MILI 6589/PUBH 6589
MEDICAL TECHNOLOGY EVALUATION AND MARKET RESEARCH
Medical Industry Leadership Institute
Carlson School of Management
and
The Division of Health Policy and Management,
School of Public Health
University of Minnesota, Twin Cities
CSOM, Room L-122, 3:45 to 5:25
Instructors: Eric Barrette, Ph.D. and Lindsay Bockstedt, Ph.D.

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:
After completing this course, students should have the skills needed to:

● Identify a population to be served by a medical technology.

● Use existing health care data to evaluate a medical technology.

● Inventory the costs of using a new medical technology and its alternative(s).

● Complete a meta-analysis of an emerging medical technology.

● Understand the design process of an evaluation.

● Complete a cost/benefit and cost/effectiveness analysis of a new technology.

● Describe the strategy for medical technology results dissemination and marketing.
• Understand the reimbursement systems financing medical technology use.

• 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 cumulative, closed book and focus on practical applications of the methods and topics discussed in class.
- 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 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

**Group Project**

Teams of no more than five students will work on the group project. The group project topics will be commissioned by a combination of class participants, instructors, and industry leaders during the first half of the semester. Groups will be determined mid-way through the course. For the first half of the semester, beginning each week, a student, instructor, and/or an industry leader will present a project proposal (2-3 minutes) using the template below:

- Topic (What is the drug, device, or policy change?)
• Significance (Why is this topic to health care?)
• Research question: (What would a med tech evaluation seek to answer about this topic?)

The project proposals will be collected and voted on by the students and teams will be assigned based on individual preferences. A superior grade will result from clever, effective use of data sources and clear and sensible analyses. Professional-quality team presentations will conclude the course. Presentations must be made in 10 minutes followed by five minutes of Q & A. A group paper describing the topic background, analysis methods, results and conclusions will be due at the time of the presentations.

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 by appointment with instructors. Appointments are best made by e-mail: bock0056@umn.edu; barre142@umn.edu
MEDICAL TECHNOLOGY EVALUATION
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SYLLABUS

Week 1: (1/26) Course Overview & Introduction to Medical Technology Market

Topics to discuss:

- 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?
- Who are the relevant stakeholders and decision makers?

Readings:

- Hartman, M., et al., “National Health Spending In 2013: Growth Slows, Remains In Step With The Overall Economy,” Health Affairs; published ahead of print December 3, 2014
- (O) Cutler, D., McClellan, M. “Is Technological Change in Medicine Worth It?” Health Affairs, 20 no. 5 (2001): 11-29

Week 2: (2/2) The Medical Technology Economy – U.S. Regulatory, Coverage & Payment Policy

Topics to discuss:

- Why are we creating evidence/information demand - who is demanding evidence, what type of evidence, and why?
- What is the ‘supply chain’ of information dissemination?
- How are new medical technologies reimbursed?

Readings:

- FDA.gov (the FDA tour)
- CMS Innovator’s Guide
- (O) Health Affairs, Richard Merrill, 1999


Guest Lecturer: Joe Fleming, Sr. Director Market Development/Patient Access Acceleration, Medtronic, Inc.

Topics to discuss:

- What is health technology assessment?
- How to quantify barriers to market adoption?
- Estimating patient populations

**Required Readings:**


**Week 4: (2/16): Clinical Evidence – Developing, Evaluating and Synthesizing**

Topics to discuss:

- What are the different trial designs and how do they differ?
- How do you judge the quality of clinical evidence?
- Evidence development planning

**Readings:**

Week 5 (2/23): Cost-Effectiveness Analysis Overview Summary & COURAGE Case

Topics to discuss:

- Identifying clinical alternatives
- CEA/CBA/CUA Ratios
- How technologies are compared
- The COURAGE Study

Readings:

- Gold, Chapter 1& 6
- Boden et al., “Optimal Medical Therapy with or without PCI for Stable Coronary Disease, NEJM, 2007
- (O) Comparative Effectiveness, NYT, 2-16-2009

Week 5: (2/23) Data 1: Measuring Effectiveness and Populations

Topics to discuss:

- Health States 101
- Specifying relevant clinical outcomes
- Quality-adjusted life years (QALYs)
- Measuring outcomes
- Estimating a population (incidence v. prevalence)

Readings:

- Gold, Chapter 4

Week 6: (3/2) Data 2: Using Secondary Data for Market Research

Topics to discuss:

- Measuring costs
- Measuring the burden of illnesses of disease
- Using administrative insurance records for market research
- Cost versus charges

Readings:


Week 7: (3/9) Midterm – Closed Book

Week 8: (3/16) Spring Break

Week 9: (3/23) Project Start-Up and Analytical Methods

Topics to discuss:

- Bayes Rule
- Uncertainty
- Decision model
- Introduction to decision analysis & Monte Carlo simulation

Readings:

- Apple et al. “Validation of the 99th percentile cutoff independent of assay imprecision (CV) for cardiac troponin monitoring for ruling out MI,” Clinical Chemistry 51, No. 11, 2005
- (O) Gold, Chapter 7 & 8
**Week 10: (3/30) Payer Evaluation of Technology**

Guest Lecture: Nancy Walczak, FSA, PhD., Vice President, The Lewin Group

Readings: TBD

**Week 11: (4/6) Price Transparency**

Topics to discuss:

- What is known about prices in the market?
- What are the benefits and drawbacks of increased transparency?

Readings:

- Whaley, C. “Association between availability of health services prices and payments for these services” JAMA. 2014; 312(16):1670-1676

**Week 12: (4/13) Pay for Value – Value-Based and Risk-Based Go to Market Strategies**

Topics to discuss:

- Getting the right price in the market
- Risk-sharing Agreements

Readings:

Week 13: (4/20) Cost-effectiveness for Medical Technology Development

Readings:

- NYT Article: Forbidden Topic in Health Policy Debate: Cost-Effectiveness

Week 14: (4/27) Final Exam – Closed Book

Week 15: (5/4) Presentations to Panel