Overview and Objectives: This course will provide a survey of effectiveness research. The curriculum will deal with conceptualization, design, sampling, modeling, data collection and analysis used in outcomes and effectiveness studies. The emphasis of the course will be largely on research methodology and study design. The course will be interactive and will use studies published in the literature as a teaching tool.

Responsibilities:

- Reading assignments: 2 types—1) required and discussed in class; 2) recommended background reading
- Students will be asked to review articles in detail which will highlight what is being discussed in the class
- Attendance and participation in class is required
- Each student will prepare a 5 page research proposal to be handed in on April 20, 2011. The proposal should be organized in NIH format as follows:

Specific Aims:

State precisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will exert on the research. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Research Strategy:

1. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses; how the proposed project will improve scientific knowledge or clinical practice in one or more broad fields.

2. Innovation
• Describe any novel theoretical concepts, approaches, methodologies, instrumentation, or interventions to be developed or used, and describe any advantage over existing methodologies, instrumentation, or interventions.

3. Approach

• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

References: Provide a bibliography of any references cited in the Research Strategy. The references should be limited to relevant and current literature (limit to 20).

Course Grading:

• Class participation and attendance 10%
• Review of papers and presentation 10%
• Draft research proposal 50%
• Final Exam 30%

Websites:

AHRQ:  http://www.ahrq.gov/
Comparative Effectiveness Research:  http://www.hhs.gov/recovery/programs/cer/index.html
Medicare:  http://www.cms.gov/
Course Schedule

Session 1. Feb 28, 2011

A. Introduction and definition of effectiveness research (1 hour)—Kapoor

- To review the history of outcomes and effectiveness research and apply it to current approaches
- To define outcomes and effectiveness research
- To summarize the types of effectiveness studies being conducted nationally

B. Conceptual foundation of effectiveness research (1 hour)—Kapoor

- To evaluate how hypotheses are formulated and tested in effectiveness research
- To recognize risk adjustment and treatments in effectiveness research and why risk adjustment is important and necessary
- To survey the broad spectrum of outcomes

Required reading:

http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande


Research proposal: Begin developing and drafting your research question, title of your proposal, consider data for the study and possible study design. To be discussed in class on March 7 and March 14.

Session 2. March 2, 2011

Study Designs (2 hours)—Kapoor

- To review the research methods used in effectiveness research
- To analyze the strengths and weaknesses of each method
- To compare the types of answers obtained from each of these methods
- To summarize types of non-experimental designs and to identify major threats to validity in these designs

Required Reading: Papers to be reviewed in class:

Association of Candesartan vs Losartan With All-Cause Mortality in Patients With Heart Failure JAMA. 2011;305(2):175-182.


Session 3. March 7, 2011

Outcome measures

A. Condition or disease specific (1 hour)—Kapoor

- To compare the uses of generic and condition specific measures
- To analyze the reasons for choosing condition specific measures
- To review examples and uses of selected condition specific measures

B. Generic Measures (not disease or condition specific) —Kapoor (1 hour)

- To summarize the domains of health measured by generic measures
- To explain the criteria for choosing a generic measure
- To review examples and uses of selected existing measures


Required Reading: Papers to be reviewed in class:


Association of Hospice Agency Profit Status with Patient Diagnosis, Location of Care, and Length of Stay. JAMA. 2011;305(5):472-479.

Fall Prevention in Acute Care Hospitals: A Randomized Trial. JAMA. 2010;304(17):1912-1918.

