I. Course Description

This course is designed to train students in the conduct of a systematic literature review and developing the skills to conduct a review built on the framework of evidence-based practice, an increasingly important standard in the arena of literature reviews. This course will draw on the skills and experience of staff of the Minnesota Evidence-based Practice Center, an AHRQ-funded program.

This course combines didactic classroom sessions with substantial project work to create a systematic literature review. Students will be taught how to perform each step in a review and will then be expected to apply it to a topic of their choosing. They will get feedback at each stage in the process. The final deliverable for the course will be a systematic literature review.

The primary target group includes doctoral and masters students in the Division of Health Policy and Management and Epidemiology who can use these skills in the conduct of their research preparatory work. Doctoral students would use the literature review as the basis for dissertation writing. Masters students could expand their reviews into Plan B and masters project papers. Fellows and junior faculty in clinical areas interested in acquiring clinical research skills would also benefit from this course, as conducting a systematic review is a good first step in developing a research proposal. Finally, clinical residents may want to take this course to improve their research skills.

II. Course Prerequisites

Some basic knowledge of epidemiology, such as that covered in PubH 6320, Fundamentals of Epidemiology, is needed. If you have questions about your readiness for this course, contact one of the instructors.
III. Course Goals and Objectives

At the completion of this course students should be able to:
1. Formulate key questions for a review.
2. Organize a literature search; identify which literature bases to search.
3. Abstract relevant information from appropriate studies in a systematic manner.
4. Rate the scientific quality of each study and the level of evidence for each question.
5. Create evidence tables and summary tables.
6. Summarize the studies’ findings.
7. Interpret the pattern of evidence in terms of strength and consistency.
8. Describe the elements of a meta-analysis and when such a step is appropriate.

IV. Methods of Instruction and Work Expectations

This course will combine a modest amount of didactic material presented in lectures and readings with a substantial amount of hands-on experience. Each student, or group of students, will be expected to choose a topic for review. (Topics that involve assessing some sort of intervention are highly recommended.) Students will work individually or in small groups to carry out each phase of a systematic literature review. They should work through each stage in parallel with the sessions of the course. They will be expected to report on their progress with each step. Those whose work is more promising will be encouraged to develop their reports into publishable papers.

Course Assignments
- Course readings, in class presentations and discussion.
- Homework on protocol of systematic literature review.
- Final paper with detailed outlines of the systematic review for a thesis, dissertation, or grant proposal.
- Presentation of the review.

Course Readings. Students are expected to read all recommended materials before the class. All recommended readings are included on the website, free for registered students.

Class Presentations. Students will work on phases of their review and present them for class review. The other students are expected to offer insights and suggestions.

Homework is essential to achieve the course outcome. A large part of this course involves conducting a literature review. Students should choose a topic (preferably involving an intervention) by Week 2. They should discuss their topic with at least one instructor. They will be expected to complete sections of the literature review as the course unfolds. All assignments are due by 10:00 am on the day of class.

Students should meet with the instructors regularly to assess progress and get assistance. Consultations with academic advisors are also encouraged.

V. Course Text and Readings


VI. Course Outline/Weekly Schedule

Note, first class session scheduled for January 27 was cancelled. Session dates moved forward as listed below.

<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Content</th>
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<tbody>
<tr>
<td>1 2/03</td>
<td>Kane</td>
<td>Introduction to evidence based analysis and systematic reviews of literature. Choosing a good review topic</td>
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<tr>
<td></td>
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<td>Readings:</td>
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<tr>
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<td></td>
<td>- Cochrane Handbook for Systematic Reviews of Interventions, Chapter 1.</td>
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<tr>
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<td></td>
<td>1.2 Systematic reviews</td>
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<tr>
<td>1.2.1</td>
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<td>1.2.1 The need for systematic reviews</td>
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<td>• What are systematic reviews, how can they be useful?</td>
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<td>• What topics are most conducive to a systematic review?</td>
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<td>• The difference between systematic reviews and advocacy reviews.</td>
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<td>• Definitions of evidence.</td>
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<td>• Statistical inference and target populations.</td>
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<td>• Level of evidence.</td>
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<td>• Reporting the evidence.</td>
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<tr>
<td>1.2.2</td>
<td>What is a systematic review?</td>
<td>We will review a systemic review article</td>
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<td>The following three papers represent examples of systematic reviews. Each shows a slightly different element.</td>
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<td>Lin SY, N Erekosima, JM Kim, M Ramanathan, C Suarez-Cervo, Y Chelladurai, D Ward, JB Segal (2013). Sublingual immunotherapy for the treatment of allergic rhinoconjunctivitis and asthma: A systematic review <em>JAMA</em> 309(12):1278-1288</td>
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<td>Homework: Students should propose a topic</td>
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### 2/10 Kane

**Formulating a well-formed study question and a logic model.**

**Readings:**
- Cochrane Handbook for Systematic Reviews of Interventions, Chapter 5: Defining the review question and developing criteria for including studies.

