I. Course Description

This course explores the scope of outcomes studies for evaluating the effectiveness of medical care by emphasizing the development of study designs matched to the research question. The course explores frequently used observation study designs, techniques for evaluating and selecting health outcomes measures, and analytical approaches appropriate to conducting health outcomes research. A core component of the course is the development of a research protocol, which will be developed in increments as the course evolves.
II. Course Prerequisites
The student should have at least an introductory course in epidemiology or health services research methods. Students without this prerequisite may take the course with the permission of the instructor. The student is expected to have a proposed research topic or a research study with which to work.

III. Course Goals and Objectives
Upon completion of the course, the student should be able to:
1. Develop researchable questions for measuring the effectiveness of medical care.
2. Generate a conceptual model for a researchable question.
3. Evaluate alternative study designs for conducting health outcomes research.
4. Translate researchable questions and conceptual models into meaningful health outcomes measures and critical independent measures.
5. Discuss how the natural history of a health condition affects the timing of health outcomes measurement.
6. Use an existing evaluation criterion to select a health outcomes measure.
7. Design a health outcomes research study that minimizes threats to validity.
8. Identify sources of data for a health outcomes research study that are feasible to collect and minimize error.
9. Understand the design parameters for conducting statistical power analysis and sample size calculations.
10. Compare and contrast approaches to analyzing health outcomes.
11. Apply scientific principles to the visual presentation of health outcomes data.

IV. Methods of Instruction and Work Expectations
The course uses didactic sessions and working sessions to teach students to use the major concepts and principles in designing a health outcomes research project. Students will complete their proposal in steps with feedback at each step.

V. Course Text and Readings


Background Reading:
VI. Course Outline/Weekly Schedule

Week 1 (1/21): Introduction to Outcomes Research (Kane)
A. Goals of health outcomes research
B. What are the outcomes?
C. Challenges to outcomes studies
D. Uses of outcomes
E. An outcomes approach
   1. Basic model
   2. Risk adjustment
   3. Treatment
F. Conceptual modeling and the five key steps in outcomes research
   1. Define a researchable question
   2. Develop a conceptual model
   3. Conduct a literature review
   4. Operationalize the variables
   5. Develop a research plan

Developing a Conceptual Model
A. Causation
B. Conceptual model
C. Explanatory models
D. Complexities of conceptual models
   1. Mediators
   2. Moderators
   3. Confounders
   4. Interactions
E. Behavioral model and access to medical care

Required Readings:

Recommended Readings:


Assignment:
Write a researchable outcomes question and develop a conceptual model for your research question. Submit proposed question and model by e-mail by January 27. Criteria for the question and model are:
- Clarity of the question clear
- Is the question answerable/doable?
- Are the variables clear?
- Are the relationships clear?
- Have relevant interactions been considered?
- Are other relevant factors/influences considered?

**Week 2 (1/28): Outcomes Research Study Design** (Kane)

A. Isolating the effects of the intervention  
B. Dealing with bias  
C. Threats to causal inference  
D. Experimental and quasi-experimental designs used for health outcomes research  
   1. Using a common language to describe study designs  
   2. Terminology – definition of terms  
   3. Dealing with selection bias  
E. Threats to validity

**Required Readings:**  

**Recommended Readings:**  

Assignment: Propose an approach to studying your proposed question. Criteria for your design:

- Is the design clear?  
- Does it fit the question?  
- Is it feasible?  
- How were threats to validity handled?

Feedback on the research designs for each project will be done by e-mail.

**Week 3 (2/4): Measurement** (Kane) [online]
A. Measurement defined
B. Scaling and the levels of measurement
   1. Nominal
   2. Ordinal
   3. Interval
   4. Ratio
C. Scaling Methods
   1. Rating scales
   2. Comparative methods
   3. Econometric methods
   4. Item response theory
D. Strategic Issues in Selecting Health Outcomes Measures
   1. Sensibility
   2. Reliability
   3. Validity
   4. Responsiveness
   5. Burden
E. Final considerations in selecting health outcomes measures

Required Readings:

Recommended Readings:

Streiner DL & GR Norman (2008). Health Measurement Scales: A Practical Guide to Their Development and Use (Fourth Ed.). Oxford: Oxford University Press. (Chapter 3, Devising Items, pp. 17-36; Chapter 4, Scaling Responses, pp. 37-75; Chapter 5, Selecting the Items, pp. 77-102; Chapter 6, Biases in Responding, pp. 103-134; Chapter 7, From Items to Scales, pp. 135-166) [Don’t get too bogged down with the statistics – class notes and Breeze presentations should capture the highlights.]


