: With successful completion of the course, you will have achieved:
1. An understanding of how to pose an appropriate question for evaluation by an evidence-based review of an important issue in nutrition and develop search terms and strategies to uncover all relevant literature.
2. An understanding of the different types of studies in nutrition (randomized clinical trials, prospective epidemiological studies, case control studies, etc.) and the issues of bias associated with each type of study.
3. An understanding of what makes an excellent scientific study and what detracts from a study being categorized as excellent (appropriate controls, statistics, length of study, how the intervention might affect the rest of the diet, etc.)
4. Knowledge of how to pull together all of the evaluated research studies into one evidence-based review and come to a conclusion as to the strength of the science behind the posed question.
5. Experience in presenting and defending your evaluations and conclusions.

Specific Learning Objectives: Students should know and be able to communicate verbally and in writing with specific examples:
1. How to conduct a formal evidence-based literature search and find all appropriate publications.
2. How to categorize a study as to the type of study and evaluate study type with respect to bias.
3. How to evaluate the quality of an individual study and rate it as excellent, good, or poor.
4. How to come to a conclusion based on the totality of the studies reviewed.
5. How to report the findings once the evidence-based review is complete.
6. How to present and defend their decisions.
7. How to work with others in a synergistic manner.

Graduate Students: Graduate students will act as team leaders for each of the evidence-based review teams. They will coordinate the teams, and make sure that the team functions as a team. The graduate student will be responsible for taking each segment of completed work from the team and writing it up in manuscript form. It will be the responsibility of the graduate student (with help from the rest of the team) to prepare the final manuscript for publication.

Evaluation:

Three Oral Presentations (50 points ea.)  150 points
Three Written Presentations (50 points ea.)  150 points
EBR Section of Manuscript  100 points

- Complete Group Section (50 points)
  - Introduction (10 pts.)
  - Literature Review (10 pts.)
  - Methods Section (10 pts.)
  - Results (10 pts.)
  - Discussion (10 pts.)
- Complete EndNote Library (50 points)

Class Attendance & Participation  100 points miss 0-1 day
  This applies to excused absences  75 points miss 2-3 days
  there will be no unexcused absences  50 points miss 4-5 days
  0 points miss 6+ days
Participation Evaluation 100 points
This grade will reflect your individual contribution as evaluated by your group. Group members will grade you on each of the following duties on a scale of 1 to 10: (Scores will be averaged.)

Leadership Role (100 points)
1. Be the point of contact for all group members and the direct contact (if necessary) between the group and the professor of the course, Dr. Lupton.
2. Schedule and conduct regular group meetings (weekly, bi-weekly)
3. Assign responsibilities to group members including:
   a. Searching different databases
   b. Distributing journal articles to group members for part/full evaluation
4. Regularly cross-check group member quality rating and categorizing articles appropriately.
5. Manage the master EndNote® Library for the group
6. Keep clear records and monitor the work of all group members (e.g., uploading the spreadsheet of articles on Google Groups® or another equivalent program).
7. Encourage and support undergraduate group members to complete work in a timely manner
8. Set realistic group deadlines to complete assigned work
9. Offer support to undergraduate students as needed for their written and oral presentations.
10. Set up meetings with librarians and reserve study rooms for group meetings

Final Presentation (50 points)
30 minute oral discussion/presentation (time and day TBD)
1. The graduate student must be able to orally demonstrate their performance as a team leader in the following areas:
2. Provide examples on how the graduate student motivated their group;
3. What the student would change about the way they managed their group;
4. How the student will use what they learned from the course for job applications or future research projects;
5. Strategies used to keep the group on task;
6. Strategies used to organize a large set of data;
7. Personal strengths and weaknesses with managing a group of people;
8. What grade does the student think he/she deserves

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<th>Grading Scale:</th>
<th>TOTAL</th>
<th>750 points</th>
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<td>90-100%</td>
<td>A</td>
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<td>59% and below</td>
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Make-up Policy: Make-up oral presentations or late written assignments will be penalized 5% per day.

Americans with Disabilities Policy Statement: The Americans with Disabilities Act (ADA) is a federal antidiscrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this legislation requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation of their disabilities. If you believe you have a disability requiring an accommodation, please contact Disability Services, Room B-118 of Cain Hall, or call 845-1637.

Academic Integrity and Honesty: The handouts used in this course are copyrighted. By “handout”, I mean all materials generated for this class, which include but are not limited to syllabus, in-class materials, and handouts. Because these materials are copyrighted, you do not have the right to copy the handouts, unless I expressly grant permission. As commonly defined, plagiarism consists of passing off as one’s own the ideas, words, writings, etc., which belong to another. In accordance with this definition, you are committing plagiarism if you copy the work of another person and turn it in as your own, even if you should have the permission of that person. Plagiarism is one of the worst academic sins, for the plagiarist destroys the trust among colleagues without which research cannot be safely communicated.

For many years, Aggies have followed a Code of Honor in an effort to unify the aims of all Aggies toward a high code of ethics and dignity. It functions as a symbol to all Aggies, promoting understanding and loyalty to truth and confidence in each other.

“Aggies do not lie, cheat or steal; nor do they tolerate those who do”

If you have any questions regarding plagiarism or cheating, please consult the Texas A&M University Student Rules, under the section Scholastic Dishonesty.

L.E.A.D.S. (Listen-Educate-Act-Dial-Seek):

Action to take during a campus emergency or Code Maroon

http://studentaffairs.tamu.edu/emergency

CLASS SCHEDULE

Week 1
Day; Date Introduction to the class. How we will work together and how you will be evaluated. What is an evidence-based review? How we will do the review for this class.
Day; Date  How to do an evidence-based review and examples. Students to purchase EndNote® from TAMU Software Licensing Library (https://software.tamu.edu).

Week 2
Day; Date  Class on how to use Endnote. Robin Sewell, Endnote specialist. Insert location.
Day; Date  Class on how to do an evidence-based review literature search. Margaret Foster, evidence-based review expert and librarian.

Week 3
Day; Date  Team assignment #1 due (search terms, databases, inclusion/exclusion criteria). Your search terms, databases etc. are to be presented in class. The people who present the information can earn up to 10 points towards their 100 total. The people who write it up can earn up to 20 points towards the total. Lecture, Where we are now and next steps.
Day; Date  How to classify studies as A, B, C, D based on experimental design. Written report for assignment #1 due. Distribute take home activity #1 – identify the study design from provided research papers.

Week 4
Day; Date  Go over the take home activity #1. Students will learn how to abstract primary articles. Distribute take home activity #2 – read the provided abstraction worksheet from an American Dietetic Association (ADA) analyst.
Day; Date  Answer student questions about the sample abstraction worksheet. Assignment #2 due. Must hand in for your group a complete list of all papers selected, and a flowchart showing total number of manuscripts found from search, number not used, etc. We will supply an example. People presenting this will get a maximum of 10 points. The people who write it up earn up to 20 points towards the total. Each graduate student leader will email the EndNote® Library for their group over the weekend.

Week 5
Day; Date  Written report for assignment #2 due. Primary articles will be assigned to all class members to abstract. Each student is a primary reviewer on their manuscripts and a secondary reviewer on another person’s manuscripts. Begin abstracting manuscripts. Guest lecturer, statistics review.
Day; Date  Assignment #3 due. Written materials and methods due. The people who write it can earn up to 20 points towards the total. How to critically evaluate a manuscript.
Week 6
Day; Date Help with abstracting and critically evaluating manuscripts.
Day; Date Paper #1 oral presentation (maximum 50 points). 3-4 presentations. s are due the following class period after your presentation including the abstraction worksheet and quality criteria checklist (maximum 50 points).

Week 7
Day; Date Paper #1 oral presentation. 3-4 presentations.
Day; Date Paper #1 oral presentation. 3-4 presentations.

Week 8
Day; Date Paper #1 oral presentation. 3-4 presentations.
Day; Date Paper #1 oral presentation. 3-4 presentations.

Week 9
Day; Date Paper #2 oral presentation (maximum 50 points). 3-4 presentations. Written reports are due the following class period after your presentation including the abstraction worksheet and quality criteria checklist (maximum 50 points).
Day; Date Paper #2 oral presentation. 3-4 presentations.

Week 10
Day; Date Paper #2 oral presentation. 3-4 presentations.
Day; Date Paper #2 oral presentation. 3-4 presentations.

Week 11
Day; Date Paper #2 oral presentation. 3-4 presentations.
Day; Date The graduate student leader will submit their groups EndNote® Library including attached pdfs and abstraction worksheets.

Week 12
Day; Date Writing; identify patterns and themes.
Day; Date Writing; identify patterns and themes. Describe take home assignment #3 (due week 13).

Week 13
Day; Date Writing; identify patterns and themes. Class discussion of sub-question spreadsheets. Graduate students signup for a 30 minute time slot to complete your final oral presentation (due by week 15).
Day; Date Writing; identify patterns and themes. Assign groups for the final oral presentation and written report.

Week 14
Day; Date Writing; identify patterns and themes.
Day; Date        Writing; identify patterns and themes. Develop conclusion statement.

Week 15
Day; Date        Final Exam time. Final presentations for all groups. Written reports due (5 pm the day before the final exam time).

Note: Although there will be no final exam, the final exam slot will be reserved for final presentations
Nutrition 489  
(Stacked with NUTR 689)  
Critical Evaluation of Nutrition & Food Science  
Literature: Evidence based reviews  
Course Syllabus, Semester, year

Instructor: Name; office; email

Teaching Assistants: Name; email

Time/Location: Day; time  
Location

Textbook: There is no textbook for the class. All readings will be based on current literature.

Course Description:  
This course is designed to develop a critical approach to evaluating the quality of the scientific literature in areas specific to nutrition and food science. The goal is to actually produce an evidence-based review by the class which could be submitted for publication. Students will learn how to develop search terms and search the scientific literature, how to categorize papers into types of studies, how to evaluate the quality of an individual study, and how to produce an evidence based review of the complete literature on a specific topic that is suitable for publication.

Prerequisites: Nutrition 203 and Stat 302  
The following knowledge base is expected of all students entering this class: A fundamental knowledge of nutrition, statistics, and technical writing.

