Catalog Description:

Innovations in medical technologies are one of the leading areas of economic growth in the world. Whether new technologies take the form of pharmaceutical, medical device, biotechnology, information technology of some combination of these innovations, the opportunities for both private enterprise and social welfare are substantial. However, these innovations are not without cost, and require reimbursement from either a privately or publicly financed health care delivery system to enter the marketplace. Thus, the strong demand for the evaluation of new medical technologies continues to grow due to the confluence of an aging society seeking new therapeutic agents to enhance health and productivity and unyielding medical care price inflation. This course aims to provide knowledge of the skills, data and methodology required to critically evaluate new medical technologies in order to meet financial investment as well as regulatory compliance objectives, such as FDA approval. The course is designed to provide the analytic tool kit for a manager of a new medical technology to formulate the evaluation necessary for this enterprise as well as effectively disseminate results in order to get a new product to market.

Course Objectives:

● To identify a population to be served by a medical technology.
● To use existing health care data to evaluate a medical technology.
● To inventory the costs of using a new medical technology and its alternative(s).
● To complete a meta-analysis of an emerging medical technology.
● To understand the design process of an evaluation.
● To complete a cost/benefit and cost/effectiveness analysis of a new technology.
● To describe the strategy for medical technology results dissemination and marketing.
● To understand the reimbursement systems financing medical technology use.
● To understand the role of government and regulatory agencies in the development and use of new medical technologies.

Method of Evaluation:

Two exams, a midterm and final, will be given. These will account for 50% of the final grade. All exams will be closed book and focus on analytic methods. A group-developed class project
describing the design and execution of an evaluation of a new medical technology will account for 40% of the final grade. The remaining 10% of the grade will be assigned for participation in weekly recitations.

Readings:

A course packet, consisting of journal articles and other relevant readings will be downloadable from the course web site.

Gold readings:
- Chapter 1
- Chapter 4
- Chapter 6
- Chapter 7
- Chapter 8

Course Logistics

- The course will meet once a week throughout a semester.
- Several classes will have 10 to 15 minute active learning exercises with actual case information.
- Re-usable data mining algorithms will be supported by the ehealthcon.hsnetwork.com web site.

Group Project

Teams of no more than five students will work on the group project. The group project will be commissioned by a combination of class participants and industry leaders mid-way through the course. You can identify a topic for vote at this time including an analysis of a chemical compound or medical technology in active development at the start of the course. A superior grade will result from clever, effective and clear use of data sources including, when appropriate, de-identified health insurance data made available for the course by the instructors. Professional-quality team presentations will conclude the course. Presentations must be made in 10 minutes and only five additional minutes of Q & A will be allowed.

Helpful library indexes include Medline, Pubmed, and Econlit. You can get to them by going to www.lib.umn.edu, and then click on Articles and Indexes.

Policy

To avoid plagiarism, please be sure to give credit when you use another person’s idea or theory, other information that is not common knowledge, or statistics. This includes both web-based and traditional sources. You should cite it in the text of the paper, as well as include a full citation on a reference page. Refer to the MLA Handbook for formatting.
The instructors will enforce the policies issued by the University of Minnesota with respect to the Student Code of Conduct.

MBA Policy

The Carlson School defines academic misconduct as any act by a student that misrepresents the student's own academic work or that compromises the academic work of another. Scholastic misconduct includes (but is not limited to) cheating on assignments or examinations, plagiarizing, i.e., misrepresenting as one's own work any work done by another, submitting the same paper, or substantially similar papers, to meet the requirement of more than one course without the approval and consent of the instructors concerned, or sabotaging another's work. Within this general definition, however, instructors determine what constitutes academic misconduct in the courses they teach. Students found guilty of academic misconduct face penalties ranging from lowering of the course grade or awarding a grade of F or N for the entire course, to suspension from the University.