Week 4 (2/11): Health Outcomes Measures

Generic Measures (Kane) [online]
A. Why use generic measures?
B. Advantages and disadvantages of using generic health outcomes measures
C. Health outcome domains
D. Generic Health Status Measures
   1. Physical Functioning
   2. Social Functioning
   3. Quality of life (see below)
   4. Emotional Functioning – Depression
   5. Cognitive Functioning
   6. Pain and Discomfort
   7. Vitality
   8. Overall Well-being
   9. Indices of Change – Transition Indices
E. Practical considerations for choosing generic measures
F. Choosing a measure

Health-related Quality of Life
A. Quality of life as a concept
B. Applications for health-related quality of life measures
C. Examples of health-related quality of life measures
   1. COOP Charts for Primary Care Practice
   2. Medical Outcomes Study — Short Form Measures
   3. Sickness Impact Profile
   4. Quality of Well-being Index
   5. EuroQol (EQ-5D)
   6. World Health Organization Quality of Life Assessment (WHOQOL)-BREF
   7. Health Utilities Index (HUI)
   8. Quality adjusted life years (QALY)

Condition-Specific Measures
9. Condition-specific measures versus generic health status measures
10. Why not generic health status measures?
11. Condition-specific health status measures
12. Physiological measures
13. The importance of the case definition in using incidence measures
14. Choice of condition-specific measures
15.

Required Readings:


Recommended Readings:


**Week 5 (2/18): Risk Adjustment** (Shippee) [online]

A. Severity and comorbidity  
B. Diagnosis-specific severity  
C. Importance of making risk adjustments for severity and comorbidity  
   1. Selection bias  
   2. Improved prediction  
   3. Subgroup analysis  
D. Data sources  
E. Considerations for selecting a risk-adjustment strategy – evaluating risk adjustment models  
   1. Identify purpose  
   2. Relative importance of diagnosis to risk adjustment  
   3. Data-related considerations – source of data, reliability, validity  
   4. Role of competing risks  
   5. Evaluating the statistical performance of a risk adjustment strategy  
F. Basic approaches to addressing selection bias  
   1. Propensity scores  
   2. Instrumental variables  
   3. Multivariable models  
G. Evaluating the performance of a risk model  
H. Attrition bias

**Required Readings:**  

Dowd BE (2011). Separated at birth: Statisticians, social scientists, and causality in health services research. Health Services Research Apr; 46(2):397-420. [Same as session 2]

**Recommended Readings:**  

**Assignment:**  
Determine how you will handle risk adjustment for your study. Submit a brief note describing your approach and the specific variables you will use.

**Week 6 (2/25): Satisfaction with Care and Demographic, Psychological, and Social Factors**  
(Shippee) [online]

**Satisfaction**  
A. The importance of patient satisfaction  
B. Theoretical models of satisfaction  
C. Factors affecting satisfaction  
D. Interpreting satisfaction  
E. Approaches to measuring patient satisfaction  
F. Definition of patient satisfaction  
G. Satisfaction measures  
   1. Health plan  
   2. Hospital
3. Ambulatory care
4. Long-term care

**Demographic, Psychological, and Social Factors**

A. Demographic, Psychological, and Social factors as independent variables and dependent variables
B. Demographic factors
C. Psychologic factors
D. Social factors

**Required Readings:**

Satisfaction with Care (pp. 159-198) in Kane RL & DM Radosevich (2010). *Conducting Health Care Outcomes Research*. Boston: Jones and Bartlett Publishers.


Techniques for addressing selection bias will be assessed by email.

