

MILI/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

Hubert Humphrey 35, 3:45 to 5:25

2 Credits

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 or 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 4
 - Chapter 6
 - Chapter 7
 - Chapter 8

Course Logistics

- The course will meet once a week throughout a semester.
 - The course will be team taught by Drs. Town and Parente.
 - 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 ehealthecon.hs.network.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.

Course Secondary Data Resources

- Diagnosis (ICD9) Code Spreadsheet
 - Procedure Code Spreadsheet

NEW Data sources for projects Inventory

Course Instructors

- Stephen T. Parente, Ph.D., Associate Professor, Carlson School of Management
 - Robert Town, Ph.D., Associate Professor, School of Public Health

Office hours will be by appointment with each instructor. Appointments are best made by e-mail: sparente@umn.edu, rjtown@umn.edu

Course Project Templates

Project Presentations

- Stroke Treatment Technology
- Asthma Technology
- [Carelink](#) Technology

Project Reports

- Stroke Treatment Technology
- Asthma Technology
- [Carelink](#) Technology

MEDICAL TECHNOLOGY EVALUATION AND MARKET RESEARCH

SYLLABUS

Week 1: (1/26) Course Overview – [Principals & Agents in Medical Technology Evaluation](#) – STP & RJT

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:

- ▶ Medtronic stock dips on FDA stent report. CNNMoney.com, October 5, 2007.
- ▶ Big Trouble for Merck, The Economist, November 4, 2004.
- ▶ Vioxx_Ingenix, Star Tribune, December, 2004.
- ▶ Biotechnology Needs to Grow Up. The Economist, 2006.
- ▶ Bench to Bed. The Economist, 2006

[Week 2: \(2/2\) The Medical Technology Economy – RJT](#)

Topics to discuss:

- Information demand – who is demanding evidence?
 - [FDA.gov \(the FDA tour\)](#)

- [Health Affairs, Richard Merrill, 1999](#)

- What is the 'supply chain' of information dissemination?
- How are new medical technologies reimbursed?
- Why are we creating evidence?

Readings:

- ▶ [McClellan & Tunis, 1/20/2005, NEJM](#)
- ▶ [Gold, Chapter 1](#)
- ▶ [Detsky, A, Laupacis, A. Relevance of Cost-effectiveness Analysis to Clinicians and Policy Makers, JAMA, July 11, 2007, 298:221-224.](#)
- ▶ [Goldman DP, Jena AB, Philipson T, and Sun E. Drug Licenses: A New Model for Pharmaceutical Pricing. Health Affairs 27, no. 1 \(2008\): 122–129.](#)
- ▶ [Danzon PM and Furukawa MF. International Prices and Availability of Pharmaceuticals in 2005. Health Affairs 27, no. 1 \(2008\): 221–233.](#)

Week 3: (2/9) Introducing Cost-Effectiveness Analysis – RJT

Topics to discuss

- Identifying clinical alternatives
- Using existing data to alternatives

Readings:

- ▶ Gold, Chapter 6
- ▶ [Mark DB, Hlatky MA, Califf RM, et al. Cost effectiveness of thrombolytic therapy with tissue plasminogen activator as compared with streptokinase for acute myocardial infarction. *N Engl J Med.* 1995;332:1418-1424.](#)

Week 4: (2/16) Use of Secondary Data for Market Research – RJT/STP

Market research memo #1 presented. Memo #1 Due 2/23/08

- [Ehealthecon SQL Server link](#) (Userid: MILI6589, password: puppydog)
- [Memo #1 instructions](#)

- [Use SQL language example using rx_sel](#)
- [WSJ Article on Pfizer acquisition, 2009.](#)
- [FDA Manufacturer web link](#)
- [Comparative Effectiveness, NYT, 2-16-2009](#)

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

Readings:

- ▶ [Parente, S.T., Weiner, J.P., Garnick, D. et al. Developing a Quality Improvement Database Using Health Insurance Data: A Guided Tour with Application to Medicare's Claims History File. American Journal of Medical Quality, Winter 1995, pp. 162-176.](#)
- ▶ [Motheral BR, Fairman KA. The use of claims databases for outcomes research: rationale, challenges, and strategies. Clinical Therapeutics 1997;19\(2\):346-366.](#)
- ▶ [Schulman KA, Yabroff KR, Kong J, Gold KF, Rubenstein LE, Epstein AJ, Glick H. A claims data approach to defining an episode of care. Health Serv Res 1999 Jun;34\(2\):603-21.](#)