Course Objectives: With successful completion of the course, you will have achieved:  
1. An understanding of how to pose an appropriate question for evaluation by an evidence-based review of an important issue in nutrition and develop search terms and strategies to uncover all relevant literature.  
2. An understanding of the different types of studies in nutrition (randomized clinical trials, prospective epidemiological studies, case control studies, etc.) and the issues of bias associated with each type of study.  
3. An understanding of what makes an excellent scientific study and what detracts from a study being categorized as excellent (appropriate controls, statistics, length of study, how the intervention might affect the rest of the diet, etc.)
4. Knowledge of how to pull together all of the evaluated research studies into one evidence based review and come to a conclusion as to the strength of the science behind the posed question.
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Specific Learning Objectives: Students should know and be able to communicate verbally and in writing with specific examples:
1. How to conduct a formal evidence-based literature search and find all appropriate publications.
2. How to categorize a study as to the type of study and evaluate study type with respect to bias.
3. How to evaluate the quality of an individual study and rate it as excellent, good, or poor.
4. How to come to a conclusion based on the totality of the studies reviewed.
5. How to report the findings once the evidence-based review is complete.
6. How to present and defend their decisions.
7. How to work with others in a synergistic manner.

Evaluation: 3 oral presentations, 50 points each
   3 written presentations, 50 points each
   Class attendance and participation in discussions and presenting for your group (100 points) (50 points for coming every time and participating).
   The other 50 is earned by presenting for the group, or writing for the group.
   Contribution to your work group (evaluated by that group) and as evidenced from your written contributions (100 points)

Total points = 500

Grading Scale: 90-100% TOTAL A 70-79 C
   80-89 B 60-69 D
   59% and below F

Make-up Policy: Make-up oral presentations or late written assignments will be penalized 5% per day.

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L.E.A.D.S. (Listen-Educate-Act-Dial-Seek):

Action to take during a campus emergency or Code Maroon

http://studentaffairs.tamu.edu/emergency \\

**CLASS SCHEDULE**

**Week 1**

*Day; Date* Introduction to the class. How we will work together and how you will be evaluated. What is an evidence-based review? How we will do the review for this class.

*Day; Date* How to do an evidence-based review and examples. Students to purchase EndNote® from TAMU Software Licensing Library (https://software.tamu.edu).

**Week 2**

*Day; Date* Class on how to use Endnote. Robin Sewell, Endnote specialist. Insert location.

*Day; Date* Class on how to do an evidence-based review literature search. Margaret Foster, evidence-based review expert and librarian.

**Week 3**
Day; Date  Team assignment #1 due (search terms, databases, inclusion/exclusion criteria). Your search terms, databases etc. are to be presented in class. The people who present the information can earn up to 10 points towards their 100 total. The people who write it up can earn up to 20 points towards the total.

Lecture, Where we are now and next steps.

Day; Date  How to classify studies as A, B, C, D based on experimental design.

Written report for assignment #1 due. Distribute take home activity #1 – identify the study design from provided research papers.

Week 4
Day; Date  Go over the take home activity #1. Students will learn how to abstract primary articles. Distribute take home activity #2 – read the provided abstraction worksheet from an American Dietetic Association (ADA) analyst.

Day; Date  Answer student questions about the sample abstraction worksheet. Assignment #2 due. Must hand in for your group a complete list of all papers selected, and a flowchart showing total number of manuscripts found from search, number not used, etc. We will supply an example. People presenting this will get a maximum of 10 points. The people who write it up earn up to 20 points towards the total.

Each graduate student leader will email the EndNote® Library for their group over the weekend

Week 5
Day; Date  Written report for assignment #2 due.

Primary articles will be assigned to all class members to abstract. Each student is a primary reviewer on their manuscripts and a secondary reviewer on another person’s manuscripts. Begin abstracting manuscripts.

Guest lecturer, statistics review.

Day; Date  Assignment #3 due. Written materials and methods due. The people who write it can earn up to 20 points towards the total.

How to critically evaluate a manuscript.

Week 6
Day; Date  Help with abstracting and critically evaluating manuscripts.

Day; Date  Paper #1 oral presentation (maximum 50 points). 3-4 presentations.

Written reports are due the following class period after your presentation including the abstraction worksheet and quality criteria checklist (maximum 50 points).

Week 7
Day; Date  Paper #1 oral presentation. 3-4 presentations.

Day; Date  Paper #1 oral presentation. 3-4 presentations.
Week 8
Day; Date  Paper #1 oral presentation. 3-4 presentations.
Day; Date  Paper #1 oral presentation. 3-4 presentations.

Week 9
Day; Date  Paper #2 oral presentation (maximum 50 points). 3-4 presentations.
Written reports are due the following class period after your presentation including the abstraction worksheet and quality criteria checklist (maximum 50 points).
Day; Date  Paper #2 oral presentation. 3-4 presentations.

Week 10
Day; Date  Paper #2 oral presentation. 3-4 presentations.
Day; Date  Paper #2 oral presentation. 3-4 presentations.

Week 11
Day; Date  Paper #2 oral presentation. 3-4 presentations.
Day; Date  The graduate student leader will submit their groups EndNote® Library including attached pdfs and abstraction worksheets.

Week 12
Day; Date  Writing; identify patterns and themes.
Day; Date  Writing; identify patterns and themes. Describe take home assignment #3 (due week 13).

Week 13
Day; Date  Writing; identify patterns and themes. Class discussion of sub-question spreadsheets.
Day; Date  Writing; identify patterns and themes. Assign groups for the final oral presentation and written report.

Week 14
Day; Date  Writing; identify patterns and themes.
Day; Date  Writing; identify patterns and themes. Develop conclusion statement.

Week 15
Day; Date  Final Exam time. Final presentations for all groups. Written reports due (5 pm the day before the final exam time).

Note: Although there will be no final exam, the final exam slot will be reserved for final presentations.
APPENDIX B

GRADUATE STUDENT RESPONSIBILITIES AS TEAM LEADERS
Graduate student responsibilities as team leaders:

1. Serve as the point of contact for all undergraduate students and the direct contact (if necessary) between the group and the professor of the course.
2. Schedule and conduct regular meetings (weekly, bi-weekly) among the group.
3. Assign responsibilities to group members including:
   a. Searching different databases
   b. Distributing journal articles to group members for part/full evaluation
   c. Assist with abstracting papers, identifying the independent/dependent variables, etc.
4. As necessary offer support to group members and make sure they are categorizing and rating articles correctly
5. Keep track and update the master EndNote Library
6. Monitor the work of all group members. This is easy to do by uploading a spreadsheet of articles that need to be evaluated on Google Groups. The team leader will have access to go online and see the work group members had done and had not done.
7. Contact group members and gently “push” them to get their work done, offer help, and support
8. Offer support to undergraduate students as needed for their written and oral presentations.
9. Set up meetings with librarians and reserve study rooms (also can be done by other group members)
APPENDIX C

INSTRUCTOR POWER POINT® PRESENTATION
Week 1: Nutrition and Food Science 489/689 introduction

Nutrition and Food Science 489/689
Evidence based reviews: A critical evaluation of the nutrition/food science literature

Insert instructor name
Email address
Phone number

Evidence based reviews

- What is an evidence-based review
  - Rules are set "up front" then followed rather than having a preconceived idea, then finding the papers to support the idea.
- If one follows the rules, any trained scientist should come to the same conclusion.

- Why should you care
  - The government now requires all groups that develop public policy to use evidence-based reviews
    - Data Quality Act, 2001
    - Dietary Guidelines
    - FDA for health claims

- Why are evidence-based reviews important
  - Provide conclusions based on science with the least amount of bias and follow a specific methodology to decrease bias, consider all pertinent science on the topic, and have transparency.
My vision for how students will use this knowledge

- It will be a marketable skill
- TAMU can build up a cadre of reviewers to tackle projects
- Grad students – in defense of their thesis/dissertation
- Dietitians – to come to conclusions on nutrition issues

Syllabus: Facts about the class

<table>
<thead>
<tr>
<th>Textbook:</th>
<th>No book, current articles and handouts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Will send PDFs by email in advance of class.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Description:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designed to develop a critical approach to evaluating the quality of the scientific literature in areas specific to nutrition and food science.</td>
</tr>
<tr>
<td>Goal is to produce an evidence-based review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Course Description: (cont.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will learn</td>
</tr>
<tr>
<td>How to develop search terms and search the literature.</td>
</tr>
<tr>
<td>How to categorize papers into types of studies</td>
</tr>
<tr>
<td>How to evaluate the quality of an individual study</td>
</tr>
<tr>
<td>How to produce an evidence-based review</td>
</tr>
</tbody>
</table>
Syllabus: Facts about the class (Cont.)

- **Prerequisites:**
  - Nutrition 202 or 203 and Stat 302
  - Knowledge of nutrition, statistics, and technical writing

- **Course Objectives:**
  (cont.)
  - If you successfully complete this course you will have achieved:
    - An understanding of how to pose an appropriate question for evaluation by an evidence-based review of an important issue in nutrition and develop search terms and strategies to uncover all relevant literature.

---

Course Objectives

- **If you successfully complete this course you will have achieved:**
  - An understanding of how to pose an appropriate question for evaluation by an evidence-based review of an important issue in nutrition and develop search terms and strategies to uncover all relevant literature.