- Benefits and harms
- Population, intervention, comparators, outcomes, setting and timing (PICOTS).
- Framing questions that can be answered.
- Conceptual model/logic model and refined hypotheses.
- Clarifying terms: dependent and independent measures.
- Intermediate and final outcomes

**In-class exercise:** Developing key questions on a common topic. Present preliminary topics

**Homework:** Students will choose a topic and identify two to three key questions, a logic model, and PICOTS format for their proposed topic. Upload slides for in-class presentation
<table>
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<tr>
<th>Session</th>
<th>Title</th>
<th>Content</th>
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| 3 2/17 Butler | Developing a protocol for a systematic review. | - Reducing bias in review process  
- Level of detail.  
- Planning analyses and major threats to consistency.  
- Identifying eligibility criteria for the studies.  
- Identifying salient variables.  
- Clinical, methodological heterogeneity. |

**Readings:**

**In-class presentations:** Students will present key questions and logic model.  
Students will evaluate each presentation using the following criteria:  
- Do the authors justify the significance of the problem?  
- Do the authors describe the theory behind the association (e.g., why interventions should work)?  
- Do the authors justify the proposed review in the context of what is already known from the published guidelines, meta-analyses, and/or accepted standards of care?  
- Do the authors provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOTS)?  
- Do the questions address important uncertainty and feasible hypotheses?  

**Homework:** Students will develop a study protocol.  
Upload slides for in-class presentation. Upload a Word document with a study protocol using a report template. Should include:  
- Definition of the target population  
- Definition of the interventions (exposure) and comparators  
- Definition of the review primary outcomes (distinguish intermediate and patient-centered outcomes)  
- Definition of secondary outcomes  
- Definition of timing to assess the outcomes  
- Definition of the settings (context) of the review
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<th>Session</th>
<th>Title</th>
<th>Content</th>
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| 4 2/24 Butler | Searching the literature and identifying studies. | - Specify inclusion study design to answer research questions  
- Specify report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility  
- Specify inclusion and exclusion criteria  
- Justify exclusion criteria |

**Readings:**
- Discussion of MeSH headings.
- Search strategies and databases.
- Bibliographic file management
- What literature to review and the role of gray literature.
- Developing search strategies according to PICOTS.
- Steps in search strategy: preliminary screen and full text review.

**In-class exercise:** Develop a search strategy based on PICOT definitions for a research question.

**In-class presentations:** Each student will present a protocol.

Students will evaluate each presentation using the following criteria:
- Do the authors provide definition of the target population?
- Do the authors provide definition of the interventions (exposure) and comparators?
- Do the authors provide definition of the review primary outcomes?
- Do the authors provide definition of the review secondary outcomes?
- Do the authors provide definition of timing to assess the outcomes?
- Do the authors provide definition of the settings (context) of the review?
- Do the authors specify inclusion study design to answer research questions?
- Do the authors specify report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale?
- Do the authors justify exclusion criteria?

**Homework:** Students will develop a search strategy and conduct a preliminary search on their topic. Upload slides for in-class presentation with search strategies, strings, and the search results. Upload a Word document with results of screening process, including PRISMA flow diagram.