**Week 7 (3/4): Treatment and Interventions** (Kane) [online]

A. What is treatment?
B. Components of treatment
   1. Medications
   2. Procedures
   3. Counseling and education
C. Metrics of treatment

**Required Readings:**


**Recommended Readings:**


**Assignment:**

Make a variables table. The table should include:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Operational Form</th>
<th>Format</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes/Dependent Variables</td>
<td></td>
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</tbody>
</table>

Submit a PowerPoint with research questions, conceptual model, and variables table. The table should be linked to the model. Criteria for review:

- Is it complete?
- Can variables be feasibly collected?
- What are the analytic implications?
Week 8 (3/11): Methods for Collecting Health Outcomes and Related Data (Shippee) [online]

A. Self-report
   1. Cornerstones of data collection
   2. Tailored Design
   4. Survey implementation system
   5. Designing a survey implementation system
B. Clinical data
   1. Medical records
   2. Electronic medical record
C. Administrative (claims) data

Required Readings:

Recommended Readings:

The variables table will be reviewed by email.

Assignment:
Describe your data source. If primary data collection, what is the sampling plan? If secondary data analysis, what is the data quality and completeness?

Week 9 (3/18) SPRING BREAK – NO CLASS

Week 10 (3/25): Analysis and the Visual Display of Health Outcomes Data (Shippee)

A. Considerations for analyzing health outcomes data
B. Sample size and power analysis
C. Interpreting data (weighing condition-specific and generic outcomes)
D. Choosing an analytic method (dealing with selection bias)
   1. Types of regression
E. The database and data dictionary
F. Data preparation
G. Visual display of health outcomes information
H. Regulatory demands accompanying health outcomes

Required Readings:

Classroom Activity:
Present data source information
Assignment:
Describe your analysis plan. What statistical tests will you use to test each part of your research question? How will you control for selection bias? Prepare dummy tables. Show regression models (if appropriate)? Include a power calculation.

Week 11 (4/1): Making Sense of It All: Interpreting the Results (Kane)
A. Organizing one’s thinking
   1. Reconciling cause specific and overall mortality rates
   2. Measuring harms
B. Search for simple measures
C. Adjusting for case mix
D. Data quality
E. Getting follow-up data
F. Using extant data sources
G. Basic analysis issues
H. Interpreting the findings
I. Ethical considerations
J. Implications for
   Disease management
   Quality improvement
K. Operational steps

Required Readings:

Classroom Activity
Present analysis plan
Criteria:
• Does the analysis plan fit the question?
• Can selection be adequately addressed?
• Is the sample adequate (size, coverage)?

Student Presentation Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Student</th>
<th>Topic</th>
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</thead>
<tbody>
<tr>
<td>4/8</td>
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<td>4/15</td>
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<tr>
<td>4/22</td>
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Week 12, 13, and 14 (4/8, 4/15, 4/22): Student Presentations

VII. Evaluation and Grading
Health Outcomes Research Study Proposal 70%
Homework (5% for each assignment) 30%
A = 100-90 points; B = 89 to 80 points; C = 79 to 70 points; D = 69 points or less
There is no final exam. Projects will be due on May 8, 2015. Proposals should be submitted in Word to both Drs. Kane and Shippee.

A 4.000 - Represents achievement that is outstanding relative to the level necessary to meet course requirements
A- 3.667
B+ 3.333
B 3.000 - Represents achievement that is significantly above the level necessary to meet course requirements
B- 2.667
C+ 2.333
C 2.000 - Represents achievement that meets the course requirements in every respect
C- 1.667
D+ 1.333
D 1.000 - Represents achievement that is worthy of credit even though it fails to meet fully the course requirements

S Represents achievement that is satisfactory, which is equivalent to a C- or better.

For additional information, please refer to:
http://policy.umn.edu/Policies/Education/Education/GRADINGTRANSCRIPTS.html.

Course Evaluation
The SPH will collect 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 Office of Admissions and Student Resources at sph-ssc@umn.edu for further information.

Student Conduct Code
The University seeks an environment that promotes academic achievement and integrity, that is protective of free inquiry, and that serves the educational mission of the University. Similarly, the University seeks a community that is free from violence, threats, and intimidation; that is respectful of the rights, opportunities, and welfare of students, faculty, staff, and guests of the University; and that does not threaten the physical or mental health or safety of members of the University community.

As a student at the University you are expected adhere to Board of Regents Policy: Student Conduct Code. To review the Student Conduct Code, please see: http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf.