- **An understanding of the different types of studies in nutrition**
  - Randomized clinical trial
  - Prospective epidemiological studies
  - Case control studies...
  - And, the issues of bias associated with each type of study
Course Objectives

- An understanding of what makes an excellent scientific study and what detracts from a study being categorized as excellent
  - Controls
  - Statistics
  - Length of study
  - The rest of the diet
- Knowledge of how to pull together all of the evaluated research studies into one evidence-based review and come to a conclusion as to the strength of the science behind the posed question

Course Objectives

- Experience in presenting and defending your evaluations and conclusions
## Specific Learning Objectives

**Students should know and be able to communicate verbally and in writing with specific examples**

1. **How to conduct a formal evidence-based literature search and find all appropriate publications.**
2. **How to categorize a study as to the type of study and evaluate study type with respect to bias.**
3. **How to evaluate the quality of an individual study and rate it as excellent, good, or poor.**
4. **How to come to a conclusion based on the totality of the studies reviewed.**
5. **How to report the findings once the evidence-based review is complete.**

6. **How to present and defend their decisions.**
7. **How to work with others in a synergistic manner.**
### Student Evaluation

**Undergraduate**
- Class attendance & participation (50 pts)
- Presenting/writing on behalf of the group (50 pts)
- 3 individual written presentations (50 pt each)
- 3 individual oral presentations (50 pt each)
- Peer evaluation (100 pts)

Total points = 500

**Graduate**
- Additional points system
  - Completion of the manuscript (100 pts)
  - Leadership role (100 pts)
  - Final oral presentation with the instructor (50 pts)

Total points = 750

90-100% = A; 80-89% = B; 70-79% = C; 60-69% = D; 59% and below = F

### Graduate Students
- Will act as team leaders for each of the evidence-based review teams.
- Will coordinate the teams, and make sure that the team functions as a team.
- Will be responsible for taking each segment of completed work from the team and writing it up in manuscript form.

It will be the responsibility of the graduate student (with help from the rest of the team) to prepare a draft manuscript for the final.
Major components of evidence-based systems

- Define the question/statement
- Collect all relevant studies
- Evaluate each study independently for:
  - Type of study (e.g. randomized clinical trial vs observational study)
  - Quality of study
- Rate the strength of the body of evidence
- Report the strength of the science and come to a conclusion

Defining the question

- Defining the question determines the search and the conclusion
- Is fish protective against CHD?
- Are omega 3 fatty acids...
- Is alpha linolenic acid...
#1 Separation of human studies from other types of data and information

- Non-human studies and other articles may be used as background
  - Animal studies
  - *In vitro* studies
  - Review articles
  - Meta analyses, unless they review all the publicly available studies

Steps in the American Dietetic Association Evidence Analysis Process*

- Select topic and assign teams
- Define questions and determine inclusion/exclusion criteria
- Conduct literature review for each question
- Analyze articles/Critical appraisal
- Complete an abstraction worksheet for all primary articles for the EBR
- Organize primary articles by quality rating and identify patterns and themes among the research
- Develop conclusion statement
- Submit a draft of the manuscript (final exam)

*Some steps have been modified to meet class needs
Summary

ADA’s Evidence Analysis Library can be found at
www.adaevidencelibrary.com
Week 1: How to do an evidence-based review

How to do an evidence-based review (with case examples from health claims submitted to FDA)

Components of an Evidence-based Review

- Define the question/statement
- Collect all relevant studies
- Evaluate each study independently for
  - Type of study (e.g. randomized clinical trial v observational study)
  - Quality of study
- Rate the strength of the body of evidence
- Report the strength of the science and make a recommendation
**End Result of Using the Evidence-based Ranking System**

- A statement linking a substance to a disease/health-related condition with a ranking as to the scientific evidence behind that statement.
  - A clear and transparent demonstration of which research studies were evaluated to provide the ranking.
  - Evidence tables showing the rigor of the evaluation.
  - Trained scientists should come to similar conclusions using the same data base.

---

**Health claims**

**What is a Health Claim**
- An express or implied statement in food labeling about the relationship of a food substance to a disease or health-related condition.

**Requirement**
- Must be about reducing the risk of a disease or health-related condition, not treating, mitigating, or curing diseases.

*Whitaker v. Thompson, 353 F.2d 947 (D.C. Cir. 2004)*
Current FDA Policy on Evaluating Health Claims

- The process for evaluating health claims applies to both conventional foods and supplements.
- Letters of enforcement discretion lay out agency thinking and criteria for health claim evaluation.

Available on the CFSAN website: www.cfsan.fda.gov

FDA’s Evidence-based review system

- New Guidance
  - July 9, 2007
- Shows their health claim evaluation process
- Same process for significant scientific agreement and a qualified claim

http://www.cfsan.fda.gov/guidance.html
**FDA enforcement discretion letters**

- Provide important information on how FDA evaluates health claim petitions
- [http://www.cfsan.fda.gov/~dms/qhc-sum.html](http://www.cfsan.fda.gov/~dms/qhc-sum.html)

---

**#1 Separation of human studies from other types of data and information.**

- Non-human studies and other articles may be used as background
  - Animal studies
  - *In vitro* studies
  - Review articles
  - Meta analyses, unless they review all the publicly available studies
#2 Have the studies identified and measured the substance and the disease

- Substance “X” reduces the risk of disease “Y” in (name the population)
  - Define the substance
  - Define the disease
- Need to test substance “X” and its effect on disease “Y”.

- Substance “X” has to be measurable.
- Disease “Y” has to be measurable as incidence, associated mortality or validated surrogate endpoints
  - These endpoints must be recognized by FDA

LDL cholesterol; total cholesterol; blood pressure
#3 Studies are characterized by type

- **Intervention Studies**
  - Randomized clinical trials are the gold standard
  - Must be able to extrapolate to the population of interest from the subjects of the trial

- **Observational Studies**
  - Higher rating for reliable biomarkers of intake of a substance.
  - Prospective (cohort studies) rated higher than retrospective.

#4 Seriously flawed studies are eliminated from further consideration

- If studies are so flawed that they make it impossible to draw scientific conclusions from the study they will be eliminated.

- **Serious flaws (Intervention Studies)**
  - Subjects already have the disease
  - Unless it is scientifically appropriate to extrapolate to individuals without the disease.

- **No appropriate control group**
  - Control too dissimilar to intervention group
  - Diet must be similar except for the intervention
  - Effects of the substance are not independent
  - Substance is part of a supplement or a mixture.
  - E.g. If substance is a lutein intervention cannot be spinach or a multivitamin.
Potentially serious study flaws

- Inappropriate statistics
  - E.g. multiple T tests
- Unapproved surrogate markers
- Insufficient length of study to detect the endpoint
- Lack of documentation that subjects actually followed the diets
  - Was advice followed
- Study population not relevant to general US population

Rest of the evaluation process

- #4 (Continued) Observational studies subjected to review for flaws that would eliminate further consideration
- #5 Remaining studies assessed for quality
  - High, moderate, low quality
- #6 Total evidence based on “surviving” studies
  - Quality and quantity of evidence
  - Relevance to US population
  - Overall consistency of the body of evidence
Case Study: Corn oil

“Substituting corn oil for solid fats may reduce your risk of heart disease.”
- Submitted 120 publications
- Step #1: Eliminate non-human studies
- 45 were not human studies

120 → 75

Case Study: Corn oil

- Step #2
  - Characterize the substance and the disease
  - 29 studies did not evaluate the substance and disease relationship
- Step #3
  - Studies characterized by type
    - Intervention (44)
    - Observational (2)

75 → 46
Case Study: Corn oil

- **Step #4: Evaluate the intervention studies for flaws**
  - No validated surrogate endpoint (3)
  - No control group consuming SFAs (7)
  - Duration too short (17)
  - Insufficient information on diet (2)
  - No statistics between control and intervention group (6)
  - Studies were replicates of each other (7)

- **Step #4: Evaluate the observational studies**
  - No validated surrogate endpoint (1)
  - No control group consuming SFAs (1)

46 → 3 studies

---

Case Study: Corn oil

- **Claim:**
  Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 g) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil.

3 studies
Case study: Green Tea and Reduced risk of cardiovascular disease (May 9, 2006)

- Model health claim
  Daily consumption of at least 5 fluid ounces (150 mL) of green tea as a source of catechins may reduce a number of risk factors associated with cardiovascular disease...

105 publications submitted

Case study: Green Tea and Reduced risk of cardiovascular disease (May 9, 2006)

- Step #1: Eliminate non-human studies (53)
  - 105 → 52
- Step #2: Eliminate studies that did not address the substance disease relationship (16)
  - 52 → 36
- Set #3: 27 intervention; 9 observational
Case study: Green Tea and Reduced risk of cardiovascular disease (May 9, 2006)

- Step #4: Eliminate studies with fatal flaws (intervention trials)
  - No valid endpoint (11)
  - Two studies were duplicates (2)
  - Improper control group (6)
  - Improper statistics (3)
  - 29 → 7

- Step #5: Evaluate the studies for quality
  - Of the remaining studies
    - None of the seven showed a significant effect of the intervention (either green tea or green tea extracts) on any surrogate endpoint.

Case study: Green Tea and Reduced risk of cardiovascular disease (May 9, 2006)

- The four observational studies (all retrospective) had inconsistent results.
  - 3 reported a correlation with green tea and decreased risk of CVD
  - 1 did not show a correlation

- Because of the 7 intervention studies which showed no effect, the petition was denied.
Case Study: enhanced omega-3 fatty acid eggs

- Consumption of one egg per day containing 660 mg of omega-3 fatty acids with a balanced ratio of omega-3 to omega-6 fatty acids (1:1) may reduce the risk of heart disease and sudden, fatal heart attack.

Case Study: enhanced omega-3 fatty acid eggs

- Major issues with FDA's consideration of a qualified health claim
  - Step #1. 74 publications (26 non human) → 46
    - Step #2. The substance. The substance is the egg with a specific fatty acid composition
      - 18 intervention trials
        - Used a fish oil supplement (7)
        - Other omega 3 supplements (8)
      - Step #2. The substance (cont.)
        - Three diet modification interventions, very different diets, much greater modification than 1 egg would make (3)
    - Step #4. Three clinical trials with the eggs:
      - No statistical comparison between groups (1)
      - No diet composition (1)
      - No control group (1)
Case Study: enhanced omega-3 fatty acid eggs

- Major issues with FDA’s consideration of a qualified health claim
  - Step #1. 74 publications (28 non human) → 46

  - Step #2. The substance. The substance is the egg with a specific fatty acid composition
    - 18 intervention trials
      - Used a fish oil supplement (7)
      - Other omega 3 supplements (5)

  - Step #3. Three diet modification interventions, very different diets, much greater modification than 1 egg would make (3)

  - Step #4. Three clinical trials with the eggs.
    - No statistical comparison between groups (1)
    - No diet composition (1)
    - No control group (1)

In summary, FDA concludes that among the 18 clinical intervention trial reports included in the petition, none is useful in evaluating the effects of PUFA-enriched eggs on heart disease risk.