Search strategy will include:
- All information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search
- Dates of the searchers
- Justification for any constraints, such as language restrictions
- Exact strings for searchers
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<th>Session</th>
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| 5 3/03  Butler | Developing data extraction forms - separate forms for RCTs and observational studies. | • Focus on the information needed to answer key questions.  
• Capturing how the variables are reported as well as actual results (minimum datasets).  
• PICOTS elements.  
• Relevant descriptive study information. |
| **In-class exercise:** Developing an abstraction form for a research question  
**In-class presentations:** Students will present the results of their literature searches. Students will evaluate each presentation using the following criteria:  
- Do the authors describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search?  
- Do the authors provide the dates of the searchers?  
- Do the authors justify any constraints, such as language restrictions?  
- Do the authors provide exact strings for searchers?  
**Homework:** Students will create an abstraction form for their own key questions and pilot test it by abstracting two articles. Upload slides for in-class presentation with abstraction forms – variables and operational definitions. Upload a completed Excel worksheet with abstraction forms and abstracted articles. |
| 6 3/10  Butler | Extracting data from a randomized controlled trial and from an observational study. Analysis of different types of the outcomes.  
**Readings:**  
Chapter 14 Adverse effects | • Developing forms  
• Creating evidence tables  
• Extracting and analyzing the outcomes: continuous, and categorical; measure of the association including relative risk, absolute risk, odds ratio, and risk difference, and the role of p values and 95% CI.  
• Overview of the statistical software used for systematic reviews.  
**In-class exercise:** Video conference demonstration of Brown EPC Meta-analyst software. Abstraction of the data from one randomized controlled clinical trial and from one observational study into the AHRQ data repository. Students will discuss their experience with their abstraction forms.  
**Homework:** Students will revise the abstraction forms and abstract ~ 5 articles. Upload a completed Excel worksheet with abstracted articles. |
| 7 3/17  SPRING BREAK | | |
| 8 3/24  Kane | Assessing bias (quality) of studies: Criteria for RCTs and observational studies.  
**Readings:**  
Cochrane Handbook for Systematic Reviews of Interventions, Chapter 8: Assessing Risk of Bias in Included Studies; and Chapter 10: Addressing Reporting Biases.  
Assessing the Risk of Bias of Individual Studies when Comparing Medical Interventions AHRQ Manuscript: Published 08 March 2012. Select for HTML or PDF File (325 kB). PDF Help. | • Definitions of quality and risk of bias.  
• Methodological and reporting quality.  
• RCTs and CONSORT.  
• Quasi-experimental designs including MOOSE.  
• Available tools for assessing quality of individual studies and what key issues standard instruments may fail to recognize. Biases in quality, including:  
  o Selection/Confounding  
  o Attrition  
  o Performance/Fidelity  
  o Detection/Ascertainment/Timing  
  o Selection of a reported result  
**Class exercise:** Evaluate risk of bias (ROB) in one RCT and one observational study that we will provide.  
**Homework:** Students will evaluate risk of bias in their eligible review studies. Upload finalized abstraction forms with abstracted articles and risk of bias evaluation. |
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<td>10&lt;br&gt;4/07&lt;br&gt;Sue Duval&lt;br&gt;PhD</td>
<td>Meta-analysis and Publication Bias&lt;br&gt;&lt;br&gt;<strong>Readings</strong>&lt;br&gt;Cochrane Handbook for Systematic Reviews of Interventions, Chapter 9: Analyzing data and undertaking meta-analyses.&lt;br&gt;Fu R, G Gartlehner, M Grant, et al. (2011). Conducting quantitative synthesis when comparing medical interventions. AHRQ and the Effective Health Care Program. <em>J Clin Epidemiol</em> Nov; 64(11):1187-97. PMID: 21477993.</td>
<td>• Pooling criteria.&lt;br&gt;• Fixed and random effects model.&lt;br&gt;• Statistical heterogeneity.&lt;br&gt;• Meta-regression.&lt;br&gt;• “Qualitative” meta-regression.&lt;br&gt;• Publication bias.&lt;br&gt;• Sensitivity analysis. Reporting meta-analysis.</td>
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<tr>
<td>11/14</td>
<td>Summarizing the findings.</td>
<td>• Creating summary tables corresponding to research hypotheses.</td>
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<tr>
<td>4/14</td>
<td><strong>Readings:</strong> Cochrane Handbook for Systemic Reviews of Interventions, Chapter 11: Presenting results and ‘Summary of findings’ tables</td>
<td>• Plotting results from the studies.</td>
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<td>• Heterogeneity and consistency of evidence: Forest plots</td>
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<td>• Reconciling differences:</td>
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<td>o Methods and design</td>
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<td>• Publication bias.</td>
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<td>• Summarizing evidence when meta-analysis is not feasible.</td>
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<td>• Generalizability.</td>
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**Class exercise:** Students will rectify contrasting findings from two articles on the same topic.