Office Hours

Office hours will be held prior to class or appointment with instructors. Appointments are best made by e-mail: bockk056@umn.edu; barre142@umn.edu

Course Secondary Data Resources

- Diagnosis (ICD9) Code Spreadsheet
- Procedure Code Spreadsheet
- Potential data sources for projects

Course Project Templates

Project Presentations
- Stroke Treatment Technology
- Asthma Technology
- Carelink Technology
- Medical Device Tax
- Bundled Payments

Project Reports
- Stroke Treatment Technology
- Asthma Technology
- Carelink Technology
- Medical Device Tax
- Bundled Payments
MEDICAL TECHNOLOGY EVALUATION
AND MARKET RESEARCH
SYLLABUS

Week 1: (1/27) Course Overview – Principals & Agents in Medical Technology Evaluation

Topics to discuss:
- Why do we need cost effectiveness analysis?
- Who are the actors in the medical technology industry and what are their incentives?
- Why have health care costs been increasing?
- Do new technologies reduce long term medical expenditures?

Readings:
- National Health Expenditure Projections, 2010-2020
- Bench to Bed. The Economist, 2006

Week 2: (2/3) The Medical Technology Economy

Topics to discuss:
- Information demand – who is demanding evidence?
- What is the ‘supply chain’ of information dissemination?
- How are new medical technologies reimbursed?
- Why are we creating evidence?

Readings:
- FDA.gov (the FDA tour)
- Health Affairs, Richard Merrill, 1999
- McClellan & Tunis, 1/20/2005, NEJM
- CMS Innovator’s Guide

Week 3: (2/10) Introducing Cost-Effectiveness Analysis
Topics to discuss:
- Identifying clinical alternatives
- Using existing data to alternatives
- CEA/CBA/CUA Ratios

Readings:
- **Gold, Chapter 1**

**Week 4: (2/17) Cost-Effectiveness Analysis Overview Summary & COURAGE Case**

Topics to discuss:
- How technologies are compared
- Cost-effectiveness plan
- The COURAGE Study
- Measuring Costs

Readings:
- **Gold, Chapter 6**
  - WSJ: A Simple Health-Care Fix Fizzles Out, February 11, 2010
  - Boden et al., “Optimal Medical Therapy with or without PCI for Stable Coronary Disease, NEJM, 2007
  - Comparative Effectiveness, NYT, 2-16-2009

**Week 5: (2/24) Measuring effectiveness**

Topics to discuss:
- Health States 101
- Specifying clinical outcomes
- Quality-adjusted life years (QALYs)
- Measuring outcomes
- Use of decision trees in effectiveness analysis

Readings:
- **Gold, Chapter 4**
Week 6: (3/3) Midterm – Closed Book

Week 7: (3/10) Using Secondary Data for Market Research

Topics to discuss:
- Estimating the demand for new technologies
- Measuring the burden of illnesses of disease
- Using administrative insurance records to estimate market demand & market research
- Cost versus charges
- Measuring costs

Readings:

Week 8: (3/17) Spring Break

Week 9: (3/24) Medical Technology Leadership Roundtable – Project Commissioning

Guest speakers: TBD

Topics to discuss:
- What evaluations are of interest to health insurers?
- How do medical providers get new services to the market? What supporting analysis do they need?
- What are the common interest of medical technology firms, providers and insurers?

Week 10: (3/31) Project Start-up and Medical Technology Market Research & Channels

Topics to discuss:
- Getting the right price in the market
- Company promotion of economic evidence
Readings:


**Week 11: (4/7) Advanced Topics 1**

Topics to discuss:
- Bayes Rule
- Uncertainty
- Introduction to decision analysis & Monte Carlo simulation

Readings:

**Week 12: (4/14) Advanced Topics 2**

Topics to discuss:
- Decision analysis & Monte Carlo simulation
- Sensitivity analyses

Readings:
- Gold, Chapters 7 & 8

**Week 13: (4/21) Cost-effectiveness for Medical Technology Development**

Readings:
- Medicare coverage center
- Health Technology Assessment international links

Week 14: (4/28) Final Exam – Closed Book

Week 15: (5/5) Presentations & Closing