Even if there were credible evidence for the proposed claim, PUFA-enriched eggs would be disqualified from bearing a health claim because of their cholesterol content.
Questions?
Week 3: Where we are now and next steps

Where we are now and next steps

Overview of today’s class

- Present an overview of each step that we have to go through.
- Look at where we are now and get consensus on whether or not we have sufficient studies and the questions are appropriate.
- Describe the next step which is “abstracting the studies.”
- Describe assignment #2 in detail and allow time for teams to decide on how to do assignment #2.
- Describe the take home assignment.
Review of the steps of doing an evidence-based review

1. Select a topic
   a. Define the question's

2. Define the search
   a. Search terms
   b. Databases
   c. Inclusion/exclusion criteria

3. Conduct the search
   a. Write up the search strategy
      b. Search terms
      c. Databases
      d. Inclusion/exclusion criteria
   b. Write up the results of the search
      - Total # retrieved; numbers and rationales for exclusion; get to the final number

4. Divide the remaining studies into
   - Primary research
   - Secondary research

5. Assign ~ same # of primary and secondary studies to each reviewer

6. Each reviewer begins abstracting a study
   - Do not classify the study or determine its quality
   - Abstracting forms are available in class/online, all must follow the same format
Review of the steps of doing an evidence-based review

- 7. Review each abstracted study for the type of experimental design (A, B, C, D)
- 8. Review each study for the quality of the study and fill out the quality form (+, - or null)
- 9. Take all of the individual studies and put into one large table (excel spreadsheet – week 12 and 13)
- 10. Determine patterns among the studies and organize the studies accordingly (week 13)
- 11. Write up the results of each “pattern” identified in #10.
- 12. Write the overall conclusion statement based on the overall evidence you have (in class, week 14).
- 13. Write the Manuscript (week 15, final)
  - Write the introduction as to why your question is important and where the gaps are in the literature
  - Write the materials and methods section
  - Write the results and refer to the tables
Review of the steps of doing an evidence-based review

13. Write the Manuscript (cont.)
   - Come to a conclusion on each of the three questions.
   - Come to an overall conclusion.

Overview of today’s class

- Present an overview of each step that we have to go through.
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Review of the steps of doing an evidence-based review

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      b. Search terms
      c. Databases
      d. Inclusion/exclusion criteria
   b. Write up the results of the search
      - Total # retrieved; numbers and rationales for exclusion; get to the final number

Step 1: Formulating the questions

- We have ____ questions. After the searches you have done do you feel that you have sufficient studies to address this question
Week 3: Type of study design

American Dietetic Association Evidence Analysis Library
- http://www.adaevidencelibrary.com/
Classifying the articles by type of research design

1. Divide into primary research and secondary research
   - Review
   - Meta-analysis or syntheses of previously reported studies

2. Type of research (by study design)
   - Study designs are organized into a hierarchy based on the ability of the design to test causal relationships.

We will use the classification system used by ADAs Evidence Analysis Process

- **Primary Reports**
  - A. Randomized controlled trial (RCT)
  - B. Cohort study
  - C. Nonrandomized trial with concurrent or historical controls
    - Case-control study
  - D. Cross-sectional study
    - Before and after study
Primary Reports

A. Randomized controlled trial (RCT)
- Patients/individuals randomized into an experimental group or control group
- Individuals are selected randomly
- “Gold Standard” study design – highest level of research design
- Double RCT

Primary Reports

B. Cohort study
- Observational study
- Group of individuals are followed over time
- Examples:
  - Diet records
  - Nurses Health Study
  - Framingham Heart Study
Primary Reports

C. Nonrandomized trial with concurrent or historical controls
   - Clinical trial with some sort of control but NOT randomized
   - Patients/subjects are non-randomly assigned to treatment, procedure, or intervention.

Primary Reports

D. Cross-sectional study
   - Observational study
   - Before and after
   - Snapshot – does not follow the same cohort of individuals overtime
Secondary reports

- Meta-analysis
- Systematic literature/evidence-based reviews
- Review article
- Consensus statement or consensus report

Questions…
Week 4: Abstracting primary articles

What is Abstracting?
- The process of critically appraising an article and capturing key information in an abstraction worksheet
- Each primary article that is critically reviewed and abstracted should be entered into the worksheet
- Worksheets are used to come to conclusions regarding the research question(s).
- Useful tool to:
  - organize information gathered in a consistent manor
  - collect author conclusions
  - locate reviewer comments
  - All abstraction worksheets should be uploaded to EndNote® along with the pdf of the article if not already attached.
<table>
<thead>
<tr>
<th><strong>Abstract Worksheet</strong> (Modeled after ADA Evidence Abstract Worksheet Template)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group Question:</strong></td>
</tr>
<tr>
<td><strong>Reviewer:</strong></td>
</tr>
<tr>
<td><strong>Date of review:</strong></td>
</tr>
<tr>
<td><strong>Complete Citation:</strong></td>
</tr>
<tr>
<td><strong>Study Design (A, B, C, D):</strong></td>
</tr>
<tr>
<td><strong>Quality Rating:</strong></td>
</tr>
<tr>
<td><strong>Research Purpose:</strong></td>
</tr>
<tr>
<td><strong>Inclusion Criteria:</strong></td>
</tr>
<tr>
<td><strong>Exclusion Criteria:</strong></td>
</tr>
<tr>
<td><strong>Description of Study Protocol:</strong> what happened in the study; describe interventions, regimens, risk factors, or procedures studied; when outcomes were measured; how intervening factors were managed.</td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
</tr>
<tr>
<td><strong>Blinding used (if applicable)</strong></td>
</tr>
<tr>
<td><strong>Intervention (if applicable)</strong></td>
</tr>
<tr>
<td><strong>Statistical Analysis</strong></td>
</tr>
<tr>
<td><strong>Data Collection Summary:</strong> outcome(s) and other indicators; important variables and methods of measurement; was blinding used? Basis for study eligiblity</td>
</tr>
<tr>
<td><strong>Timing of Measurements</strong></td>
</tr>
<tr>
<td><strong>Dependent Variables</strong> (Note: some correlation, descriptive studies do not designate independent and dependent variables. In that case, just list key study variables).</td>
</tr>
</tbody>
</table>

**Abstracting Instructions**

- **Group Question**
- **Reviewer**
- **Date of Review**
- **Complete citation: In the Journal of the American Medical Association (JAMA) format**
- **Study Design: A, B, C, or D**
- **Quality rating: (+, Ø, -); we will learn this next week**

Abstracting Instructions

- **Research purpose:** Statement of purpose or research question (usually 1-2 sentences)
- **Inclusion criteria:** Requirements for study eligibility
  - Use bullets
  - Informed consent if mentioned
- **Exclusion criteria:** Items that disqualify an individual
  - Use bullets
  - Sometimes they are opposite from inclusion criteria
  - E.g.; include individuals over the age of 20 = exclude individuals 19 and younger

---

**Abstracting Instructions:**

**Description of Study Protocol**

- **Recruitment:**
  - E.g.: recruited from clinics or grocery stores; random selection based on census data
- **Blinding used:**
  - List if the author mentions blinding of subjects, providers, and/or investigators/data collectors. If not, assume no blinding was used and write “no-blinding”
Description of Study Protocol

- Description of study protocol:
  - Give the highlights of the study
  - Types of comparisons or groups
  - Methods of assignment to groups (random, convenience, etc.)
  - Number and timing of data collection points
  - Procedures for follow up of subjects
  - If applicable, list treatment and control or comparison groups

Intervention

- List the intervention, regimen, risk factors or procedures studied
- Include type, dose, duration or intensity
- Usually the independent variable
  - E.g.: counseling by dietitians
  - Administration of a zero (0) kcal snack, 150 kcal snack, or 300 kcal snack
  - Medication management to control blood glucose between 80 and 140 mg/dL
Abstracting Instructions: Description of Study Protocol

- Statistical Analysis:
  - Name the statistical tests used
  - Indicate if multivariate analyses were done to control or adjust for other variables
  - Intent to treat analyses applies to any type of intervention study (pre-post, nonrandom trial and RTCs)
  - Report the results of a power analysis if one was conducted. This is the probability that the test will reject a false null hypothesis (or Type 2 error). The author will say something like *n subjects were needed for 80% power*

Abstracting Instructions: Data Collection Summary

- Timing and method of measurements:
  - E.g.: Weight loss was tested at 3 months, 6 months, and 1 year
  - Hemoglobin A1c was tested at baseline and at quarterly clinic visits
  - Subjects completed a validated food behavior checklist and were weighed at baseline, 6 and 12 months
Abstracting Instructions: Data Collection Summary

- Dependent variables (outcomes):
  - E.g.: Percent of body weight lost
  - Change in cholesterol levels
  - Change in hemoglobin A1c
- Independent variables
  - E.g.: Consuming a high fat/low carbohydrate diet
  - Method of nutrition counseling
- Control variables

Note: some correlation, descriptive studies do not designate independent and dependent variables. In that case, just list key study variables

Abstracting Instructions: Description of Actual Data Sample

- Initial n:
  - Report the number of participants who actually entered the study, not the number of individuals screened. List the breakdown of participants (e.g., males and females; obese and non-obese)
- Final n (attrition):
  - Accounts for dropouts
  - Attrition is important because loss of subjects leads to bias and weakens the validity of the study
  - A good quality study has a dropout rate of <20%
Abstracting Instructions:
Description of Actual Data Sample

- Age:
  - List the age range (usually in table format)
  - A difference is not significant unless P < 0.05
- Ethnicity: List this information if available, if not write “not described”
- Other relevant demographics
- Anthropometrics: Were groups the same or different on important baseline measures like BMI?
- Location: Report the city, state and/or country

Abstracting Instructions:
Summary of Results

- Primary findings:
  - Helpful to make tables here but do not copy all the tables from the article
  - List the findings that answer your research question; include quantitative information and statistical significance
  - List results that pertain to the dependent variables
  - Include P values or odds ratios with confidence intervals (CI)
  - If it was not significant, it may be helpful to summarize those points in a bulleted list
- Other findings: useful information you have not listed
Abstracting Instructions

- Author conclusions: Summarize what the author said
- Reviewer comments: always written in *italics*
  - List strengths or limitations you feel are important
- Funding source:
  - List the specific name of the funding source