Review abstracts:

Care Coordination: Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficiaries. 15 Randomized Trials. JAMA. 2009;301(6):603-618. http://jama.ama-assn.org/content/301/6/603.full.pdf;

**Proposal Development:** Hand in a title and specific aims (1 page)

**Session 4. March 9, 2011.**

Outcome Measures: Patient Satisfaction (2 hours)—Kapoor

- To create the conceptual foundation for patient satisfaction
- To summarize methods of measuring patient satisfaction
- To evaluate the role of patient satisfaction in improving quality
- To review instruments available for measuring patient satisfaction

**Recommended Reading:** [https://www.cahps.ahrq.gov/default.asp](https://www.cahps.ahrq.gov/default.asp)

**Required Reading:**


**Proposal Development:** Discussion of specific aims and significance

**Session 5. March 14.**

Sources of Data in Outcomes Research (2 hours)—Kapoor

- To summarize sources of data including administrative, medical records and survey data
- To compare the strengths and weaknesses of each type of data
- To review examples of the uses of these data for outcomes studies

**Required Reading:** Iezzoni, LI. Chapters 5, 6


**Proposal Development:** Begin developing approach: study design, setting, participants (subjects), outcomes, data acquisition and analysis

**Session 6. March 16, 2011**

Outcome measures: Cost and resources use (2 hours)—Kraemer
• To describe how cost, resource use, and LOS are used as outcomes measures
• To recognize methodological issues in measurement and analysis of these outcomes
• To summarize the use and limitations of these measures

Session 7 and 8. March 21 and 23, 2011

Risk adjustment: Severity of Illness and Comorbidity (March 21, 23)—Kapoor

• To review the conceptual models and dimensions of risk
• To study some of the existing measures of severity
• To critique problems with measuring severity
• To explain the methodology of risk adjustment
• To sample the uses of risk adjustments
• To examine the effects of different risk adjustment tools in similar data
• To review the concept of comorbidity and why it should be measured
• To explain methodological issues in the assessment of comorbidity
• To review examples of existing measures of comorbidity

Reading: Iezzoni, LI. Chapters 1,2, 3

Required Reading:


Proposal Development: Develop sections on approach and innovations; submit a draft on March 23.


Review and discussions of proposals in small groups (March 28)


• Payment for Health Care: Medicare, Medicaid, Private Insurance and Managed care—Kapoor

  • To describe the history of health insurance in the US (Medicare, medical assistance, private insurance, managed care)
  • To compare health care coverage in other countries to the US
  • To review different payment methods for health care (e.g., FFS, Capitation etc) and their effect on outcomes and cost
  • To review examples of how insurance status is used in outcomes research
Required Reading:


Recommended Readings:


Session 11. April 4, 2011.

Comparative Effectiveness Research—Fowler (April 6)

• To describe the rationale for CER and why is it important
• To examine methods for CER: RCTs, observational studies, systematic reviews, modeling and others
• To analyze the strengths and limitations of CER studies
• To review the relationship of CER to cost and cost-effectiveness
• To summarize use of CER in practice guidelines, policy and decision making

Required Reading:

Book: Initial National Priorities for Comparative Effectiveness Research. IOM pages 30-56

**Recommended Reading:**


**Session 12. April 6, 2011**

Health Care Disparities—Myaskovsky and Huassmann

- To learn key definitions within the field of research in health and healthcare disparities, including race/ethnicity, vulnerable populations, and disparities in health and health care.
- To describe the evolution of the field of health and healthcare disparities research within the broader realm of health services research.
- To describe key conceptual models for detecting, understanding and reducing/eliminating disparities in health and health care.
- To be familiar with seminal studies on healthcare disparities.
- To review local and national funding as well as collaborative opportunities in health and healthcare disparities research.

**Required Reading:**


**Session 13. April 11, 2011.**

Quality of Health Care—Kapoor

- To examine various definitions of quality of care and concepts behind it
- To compare various methods of measuring quality
- To appraise approaches to improvement in quality of care
- To examine gap in quality in the U.S.

**Required Reading:**

Session 14. April 13, 2011

Quality of Health Care: Medical Errors and Patient Safety—Kapoor

- To review the scope of patient safety concerns in the US
- To summarize the reasons for medical errors
- To analyze interventions that may reduce errors
- To describe the research agenda on patient safety

Recommended Reading:

Books: To Err is Human: Chapter 1-3; Crossing the Quality Chasm: Chapter 1-2.


Review and final exam (April 20); submit the final proposal.