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

Session 1 (1/22): 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 5 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?
Session 2 (1/29): 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:
Create a research design that uses the Shadish/Campbell format. Submit in PowerPoint by Wednesday morning 2/5. The design should fit the question and be feasible. Discuss potential threats to validity and how you will handle them.

Session 3 (2/5): Measurement (Radosevich)
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.]


Class Activity:
Discuss the research designs for each project. Criteria include:
   • Is the design clear?
   • Does it fit the question?
   • Is it feasible?
   • How were threats to validity handled?

Session 4 (2/12): Health Outcomes Measures

Generic Measures (Kane)
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
**Condition-Specific Measures** (Kane)
A. Condition-specific measures versus generic health status measures
B. Why not generic health status measures?
C. Condition-specific health status measures
D. Physiological measures
E. The importance of the case definition in using incidence measures
F. Choice of condition-specific measures

**Health-related Quality of Life** (Radosevich)
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)

**Required Readings:**


**Recommended Readings:**


Session 5 (2/19): Risk Adjustment (Radosevich)
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.

Session 6 (2/26): Satisfaction with Care and Demographic, Psychological, and Social Factors (Kane)
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:


Class activity:
Presentation of techniques for addressing selection bias.

Session 7 (3/5): Treatment and Interventions (Kane)
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>
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</tr>
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<tr>
<td>Independent Variables</td>
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</tbody>
</table>

Submit a PowerPoint by Wednesday morning 3/12

Session 8 (3/12): Methods for Collecting Health Outcomes and Related Data (Radosevich)
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:

Classroom Activity:
Present variables table
Criteria for review:
• Is it complete?
• Can variables be feasibly collected?
• What are the analytic implications?

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? Include a power calculation

Session 9 (3/26): Analysis and the Visual Display of Health Outcomes Data (Radosevich)
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)?
Session 10 (4/2): 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:
Making Sense of It All: Interpreting the Results (pp. 323-342) in Kane RL & DM Radosevich (2010).

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>
</tr>
</thead>
<tbody>
<tr>
<td>4/9</td>
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<tr>
<td>4/16</td>
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</tr>
</tbody>
</table>

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

Course Evaluation
The SPH collects student course evaluations electronically using a software system called CoursEval: www.sph.umn.edu/courseval. The system sends 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](http://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](http://www.umn.edu/regents/polindex.html).

**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](http://www.umn.edu/regents/polindex.html).

**Course Withdrawal**

Students should refer to the Refund and Drop/Add Deadlines for the particular term at [onestop.umn.edu](http://www.umn.edu/regents/polindex.html) 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](mailto: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](http://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/](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).