Appropriate ADA Style

- Spacing:
  - Use a single space after punctuation (not double-space)
  - No comma before "and"
  - No comma before "or"
  - No spaces before and after =, < and > symbols (e.g., P>0.0001)
  - Use an extra space after these symbols when the following number is negative (< -1).
- Symbols:
  - Do not use a slash (/ ) to separate terms such as +/-; instead use ± or the greater than or less than symbol which you can then format the font to underline (< or >)
  - Write fractions as ¾ not 3/4.
Appropriate ADA Style

- Punctuation:
  - Periods and commas belong inside end-quotes
  - All other punctuation goes outside end-quotes
  - Italicize title of periodical
  - Use subscripts and superscripts appropriately: O$_2$ not CO$_2$; m$_2$ not m$_2$
  - P-Value expressed as capital P (P<.001)
  - Spell out integers zero through nine unless followed by decimal (one or 1.0)
  - Decimals must be preceded by 0. (P<0.001) not (P<.001).
  - Spell out percentile; not %ile
  - Spell out units of time: minutes not min; seconds not sec, etc.
  - Last bulleted item must end with punctuation
  - Capitalize L for liter (e.g., dl. and L) but not for milliter (ml is correct)
  - Always use comma separators: 1,000,000

Appropriate ADA Style

- Avoid the following frequent mistakes
  - Be sure to list units (patients were followed up at 6, 12 and 24) Is that 6 weeks or 6 months?
  - Define acronyms you are using on tables in the results sections. You can put a note under the table. For example not everyone would understand RYGBP. Spell it out somewhere as Roux-en-Y Gastric Bypass (RYGBP).
  - Data always “are” (not “is”) because data are plural. Datum is singular.
    - Nutrient data were obtained (no data was obtained)
Appropriate ADA Style

- Avoid the following frequent mistakes
  - Watch your subject/verb agreement—this must be the most common grammatical error (examples)
    - “Patients received an internal medicine and psychiatry evaluation” (better to say patients received internal medicine and psychiatry evaluations or patients received an internal medicine and a psychiatry evaluation)
    - “If there are treatment groups and a control, list them” is correct even if the grammar checker says it should read “there is treatment groups and...” treatment is an adjective modifying groups. It would not be correct to say is (singular) groups (plural).

Questions
Week 5: Organizing your slides for paper #1 and #2 oral presentations

Organization your slides for Paper #1 and #2 oral presentations

Full citation for study including: authors, title, Journal, volume, page numbers and date

Your question and your name

Slide Two

- Type of study (e.g. randomized control trial; cohort study, etc.)
- What was the purpose of the study?
  - The research question asked
  - What did the investigator want to find out?
- What was the population studied?
  - Country, male/female, age groups, anything else about the population (e.g. level of education)
Next Slides

- How was the population selected?
  - If an intervention study then were the intervention groups comparable?
  - Show us
  - If an observational study was it prospective or retrospective?
- Describe the intervention
  - What did subjects have to do?
  - Is this well described?
  - If this is not an intervention, how were the groups compared?

Next Slides

- What endpoint were measured and when were they measured?
  - If an intervention list each thing that was measured
  - If an observational study list what other aspects were “controlled for”
- What were the outcomes?
  - You need to show data
  - If there are large tables and the only parts pertinent to your question are one part of that table make new figures
Next Slides

- How were the data analyzed and which of the results were significantly different and which were not different?
  - Use a system to show what is different and explain your system
- What were the conclusions of this study?
- Do you agree with the conclusions (why/why not)?
- What were the limitations of the study?
- What quality rating did you award this study and why?

Next Slide

- Did this study help you answer your question?
  - If yes, say how
  - If no, say why
- Did you learn other things from this study?
  - Important papers to find from back-referencing
  - Things to look out for in the future
Final Slide

• Conclude with a slide to allow time for questions – this slide can be titled “Questions”
APPENDIX D

STUDENT HANDOUTS
Tips for conducting an online search

A. Broadly use key terms when initially searching for applicable articles. When you find a few applicable articles that discuss exactly what you are researching use their key terms either listed as key terms or words in the article or from the title or abstract. This will help the group narrow down their search for more relevant articles. It is suggested to narrow the initial search from review articles used for back-referencing. Back-referencing is the process of identifying relevant citations cited from articles that specifically answer the research question. Back-referencing helps not only identify articles that should be caught in your search but also narrow down search terms used in the papers. Articles should be equally divided among group members to back-reference. At this point in the search process, it is important to focus on how and if the articles answers your research question, not classifying the study design and determining the quality rating of the articles.

B. Deciding on key terms:

   a. If the topic you are searching is an international topic, review international journals for different phrases and spelling of terms (e.g., colors and colores; fiber and fibre, weight loss and slimming).
   b. If the group does a search in Medline Ovid and decides to limit the search to human subjects as a limit, select “not animal” instead of “human.” Often times “human” in Medline does not get tagged as a human study and key human articles may be excluded from the search (67).
   c. It may be necessary to add more search terms if more than 1000 articles are collected or add limits such as English language only, only males, or year limits (67).
   d. Use quotation marks around phrases that you wish to keep together. For example, “Nutrition Facts Panel” or “front-of-pack.” This is referred to as phrase searching.
   e. Use the same key terms for each database and use thesaurus terms. Thesaurus terms are a set list of terms determined by someone in which they determine how to best categorize the article. These terms will vary from database to database (67). This will expand your search specific to the database you are searching. Searching only one database will severely limit your search; therefore it is necessary to search more than one database. Note: Ebsco provides the option to search in all Ebsco databases including CINAHL and Medline at one time. To conduct a good systematic search it is recommended to search databases individually using the same key terms, not two or more at one time. Do not select this option in Ebsco.
f. Truncation is a search tool that offers flexibility within your search and allows the database to search for multiple forms of the key term(s) entered. For example, if a key term “snack*” is entered, articles with be identified that mention “snacks” and “snacking.” This allows the student to be more selective in their search. However, the truncated symbol is specific to the online database (see chart below).

<table>
<thead>
<tr>
<th>Truncation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Online Database/Vendor</strong></td>
</tr>
<tr>
<td>Medline Ovid</td>
</tr>
<tr>
<td>PubMed</td>
</tr>
<tr>
<td>CINAHL (ebsco)</td>
</tr>
<tr>
<td>PsycINFO (CSA)</td>
</tr>
<tr>
<td>Agricola (ebsco)</td>
</tr>
<tr>
<td>Cab Abstracts (Ovid)</td>
</tr>
</tbody>
</table>

g. Wildcard is another search tool to improve your overall search for relevant articles. A wildcard is a character or symbol such as an “?” or “#” that can be substituted in the middle of a key search term to allow your search to be more inclusive such as the inclusion of the international spelling of the same word. If a key term is “behavior,” written in the American language, it is important to include the international spelling, “behaviour.” To avoid searching for “behavior AND behaviour”, a wildcard character can be inserted. If searching in Ebsco the key term would look like this: “behavior#r.”

<table>
<thead>
<tr>
<th>Wildcard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Online Database/Vendor</strong></td>
</tr>
<tr>
<td>CINAHL (ebsco) &amp; Agricola (ebsco)</td>
</tr>
<tr>
<td>PsycINFO (CSA)</td>
</tr>
</tbody>
</table>

h. Proximity searching is a tool used to search for words that are closely related or in close proximity with each other. For example, if the student wants to find all articles that mention “food” and “label” either next to each other (“food label”) and also those articles that list “food” and “label” within two words of each other, the student would enter the key term like this: “food w2 label”.

Proximity searching

<table>
<thead>
<tr>
<th>Online Database/Vendor</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>CINAHL (ebsco) &amp; Agricola (ebsco)</td>
<td>N5 (near 5 words) or W2 (2 words after)</td>
</tr>
<tr>
<td>PsycINFO (CSA)</td>
<td>Near (within 10 words) or within # (# of words apart)</td>
</tr>
</tbody>
</table>

C. Popular online databases for food and nutrition journals (not all inclusive; accessible from www.library.tamu.edu)
   a. Medline Ovid
   b. PubMed
   c. CINAHL (ebsco)
   d. PsycINFO (CSA)
   e. Agricola (ebsco)
   f. Cab Abstracts (Ovid)

D. Subject headings. When searching Medline Ovid for “food label” multiple “subject headings” appear. “Subject headings” are another word for thesaurus terms. Selecting these terms can further narrow your search, however; it is important to click on “scope” before you select the subject heading term to determine its appropriateness as a search term (see Screen 1 below).
Clicking on “scope” for the subject heading “food labeling” (Screen 2) brings up useful information if the group selects “food labeling” as a search term. The MeSH (Medical Subject Headings) is the controlled vocabulary thesaurus for the National Library of Medicine. The terms are listed in a hierarchical order from basic to more specific (68). The MeSH database located at http://www.nlm.nih.gov/mesh/meshhome.html is useful to build search terms and find MeSH headings specifically to answer the research question. Screen 2 displays the MeSH subject heading as “food labeling” suggesting that even though the group may have typed in “food label” as their initial search term, “food labeling” is different terminology for a very similar concept. Also listed are other terms below in which “food labeling” can be used such as “food product labeling” and “nutrition labeling”.

Screen 1
E. To get a feel if the group’s search terms are pulling applicable articles to answer their specific research question the team leader should equally divide the articles among group members to review the title and abstract and crosscheck the applicability of the articles. Make a list of primary articles that directly answer the question. Refine the search terms to make the search more efficient yet making sure the original primary articles found are still collected in the refined search.

F. It is highly suggested to schedule group meetings in a study room at the Medical Sciences Library or another library in which group members can either checkout a laptop from the library or group members are able to bring their own laptop. This makes searching more efficient. All group members can use a computer at the same time and search different databases. Group members can discuss the articles they are finding and offer help to others as needed.

G. Keep track of all the searches each individual group member is conducting either in a Microsoft Excel spreadsheet, a word document, or a free online database such as Google Groups®. Communicate all searches with the group to avoid doing duplicate searches from the same databases and remain consistent with the overall key terms.

H. Make an appointment with a research librarian at the Medical Sciences Library or Margaret Foster at Evan’s Library after you have developed an idea of the area
you are researching and have conducted a few searches as a group. Librarian's can help narrow down your search terms and suggest applicable databases to search.