Note that the conduct code specifically addresses disruptive classroom conduct, which means "engaging in behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning. The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities."

Use of Personal Electronic Devices in the Classroom
Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. To this end, the University establishes the right of each faculty member to determine if and how personal electronic devices are allowed to be used in the classroom. For complete information, please reference: http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html.

Scholastic Dishonesty
You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means 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; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis. (Student Conduct Code: http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf) If it is
determined that a student has cheated, he or she may be given an "F" or an "N" for the course, and may face additional sanctions from the University. For additional information, please see: http://policy.umn.edu/Policies/Education/Education/INSTRUCTORRESP.html.

The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: http://www1.umn.edu/oscai/integrity/student/index.html. If you have additional questions, please clarify with your instructor for the course. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam.

**Makeup Work for Legitimate Absences**
Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Such circumstances do not include voting in local, state, or national elections. For complete information, please see: http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html.

**Appropriate Student Use of Class Notes and Course Materials**
Taking notes is a means of recording information but more importantly of personally absorbing and integrating the educational experience. However, broadly disseminating class notes beyond the classroom community or accepting compensation for taking and distributing classroom notes undermines instructor interests in their intellectual work product while not substantially furthering instructor and student interests in effective learning. Such actions violate shared norms and standards of the academic community. For additional information, please see: http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html.

**Sexual Harassment**
"Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment in any University activity or program. Such behavior is not acceptable in the University setting. For additional information, please consult Board of Regents Policy: http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf.

**Equity, Diversity, Equal Opportunity, and Affirmative Action**
The University will provide equal access to and opportunity in its programs and facilities, without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression. For more information, please consult Board of Regents Policy: http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EQ_OA.pdf.

**Disability Accommodations**
The University of Minnesota is committed to providing equitable access to learning opportunities for all students. Disability Services (DS) is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations.
If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DS at 612-626-1333 to arrange a confidential discussion regarding equitable access and reasonable accommodations.

If you are registered with DS and have a current letter requesting reasonable accommodations, please contact your instructor as early in the semester as possible to discuss how the accommodations will be applied in the course.

For more information, please see the DS website, https://diversity.umn.edu/disability/.

**Mental Health and Stress Management**
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 and may reduce your ability to participate in daily activities. University of Minnesota services are available to assist you. You can learn more about the broad range of confidential mental health services available on campus via the Student Mental Health Website: http://www.mentalhealth.umn.edu.

**The Office of Student Affairs at the University of Minnesota**
The Office for Student Affairs provides services, programs, and facilities that advance student success, inspire students to make life-long positive contributions to society, promote an inclusive environment, and enrich the University of Minnesota community.

Units within the Office for Student Affairs include, the Aurora Center for Advocacy & Education, Boynton Health Service, Central Career Initiatives (CCE, CDes, CFANS), Leadership Education and Development –Undergraduate Programs (LEAD-UP), the Office for Fraternity and Sorority Life, the Office for Student Conduct and Academic Integrity, the Office for Student Engagement, the Parent Program, Recreational Sports, Student and Community Relations, the Student Conflict Resolution Center, the Student Parent HELP Center, Student Unions & Activities, University Counseling & Consulting Services, and University Student Legal Service.

For more information, please see the Office of Student Affairs at http://www.osa.umn.edu/index.html.

**Academic Freedom and Responsibility: for courses that do not involve students in research**
Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

Reports of concerns about academic freedom are taken seriously, and there are individuals and offices available for help. Contact the instructor, the Department Chair, your adviser, the associate dean of the college, or the Vice Provost for Faculty and Academic Affairs in the Office of the Provost.
OR:

Academic Freedom and Responsibility, for courses that involve students in research

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom and conduct relevant research. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

When conducting research, pertinent institutional approvals must be obtained and the research must be consistent with University policies.

Reports of concerns about academic freedom are taken seriously, and there are individuals and offices available for help. Contact the instructor, the Department Chair, your adviser, the associate dean of the college, or the Vice Provost for Faculty and Academic Affairs in the Office of the Provost.

* Language adapted from the American Association of University Professors "Joint Statement on Rights and Freedoms of Students".