**Homework:** Students will develop summary tables with key-messages. Upload slides for in class presentation with summary tables and key messages. Upload a Word or PDF document with evidence tables and summary tables. Use a report template.

| 12/14    | Writing the report or paper, including templates, outlines, and storyline. | • Discussion of transparency                                           |
|          |                                                                       | • Strength and consistency of the evidence, and explanation of inconsistencies |
|          |                                                                       | • Implications for practice and policy                                  |
|          |                                                                       | • Affecting limitations                                                 |
|          |                                                                       | • Tabulation of research needs                                            |

**Class exercise:** Students will present summary tables and conclusions. Students will evaluate summary tables and conclusions using PRISMA checklist

Students will use the following criteria to evaluate them:
- Is the message clear?
- Is it actionable?

| 13-14    | **Presentations:** Each student or student group will give a PowerPoint presentation. Student reviewers of the presentations will write critiques using protocol provided. Presentations should include key questions, conceptual model, search strategy, data analysis, and interpretation. | |
| 4/28 - 5/05 |                                                                                     | |

| 5/12     | **Final Paper due on May 12:** Upload Word document of a systematic review that includes an introduction, key questions, a conceptual model, search strategy, data analysis, and interpretation. Use the guidance provided. | |
VII. Evaluation and Grading

Students’ grades will be based on articulation in class and in each stage of their project work. The grade for the course will be based primarily on the quality of the final paper and/or presentation. A paper is required for a letter grade. Higher levels of performance will be expected from group projects.

The basis of the grade will be as follows:

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<th>Component</th>
<th>Percentage of Grade</th>
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<tr>
<td>Final literature review report</td>
<td>75%</td>
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<tr>
<td>Class presentations, exercises, and homework</td>
<td>25%</td>
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The course can also be taken S/N.

Late Penalties
Assignments submitted late will be subject to a grade reduction. Unless some special arrangement has been negotiated with the instructor based on extenuating circumstances, each week late will result in a one unit reduction (i.e., from B to B-).

Incomplete Grade
An incomplete grade is permitted only in cases of exceptional circumstances and following consultation with the instructor. In such cases an “I” grade will require a specific written agreement between the instructor and the student specifying the time and manner in which the student will complete the course requirements. Extension for completion of the work will not exceed one year.

University of Minnesota Uniform Grading and Transcript Policy
A link to the policy can be found at onestop.umn.edu.

Course Evaluation
The SPH collects student course evaluations electronically using a software system called CoursEval: www.sph.umn.edu/courseval. The system will send email notifications to students when they can access and complete their course evaluations. Students who complete their course evaluations promptly will be able to access their final grades just as soon as the faculty member renders the grade in SPHGrades: www.sph.umn.edu/grades. All students will have access to their final grades through OneStop two weeks after the last day of the semester regardless of whether they completed their course evaluation or not. Student feedback on course content and faculty teaching skills are an important means for improving our work. Please take the time to complete a course evaluation for each of the courses for which you are registered.

Incomplete Contracts
A grade of incomplete “I” shall be assigned at the discretion of the instructor when, due to extraordinary circumstances (e.g., documented illness or hospitalization, death in family, etc.), the student was prevented from completing the work of the course on time. The assignment of an “I” requires that a contract be initiated and completed by the student before the last official day of class, and signed by both the student and instructor. If an incomplete is deemed appropriate by the instructor, the student in consultation with the instructor, will specify the time and manner in which the student will complete course requirements. Extension for completion of the work will not exceed one year (or earlier if designated by the student’s college). For more information and to initiate an incomplete contract, students should go to SPHGrades at: www.sph.umn.edu/grades.

University of Minnesota Uniform Grading and Transcript Policy
A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable)
For full-semester courses, students may change their grade option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e., summer and half-semester courses) can be found at onestop.umn.edu.

Course Withdrawal
Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.
Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Student Services Center at sph-ssc@umn.edu for further information.

**Student Conduct, Scholastic Dishonesty, and Sexual Harassment Policies**

Students are responsible for knowing the University of Minnesota Board of Regents' policy on Student Conduct and Sexual Harassment found at www.umn.edu/regents/polindex.html.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the SPH Associate Dean for Academic Affairs who may file a report with the University’s Academic Integrity Officer.

The University’s Student Conduct Code defines scholastic dishonesty as “plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis.”

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: http://writing.umn.edu/tww/plagiarism/.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to http://tutorial.lib.umn.edu/ and click on “Citing Sources.”

In addition, original work is expected in this course. Unless the instructor has specified otherwise, all assignments, papers, reports, etc. should be the work of the individual student. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

**Disability Statement**

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612-626-1333 (voice or TTY).

**Mental Health Services**

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating, and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance or reduce a student’s ability to participate in daily activities. University of Minnesota services are available to assist you with addressing these and other concerns you may be experiencing. You can learn more about the broad range of confidential mental health services available on campus via www.mentalhealth.umn.edu.