I. While searching to find applicable articles start thinking about a narrow focus you may want to research, inclusion/exclusion criteria, and discuss limits with your group such as a specific time-frame, English language, human studies, children vs. adults vs. adolescents, etc. The group must be able to rationalize the reason for each limit and inclusion/exclusion criteria. Inclusion criteria are specific characteristics you want to find in the articles (e.g., adults between the ages of 18 and 55, studies that test consumer use of the nutrition facts panel (NFP), subjects from the U.S. only). Exclusion criteria are characteristics you do not want to find in the articles (e.g., persons not between the ages of 18 and 55, studies that did not test consumer use of the NFP, subjects from areas outside of the U.S.).

J. Every group member should have EndNote® on their personal computer. EndNote can be purchased at no cost from the TAMU Software Licensing Library (https://software.tamu.edu).

K. When you find what seem to be applicable articles, don't get bogged down with the details from the text but read the abstract and if it seems to be in the ball park of your topic move on, you will do a much more in-depth look at the entire article later. But, of course if you think it is necessary to read the entire article than do so.

L. When the group feels comfortable and confident about the articles collected, upload the articles to EndNote®. The master EndNote® should be maintained by the team leader. The team leader will need to check for duplicate articles in EndNote®. It is helpful to have the pdfs of the articles attached to each citation if possible. Another helpful tool is creating a free account with an online database that allows each group to upload documents and communicate with all group members at one time such as Google Groups®. One account can be set up for the entire group. Google Groups® can be accessed from http://groups.google.com and is useful to upload a spreadsheet of all articles collected from the group and equally divide articles among members to review. This allows all group members to see an entire list of articles and make comments and rationalize why the article meets or does not meet the inclusion/exclusion criteria. Eventually, a second version of the spreadsheet will be updated including only applicable primary and secondary articles to be graded. This tool is very useful as a real time document; as soon as group members update the spreadsheet all other members are able to view changes right away. Often times sending multiple Microsoft Excel spreadsheets via email can cause confusion regarding which spreadsheet is the most updated.
M. If you are unable to electronically locate an article from the TAMU library website (http://library.tamu.edu/), under “get resources” select “Get it for me.” This is a service the library offers faculty, staff and students to locate and if necessary purchase articles that the TAMU library does not own. After the student sends in the request with the required information the library will email the article to the student. This can take up to 2 weeks but is often sent within a few days.
It is a good use of your time to begin organizing your EndNote® library now rather than wait until the last minute. After the primary articles are assigned equally to the class for abstraction (week 5) you will want to follow the suggestions below when organizing your library. This will save you time in the end when you begin to write the manuscript.

Note: some information below is specific to the Journal of the American Dietetic Association (J Am Diet Assoc) to provide students with an understanding of the details required by some journals. For specific instructions for authors of a specific journal visit the journal’s homepage to locate this information. Journals have different requirements for citing references, submitting tables/figures/graphs, the type of manuscripts they accept, word count, how to submit a manuscript, etc. Although the draft of the class manuscript will not be ready for publication, the class may agree on a journal they think the EBR would be most appropriate. Therefore the class would follow the instructions for authors for that specific journal.

As you find more articles to add to your EndNote® library some authors may have published more than one paper in one year. To avoid confusing one pdf from another, always save the pdf with the first authors last name, publication year, abbreviated journal title, and volume (e.g., Smith 2008 JADA 92). Always attach the pdf to the appropriate citation in EndNote® plus the completed abstraction worksheet.

Creating a bibliography format that EndNote® does not have in their “bibliographic output style.”

EndNote® does not include the “bibliographic output style” for the J Am Diet Assoc and some others. In other words, EndNote® will usually have the style of the journal you are looking for and will automatically format citations to meet the journal requirements. However, the J Am Diet Assoc uses a modified version to the Journal of the American Medical Association (JAMA) citation format (found in EndNote®) and therefore each student will need to modify this format to meet J Am Diet Assoc requirements.

The following are step-by-step instructions to personalize a bibliography style from scratch.

1. In EndNote® select “Edit” – “Output Style” – then “New Style”
2. Enter “JAMA” for the “Based on” category
   a. Enter “JADA” for the “Category”
   b. At the end EndNote® will ask you to name the bibliography format, name is “JADA edited” or something similar
3. Under Citations perform the following steps to create the format your citations will be displayed in the paper:
   a. Temples: Use the “Insert Field” tab and select “Bibliography Number”. In the paper citation number will be displayed in parenthesis. For example “(3)”.
   b. Ambiguous Citations: Do not select anything in this category
4. Under Bibliography perform the following steps to create the format your citations will be displayed at the bottom of the paper for the bibliography section:

a. **Temples:** Use the “Reference Types” to select the reference you want to edit. For this purpose select “Journal Article.” If you have other citations such as government documents or websites to cite in your paper you will select the appropriate “Reference Type” and choose the format you wish for it to be displayed. After you have selected “Journal Article” use the “Insert Field” tab to display this format: Author. Title. Journal. Year; Volume: Pages.

b. **Author Lists:** Delete “and” and add a comma plus 1 space: “[,]”. Do this for both of the “ands”. It should look like this: 1 to 2 / [,space] / [,space] and 1 to 100 / [,space] / [,space]. Next select “List all author names.” Note: some journals only want the first 3 authors listed and therefore you would adjust that information here. Delete “and” so that the author names are displayed without “and” before the final author.

c. **Author Name:** Following the J Am Diet Assoc requirements, the last name of all authors should come first followed by the initials (no spaces between the initials). Follow the format below:

   i. **First author:** “Smith Jane”
   
   ii. **Other authors:** “Doe John”
   
   iii. **Capitalization:** select “As Is”
   
   iv. **Initials:** “AB”

d. **Editor Lists:** Follow the same instruction at 4b above

e. **Editor Name:** Follow the same instructions as 4c above

f. **Layout:** From the “Insert Field” tab select “Bibliography Number”

g. **Sort Order:** This will determine how the citations are sorted in the bibliography of the paper. Some journals want the citations in alphabetical order based on the first authors last name while others want the citations ordered based on their appearance in the paper. For the J Am Diet Assoc select “Order of appearance.”

h. **Title Capitalization:** This determines how the title of the paper is displayed in the bibliography. The J Am Diet Assoc wants “sentence-style capitalization” – select this option.
5. Save the changes and double check that your citations are displayed correctly.
6. Select “Edit” – “Output Style” – then “Open Style Manager” and select “JADA edit”. Back out of it and “JADA edit” should now show up as an “Output Style” and this should be selected. All of your citations will now appear in your manuscript and in EndNote® following the JADA format as you have created.
7. For further EndNote® help contact a research librarian. The two EndNote® librarians at Texas A&M University (TAMU) are Robin Sewell (Medical Science Library); phone: 979-845-0650; Email: rsewell@medlib.tamu.edu and John Paul Fullerton (Evans Library); phone: 979-458-1393; Email: j-fullerton@tamu.edu.

**Abbreviating journal titles in EndNote®**

Some journals want you to abbreviate the journal title to save space in the paper. EndNote® can do this for you but it is important to always double check your citations in case EndNote® is unable to recognize the journal.

To modify your journal term list follow the instructions below:

1. In EndNote® go to “Tools” – “Open Term Lists” and select “Journal Term List”
   a. Select all the existing titles on the Journal Term List and delete them.
      This will not affect the title in your library citations
   b. Now click on the tab at the top of the window that says “Term Lists”
   c. Click on “Import Term list” and navigate to C:\Program
      Files\EndNote\Term Lists. Your computer may list the version of
      EndNote, for example EndNote X3.
      Import all the term lists that look like they will be relevant to your library
      by clicking on a list and opening it.
   d. Click on the “Journal List” tab to see what has been imported. You may
      need to go into the term list and add any journals that are missing.
      According to an EndNote® librarian, EndNote® does not have a good set
      for Nutrition journal abbreviations.
2. If EndNote® is unable to abbreviate a journal you have entered you have 3
   options of locating the correct abbreviation.
   a. Visit ftp://nlmpubs.nlm.nih.gov/online/journals/lsiweb.pdf to access the
      National Library of Medicine’s list of journal abbreviations (69), or…
   b. You can utilize PubMed to access approved journal abbreviations. From
      TAMU’s library website (www.library.tamu.edu) select “databases”, type
      “Pubmed” select the preferred version. Under “More resources” select
      “Journals in NSBI Databases”. At the top of the page type in the desired
      journal title and the approved list of abbreviations will appear. Note: In
      the J Am Diet Assoc requirements, if the journal does not have an official
      abbreviation than the full name of the journal should be displayed.
   c. A short list of journals and their abbreviations has been created for this
      class and can be found below.
Common journal abbreviations used for nutrition and food science journals.

Note: if a journal abbreviation does not exist the entire name of the journal will appear to the right.

Academy of Marketing Science Review: Academy of Marketing Science Review
Adolescence: Adolescence
American Journal of Health Promotion: Am J Health Promot
Appetite: Appetite
Australian Journal of Nutrition and Dietetics: Australian Journal of Nutrition and Dietetics
BMC Public Health: BMC Public Health
British Food Journal: Br Food J
Canadian Journal of Dietetic Practice and Research: Can J Diet Pract Res
Early Child Development and Care: Early Child Dev Care
European Review of Agricultural Economics: European Review of Agricultural Economics
Food Australia: Official Journal of CAFTA And AIFST
Food Policy: Food Policy
Food Quality and Preference: Food Qual Prefer
Health Economics: Health Econ
Health Promotional International: Health Promot Int
International Journal of Consumer Studies: International Journal of Consumer Studies
Journal of Advertising: J Advert
Journal of Agricultural Economics: Journal of Agricultural Economics
Journal of Behavioral Medicine: J Behav Med
Journal of Consumer Research: J Consum Res
Journal of Food Distribution Research: Journal of Food Distribution Research
Journal of Food Products Marketing: Journal of Food Products Marketing
Journal of Health Care for the Poor and Underserved: J Health Care Poor Underserved
Journal of Marketing: J Mark
Journal of Marketing Research: J Mark Res
Journal of Nutrition: J Nutr
Journal of Nutrition Education: J Nutr Educ
Journal of Nutrition Education & Behavior: J Nutr Educ Behav
Journal of Public Policy and Marketing Health Services: Journal of Public Policy and Marketing Health Services
Journal of Public Policy and Marketing: J Public Policy Mark
Journal of the American Dietetic Association: J Am Diet Assoc
Journal of the Science of Food and Agriculture: J Sci Food Agric
Nutrition Food Science: Nutr Food Sci
Nutrition Reviews: Nutr Rev
Nutrition Today: Nutr Today
Public Health Nutrition: Public Health Nutr
The Diabetes Educator: Diabetes Educ
The Journal of Consumer Affairs: J Consum Aff
The New Zealand Medical Journal: N Z Med J
Topics in Clinical Nutrition: Top Clin Nutr

Sample flow chart
Documents retrieved from electronic literature database: 978

Application of inclusion/exclusion criteria based on abstract and full text (if necessary).