Week 5: (2/23) Measuring costs – STP

Memo #1 (from 2/16) due

Topics to discuss

- Defining costs
- Cost versus charges
- Measuring costs
- Discount rates
- Time preferences

Readings:

- ▶ [Parente, S. "Estimating the Economic Cost Offsets of Using Dermagraft-TC as an Alternative to Cadaver Allograft in the Treatment of Graftable Burns," *Journal of Burn Care and Rehabilitation* 18, 1 \(1997\).](#)
- ▶ [Bridges et al, JAMA 2000. - - - READ THIS](#)
- ▶

Week 6: (3/2) Measuring effectiveness – STP

League Table exercise (from 2/16) due

Topics to discuss:

- Health States 101
- Specifying clinical outcomes
- Measuring outcomes
- Use of decision trees in effectiveness analysis

Readings:

- ▶ [Value-Based Insurance Design. Chernew ME, Rosen AB, Fendrick AM. *Health Affairs*, 26, no. 2 \(2007\): w195–w203.](#)

- ▶ [Cost Of Living Now Outweighs Benefits The Onion - America's Finest News Source, April 13, 2005.](#)
- ▶ [Palmer C et al. A cost-effectiveness clinical decision analysis model for schizophrenia. Am J of Managed Care. 1998;4:345-355.](#)
- ▶ [S. Ramsey. Economic Analyses and Clinical Practice Guidelines: Why not a match made in heaven? Editorial in JGIM 2002; 17:235-237.](#)
- ▶ Gold, Chapter 4
 - ▶

Week 7: (3/9) Midterm – Closed Book

Week 8: (3/23) Medical Technology Leadership Roundtable – Active Learning

- Guest speakers (invited):
 - Richard Justman, MD, [United Health Group](#)
 - Joseph Fleming, [Medtronic](#)
 - Jade Sadosty, [Mayo Clinic](#)

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?

Readings

- ▶ [Sculpher M, Drummond M, O'Brien B. Effectiveness, efficiency, and NICE. \[editorial\] BMJ 2001;322:943-44.](#)



Week 9: [\(3/30\) Project Jump Starts & Advanced Topics 1 - STP](#)

Topics to discuss

- Cost/Benefit Ratios
- Cost/Effectiveness Ratios
- Sensitivity analyses
- Uncertainty
- Monte carlo simulation

Readings:

- ▶ [Smith and Roberts: Cost-effectiveness of sildenafil. Annals of Internal Medicine 2000;132:933-37.](#)
- ▶ [Rennie D, Luft HS. Pharmacoeconomic analyses: making them transparent, making them credible. JAMA. 2000;283:2158-60.](#)

Week 10: [\(4/6\) Advanced Topics 2 - RT](#)

Topics to discuss

- Statistical Uncertainty
- Baye's Rule
- Monte Carlo simulation

Readings:

- ▶ Gold, Chapters 7 & 8

- ▶ [Neumann PJ, Kuntz KM, Leon J, Araki SS, Hermann RC, Hsu MA, and Weinstein MC. Health Utilities in Alzheimer's Disease: A Cross-Sectional Study of Patients and Caregivers. Medical Care, 1999;37:27-32.](#)

Week 11: [\(4/13\) International Considerations](#) – STP

- ▶ [Medicare coverage center](#)
- ▶ [Health Technology Assessment international links](#)
- ▶ [Neumann et al. Medicare's National Coverage Decisions, 1999-2003: Quality of Evidence and Review Times. Health Affairs, 24\(1\), 2005, pp.243- 254.](#)

Week 12: (4/20) Medical Technology Market Research & Channels

Alex Clyde, Medtronic

Topics to discuss:

- Getting the right price in the market
- Corporate strategy in the real world
- Technology company promotion of economic evidence

Readings:

- ▶ [Lubeck DP, Mazonson PD, Bowe T. Potential effect of tacrine on expenditures for Alzheimer's disease. Medical Interface. 1994;Oct:130-138.](#)
- ▶ [Henke CJ, Burchmore MJ. The economic impact of tacrine in the treatment of Alzheimer's disease. Clin Ther. 1997;19\(2\):330-344.](#)
- ▶ [Lyles A. Direct marketing of pharmaceuticals to consumers. Annual Review of Public Health. 2002;23:73-91.](#)

Week 13: (4/27) Final Exam – Closed Book

Week 14: (5/4) Presentations & Closing