Documents retained in full text for detailed examination based on inclusion criteria: 279

Documents excluded based on abstract and full text (if necessary): 699

Full text examined; articles categorized as primary and secondary research.

Final peer-reviewed articles (primary research) retained: 26

Secondary articles used for background information: 253

Question #1
Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product? 10*

Question #2
Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard BOP nutrition labels? 21*

Figure. Flowchart presenting the search results from electronic databases and back-referencing. Articles included in the systematic literature review addressed the two research areas: #1 Can consumers use FOP and standard BOP nutrition labels to select the more nutritious product? and #2 Do consumers change their purchasing and/or eating behavior because of the use of FOP or standard BOP nutrition labels?
*Overlapping articles exist among the 2 categories for the systematic literature review.
How to organize your articles and assign reviewers
As soon as each group has a final set of articles from each database all articles will need to be evaluated to determine if they answer the groups specific research question and meet the exclusion and inclusion criteria. The first round of evaluations can be performed by reading the title and abstract of the articles. If enough information cannot be gathered this way, the entire text will need to be read. The graduate student will need to make one EndNote® library to eliminate duplicates. After this step it is suggested to create a Google Groups® account for the group following the example document above. Google Groups® can be accessed from http://groups.google.com. Multiple students can access and work on the spreadsheet at the same time and updates are viewed as soon as changes are made.

The graduate student will create columns and equally assign articles to each group member. Below is a suggested way to organize your spreadsheet.

**Column:**
- **A.** Full citation
- **B.** Year of publication
- **C.** Article type; list if the article is a peer-reviewed primary article, a review article, a government document such as from the FDA Federal Register, or other types of articles such as magazine articles, bulletins, etc.
- **D.** Reviewer
- **E.** Second reviewer; this column will be left blank during this round of evaluations.
- **F.** Verdict; in other words does the article answer the research question and meet the exclusion and inclusion criteria. If the article does not answer the research question and/or meet the exclusion and inclusion criteria a “No” will be written in this column. If the article does answer the research question and/or meet the exclusion and inclusion criteria a “Yes” will be entered in this column. The reviewer will now proceed to column I to enter the reason(s) why.
- **G.** Study design (A, B, C, D, or Info); if the article is a review article or a non-peer reviewed article that can be used as background information for the introduction of the paper than write “Info” in this column. Otherwise, leave this column blank until the second round of evaluations.
- **H.** Quality rating; this column will be left blank during this round of evaluations
- **I.** Reason; this column will need to be filled out for each citation to keep track of why articles were excluded or included. This information will be entered into the Materials and Methods section of the paper at a later date.
- **J.** PDF; this column can be used to copy a link to the article for a quick review in the future or create a hyperlink to the pdf article.
- **K.** Add additional columns as necessary

The graduate student will need to monitor the groups work and ask questions or assign himself or herself as the second reviewer if they question a verdict score made by another student. It is important during this time to make sure all group members...
understand the research question and give examples of articles that are included and excluded and why.

**Week 5 through week 12**
For the second phase of evaluations the graduate student may choose to create another spreadsheet. This spreadsheet will include only primary and secondary articles that answered “Yes” in column F. Creating a second spreadsheet will avoid clutter.

During this phase of evaluations students will read the entire article and complete an electronic abstraction form. Students will enter and complete columns G (study design) and column H (quality rating). A second reviewer will be assigned by the graduate student to avoid bias and ensure consistency. If questions arise the graduate student should be notified and the instructor as necessary.
## Electronic Abstraction Worksheet* (Modeled after ADA’s Evidence Abstract Worksheet Template)

| **Group Question:** |  |
| **Reviewer:** |  |
| **Date of review:** |  |
| **Complete Citation:** |  |
| **Study Design (A, B, C, D):** |  |
| **Quality Rating:** | (+, Ø, -) Based on quality criteria checklist |
| **Research Purpose:** | Research question being investigated in study |
| **Inclusion Criteria:** | Requirement for study eligibility |
| **Exclusion Criteria:** | Items that disqualify an individual from participation in study |
| **Description of Study Protocol:** | what happened in the study; describe interventions, regimens, risk factors, or procedures studied; when outcomes were measured; how intervening factors were managed |
| **Recruitment** |  |
| **Blinding used (if applicable)** |  |
| **Description of study protocol:** |  |
| **Intervention** |  |
| **Data Collection Summary:** outcome(s) and other indicators; important variables and methods of measurement; was blinding used? |  |
| **Timing of Measurements** |  |
| **Dependent Variables (Note: some correlation, descriptive studies do not designate independent and dependent variables. In that case, just list key study variables).** |  |
| Variable 1: brief description (how measured)? |  |
| Variable 2: brief description (how measured)? |  |
| etc. |  |
| **Independent Variables (Note: some correlation, descriptive studies do not designate independent and dependent variables. In that case, just list key study variables).** |  |
| **Control Variables** |  |
| **Description of Actual Data Sample:** relevant descriptions of sample and comparison of groups at baseline; note loss of subjects (withdrawals, dropout, response rate, etc.) |  |
| **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; abstract results including quantitative data and statistics; be specific tables are often created in this section |  |
| **Variables** | Treatment Group | Control group | Statistical Significance of Group Difference |
| **Dep var 1** | Mean, CI. | Mean, CI. | Stat signif difference between groups |
| e.g., 4.5±2.2 | e.g., 3.5±2.0 | e.g., p=.002 |
| **Dep var 2** |  |
| etc. |  |
| **Author Conclusion:** |  |
| **Reviewer’s Comments:** identify concerns that affect study validity and generalizability; list study strengths and limitations |  |
| **Funding Source:** | Enter the specific name of the funding source |

APPENDIX E

STUDENT ORAL AND WRITTEN ASSIGNMENT INSTRUCTIONS

AND TEMPLATES
Assignment #1 oral presentation

Due week 3

The person who presents the Power Point® presentation can receive a maximum 10 points toward the total 100 points. The person who writes up this presentation as a “Materials and Methods” section for the next class can receive a maximum 20 points (see page 2 for details).

What to present to the class – 10 minute (maximum) Power Point® presentation

1. Title slide – The question you are asking and the name of your team members
2. Second slide – What databases did you use to conduct your search?
3. Third slide – What were your search terms for each database?
4. Fourth slide – What were your inclusion and exclusion criteria?
5. Fifth slide – How many articles did you find using these databases, search terms, and inclusion/exclusion criteria?
6. Where do you stand in the search process now (use as many slides as you need)
   a. Do you need to modify your question?
   b. Do you need to use additional search terms?
   c. Do you need to change your inclusion/exclusion criteria?
   d. Do you need to use additional databases?
Assignment #1 written report

Outline for the report (1-2 pages)

A. *Title Page*
   1. On this page list the overall question for the class
   2. List the question specific for your group
   3. List the names of the individuals in your group with the graduate student first and the others in alphabetical order. Be sure to spell the names correctly and also include the middle initials. Do not put nicknames, rather include full names.
   4. After these points (above) put your full name as the writer of the report
   5. Put the date that this is due
   6. The title page should be double spaced and centered (not left margin).

B. *Second page and following pages as needed.*
   1. Heading should be as follows: Question # (1,2, or 3 for example) then state your question.

C. *Materials and Methods*

   *Search Strategy.* In order to address this question we searched the following databases: (list the databases). Our search terms were: (list your search terms). If they varied a little with the database note that also. Our exclusion criteria were: (list your exclusion criteria and justify them). Our inclusion criteria were: (list your inclusion criteria and justify them).

D. *Results*

   Using the search strategy described above we located “X” number of articles. We then checked those articles for relevance to the question and inclusion/exclusion criteria. “X” articles were eliminated for the following reasons. Note: You do not have to give these reasons or the articles eliminated at this time but do use this sentence and leave a blank in “X”.

   Of the remaining articles, “X” were reviews and meta analyses which will used for background information but not for the evidence based review. This resulted in “X” articles for the evidence-based review. Note: You do not have to have this number at this time. The reviews and meta analyses were also used for back referencing and this produced an additional “X” articles. Write this sentence but you do not have to have the answer here.

E. *Lessons Learned*
Write one or two paragraphs at the most as to what you learned by 1) conducting the search and 2) listening to the presentation in class and the comments on that presentation as to how you might have done better.
Assignment #2 oral presentation

Due week 4

At this point your group should have a firm set of search terms, databases, and inclusion/exclusion criteria to answer your specific research question. Each group will need to have reviewed the abstract and title of all articles captured in your search and eliminated based on the criteria listed above.

The person who presents the Power Point® presentation can receive a maximum 10 points toward the total 100 points. The person who writes up this presentation as a “Materials and Methods” section for the next class can receive a maximum 20 points (see page 2 for details).

What to present to the class – 10 minute (maximum) Power Point® presentation

7. Title slide – The question you are asking and the name of your team members
8. Second slide – What databases did you use to conduct your search?
9. Third slide – What were your search terms for each database?
10. Fourth slide – What were your inclusion and exclusion criteria?
11. Fifth slide – How many articles did you find using these databases, search terms, and inclusion/exclusion criteria? This is the total number before you eliminated articles.
12. Sixth slide: The following information should be displayed as a flow chart (see class handout for a sample flow chart).
   a. Based on your research question and inclusion/exclusion criteria how many articles did you eliminate and why?
   b. What is the total number of articles pertinent to answer your question?
   c. How many primary articles can be used for the evidence-based review?
   d. How many secondary or review articles can you use for background information for the introduction of the paper?
Assignment #2 written report

Outline for the report

F. Title Page
   1. On this page list the overall question for the class
   2. List the question specific for your group
   3. List the names of the individuals in your group with the graduate student first and the others in alphabetical order. Be sure to spell the names correctly and also include the middle initials. Do not put nicknames, rather include full names.
   4. After these points (above) put your full name as the writer of the report
   5. Put the date that this is due
   6. The title page should be double spaced and centered (not left margin).

G. Second page and following pages as needed.
   1. Heading should be as follows: Question # (1, 2, or 3 for example) then state your question.

H. Materials and Methods

Search Strategy. In order to address this question we searched the following databases: (list the databases). Our search terms were: (list your search terms). If they varied a little with the database note that also. Our exclusion criteria were: (list your exclusion criteria and justify them). Our inclusion criteria were: (list your inclusion criteria and justify them).

I. Results

Using the search strategy described above we located “X” number of articles (Figure 1, include the flow chart in this report). We then checked those articles for relevance to the question and inclusion/exclusion criteria. “X” articles were eliminated for the following reasons.

Of the remaining articles, “X” were reviews and meta analyses which will used for background information but not for the evidence based review. This resulted in “X” articles for the evidence-based review. The reviews and meta analyses were also used for back referencing and this produced an additional “X” articles.

J. Lessons Learned

Write one or two paragraphs at the most as to what you learned by 1) performing the first round of evaluations and 2) comments or suggestions made by peers or the instructor on your groups oral presentation.

K. Bibliography
Include a full list of primary articles that will be used for the evidence based review. If the instructor request references follow the citation format of the Journal of the American Dietetic Association in EndNote®, refer to the class handout *Organizing your EndNote® Library* for instructions. Each group’s EndNote® library should be emailed to the instructor or teaching assistant. All secondary articles need to be in a separate group folder titled “secondary articles.” PDFs of all articles need to be attached to the appropriate article. The EndNote® library will need to be compressed before emailed and should be titled by the group’s letter and date. For example, group A will title their library as, “Group A 09_21_10”.

To compress an EndNote® library go to file ➔ compressed library ➔ make sure create, all references, and with file attachments are all selected. Click Next and save the file. Then attached the compressed library to an email.
Assignment #3 written report

The person who writes that “Materials and Methods” section can receive a maximum 20 points.

Outline for the Materials and Methods section

A. Title Page
   1. On this page list the overall question for the class
   2. List the question specific for your group
   3. List the names of the individuals in your group with the graduate student first and the others in alphabetical order. Be sure to spell the names correctly and also include the middle initials. Do not put nicknames, rather include full names.
   4. After these points (above) put your full name as the writer of the report
   5. Put the date that this is due
   6. The title page should be double spaced and centered (not left margin).

B. Second page and following pages as needed.
   1. Heading should be as follows: Question # (1,2, or 3 for example) then state your question.

C. Materials and Methods

   Literature Search. In order to address this question we searched the following databases: (list the databases). Our search terms were: (list your search terms). If they varied a little with the database note that also. Our exclusion criteria were: (list your exclusion criteria and justify them). Our inclusion criteria were: (list your inclusion criteria and justify them). The following types of studies were excluded from the review process because…

D. Classification of Studies as Primary or Secondary

   All studies meeting inclusion/exclusion criteria were further divided into two categories: primary research (original studies) and secondary research (reviews, meta-analyses and/or syntheses of previously reported studies). Describe why secondary articles are not used in the evidence-based review portion if the paper and what these types of studies are used for.

E. Updated Flow Chart

   Include the group’s updated flow chart.
Final Assignment

Due week 15

Final oral presentation:

All students are required to equally present the work completed in their designated group during the final Power Point® presentation. It is up to the each group to equally split up the work and present their findings as presented in the written report. Individual group members can receive a maximum 50 points toward the total 150 points.

Final written report: Draft of the manuscript

The final written report is due at 5 pm the day before the final to allow time for the TA to make copies for the entire class to review during the final exam time. Individual group members can receive a maximum 50 points toward the total 150 points.

A. Introduction
   1. Why is the overall topic important?
      i. What do we mean by sub-question #1 and why is this important?
      ii. What do we mean by sub-question #2 and why is this important?
      iii. What do we mean by sub-question #3 and why is this important?
      iv. Etc.
      v. Include supporting references

B. Materials and Methods
   1. Search terms (combine all terms from each group)
   2. Inclusion/exclusion criteria
   3. All databases used
   4. How it was decided which papers went under which questions
   5. Dividing into primary and secondary articles and how each was used
   6. Determining the research design (A,B,C,D)
   7. Abstracting the studies
   8. Determining the quality of the studies (list the ADA quality criteria here and then explain how articles were presented in class and scores were agreed upon)
   9. Coming to conclusion on each of the sub-questions

C. Results
   1. How many total articles were found? How many were eliminated (list the reasons)?
   2. How many primary articles pertained to each of the sub-questions?
   3. Include a flow chart illustrating the above information and following the example from week 3, *sample flow chart.*
   4. List all sub-questions and how the primary studies answered the questions. Focus on patterns discussed in class.
5. Do the results of each of the questions agree or disagree with any previous reviews (with comparisons to the reviews or other secondary articles?) If not, why?

D. Discussion

1. Overall conclusion and recommendations as to what should be done in the future
APPENDIX F

INSTRUCTOR ORAL EVALUATION FORMS
Assignment #1 Oral Evaluation Form
Critical Evaluation of Nutrition & Food Science
Literature: Evidence Based Reviews

Name of Presenter: ____________________________________________________________

Date: __________

Group (Circle One): A B C

<table>
<thead>
<tr>
<th>Slide</th>
<th>Content</th>
<th>Points</th>
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<tr>
<td>Slide 1</td>
<td>Research question/team members</td>
<td>/1</td>
</tr>
<tr>
<td>Slide 2</td>
<td>Databases used</td>
<td>/2</td>
</tr>
<tr>
<td>Slide 3</td>
<td>Search terms</td>
<td>/2</td>
</tr>
<tr>
<td>Slide 4</td>
<td>Inclusion/exclusion criteria</td>
<td>/2</td>
</tr>
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<td>Slide 5</td>
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<tr>
<td>Final slides</td>
<td>Next steps/changes to make</td>
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<tr>
<td>Total</td>
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</table>

Extra Comments: _______________________________________________________________

___________________________________________________________________________

___________________________________________________________________________
Assignment #2 Oral Evaluation Form
Critical Evaluation of Nutrition & Food Science
Literature: Evidence Based Reviews

Name of Presenter: ___________________________________________________

Date: __________

Group (Circle One): A     B     C

<table>
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<th>Slide</th>
<th>Content</th>
<th>Points</th>
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</thead>
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<td>Slide 1</td>
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<tr>
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<td>Slide 4</td>
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<tr>
<td>Final slides</td>
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<td>Total</td>
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</table>

Extra Comments: ____________________________________________________________
________________________________________________________________________
________________________________________________________________________
# Paper #1 and #2 Oral Evaluation Form

Critical Evaluation of Nutrition & Food Science Literature: Evidence Based Reviews

Name of Presenter: _______________________________________________

Date: __________

Group (Circle One): A   B   C

<table>
<thead>
<tr>
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<th>Content</th>
<th>Points</th>
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<tr>
<td>Type of Study</td>
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<td>Purpose of the Study</td>
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<tr>
<td>Population</td>
<td>Identify the specific population studied; how it was selected</td>
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<tr>
<td>Intervention</td>
<td>Were the groups comparable?</td>
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<tr>
<td>Endpoints</td>
<td>What endpoints were measured; when were they measured?</td>
<td>/5</td>
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<tr>
<td>Outcomes</td>
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<td>/5</td>
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<tr>
<td>Statistical Analysis</td>
<td></td>
<td>/5</td>
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<tr>
<td>Conclusion</td>
<td>What were the conclusions of the study? Do you agree with the conclusions?</td>
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</tr>
<tr>
<td>Limitations</td>
<td>What were the limitations to the study?</td>
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</tr>
<tr>
<td>Relevance to Question</td>
<td>Did this study help answer your question?</td>
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<td>Total Points</td>
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Extra Comments:
APPENDIX G

STUDENT TAKE-HOME ACTIVITIES/ASSIGNMENTS
Take home activity #1: Identifying the study design

Assign this assignment at the end of week 3. Discuss the results at the beginning of week 4.

Provide students with 4-5 papers and require them to identify the study design for week 4. The instructor may provide hard copies, send the pdfs via email, or provide the full citation and have the students look up the pdfs from www.library.tamu.edu for practice. At the beginning of week 4 discuss how the students categorizes the studies and why. Clear up confusion as necessary.

Randomized control trials (A):


Cohort studies (B):


Nonrandomized trials with concurrent or historical controls, case-control studies (C):


Cross-sectional studies, trend studies, case series, case reports, and before and after studies (D):

Peer Group Evaluation

Nutr 489/689: Critical Evaluation of Nutrition & Food Science Literature:
Evidence based reviews
Insert semester and year
Please comment on the following areas for one group member only.

Your Name ____________________________________________
Your Group (sub-question #1, #2, #3, etc.) __________
Group member you are evaluating ___________________________

1. Performance in the group (e.g., reliability for meetings, contributing to group assignments, meeting deadlines, etc.)

2. If given the opportunity, would you want to work with this team member again?

3. In one sentence, what is your overall impression of this member's performance?

4. What overall grade would you give this group member? (e.g., A, B, C, etc)

[Do not base your evaluations on friendship or personality conflicts. Your input can be a valuable indicator to help assess contributions in a fair manner. THESE EVALUATIONS WILL NOT BE SEEN BY YOUR GROUP MEMBERS.]
VITA

Name: Lindsey Briggs Field

Address: 213 Kleberg Center
          2253 TAMU
          College Station, Texas 77843-2253

Email Address: Lbfield@tamu.edu

Education: B.S., Nutritional Sciences, Texas A&M University, 2004
           M.S., Nutrition, Texas A&M University, 2011