



HEALTH CARE TECHNOLOGY POLICY



PH222A (#76130)

Fall 2009

Mondays 4-6pm

2030 VLSB

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Health Economics

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Technology (BCHT)

Course Objectives & Structure:

New drugs, biologics, diagnostics, and medical devices are extending life and reducing disability for patients, including many with the most severe conditions, and the life sciences sector is among the most innovative in the economy. Yet payment for new clinical technologies is exerting severe fiscal pressures on public and private health financing systems, contributing to cost growth and, thereby, to the erosion of insurance coverage for millions of vulnerable citizens. A wide range of legislative and regulatory proposals impact the technology development, payment, and utilization process, including comparative effectiveness research, authorization of biosimilars, pricing and payment methods, limits on financial conflicts of interest, price transparency, and others.

This course focuses on the policy challenges and opportunities for the development, financing, and use of new health care technologies. The central focus is on the imperative to balance

innovation and affordability through the evaluation of clinical and economic performance, new forms of insurance and consumer cost-sharing, regulation of safety and effectiveness, methods of pricing and payment, and incentive alignment among physicians, patients, payers, and technology producers. We will integrate elements from the national health care reform process as it unfolds. Guest speakers will be brought in from the biotechnology, medical device, and insurance sectors.

Learning objectives:

- Students will understand the basic structure of safety and effectiveness regulation for new drugs and devices at the Food and Drug Administration and be able to participate in the contemporary debates over:
 - The appropriate role for ‘comparative effectiveness research’ to support that structure,
 - The appropriate regulatory approval pathway for ‘biosimilars’ and how these differ from the pathway for ‘generic’ oral pharmaceuticals
 - The debate over the role, if any, for cost effectiveness in regulatory approval for new medical technologies
- Students will understand the basic structure of insurance coverage for new medical technologies at both Medicare and the private health insurance firms, and be able to participate in the contemporary debates over how to improve the value of covered technologies through such mechanisms as:
 - Prior authorization, step therapy, and ‘coverage with evidence development’
 - Pricing and reimbursement methods
 - Consumer cost sharing in health insurance, including ‘four tier formularies’
- Students will understand the basic structure of how physicians and hospitals choose which new technologies to adopt, and be able to participate in contemporary debates over appropriate versus inappropriate financial incentives relating to technology adoption, including:
 - Physician and hospital payment methods
 - Price transparency for medical devices and other therapies
 - Limits on physician financial conflicts of interest

Students are expected to read the course materials for each section prior to coming to class and to participate in class discussions. Course readings are available at bspace.berkeley.edu. Questions should be addressed to Professor Robinson via email (james.robinson@berkeley.edu) or in office hours (Mondays 2-4 and by appointment, 247B University Hall).

Course Requirements and Grading:

- 1) 25% - The first assignment will be handed out in class October 5 and due back in class three weeks later, October 26. You will be asked to write a 10 page paper analyzing proposals for enhanced 'comparative effectiveness research' and for 'cost effectiveness analysis' to support insurance coverage and payment decisions for new biomedical technologies.
- 2) 25% - The second assignment will be handed out in class November 2 and due back in class two weeks later, November 16. You will be asked to write a 10 page paper analyzing current insurance coverage for high-cost cancer drugs, interpret proposals for 'value based benefit design', and propose a benefit design for cancer drugs that incorporates value principles.
- 3) 25%. The third assignment will center on the potential implications of health care reform for the process of development, purchasing, and use of new diagnostic and therapeutic technologies. Students will be assigned to groups of four and will analyze particular aspects of the reform legislation as it unfolds during the fall. Each group will present its analysis on the last day of class, December 7, to an audience that includes several outside experts as well as the class.
- 4) 25% - Attendance and class participation.

Course Schedule and Readings:

1. (August 31): Introduction and Overview

2. (September 14): Balancing Innovation and Affordability in Health Care Technology

Readings:

PR Orszag, P Ellis. The Challenge of Rising Health Care Costs: A View from the Congressional Budget Office. NEJM 2007; 357:1793-95.

<http://content.nejm.org/cgi/reprint/357/18/1793.pdf>

D Cutler and M McClellan. "Is Technological Change in Medicine Worth it?" Health Affairs, 2001; 20(5):11-29. <http://content.healthaffairs.org/cgi/reprint/20/5/11>

Congressional Budget Office. Technological Change and the Growth of Health Care Spending. Washington DC: US Congress, Congressional Budget Office. January 2008. <http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf>

California Healthcare Institute. California Biomedical Institute 2009 Report.

<http://www.chi.org/uploadedFiles/2009%20California%20Biomedical%20Industry%20Report%20FINAL.pdf>

3. (September 21): Comparative Effectiveness Research

Readings:

Congressional Budget Office. Research on the Comparative Effectiveness of Medical Treatments. Washington DC: CBO. December 2007.

https://www.ecri.org/Documents/CERC/CBO_12-18-ComparativeEffectiveness.pdf

Tunis, SR, DB Stryer, CM Clancy. "Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy." JAMA 2003; 290(12): 1624-1632. <http://jama.ama-assn.org/cgi/reprint/290/12/1624>

Institute of Medicine. Initial National Priorities for Comparative Effectiveness Research. Report Brief, June 2009. www.iom.edu/cepriorities

RH Brook. Possible Outcomes of Comparative Effectiveness Research. JAMA 2009; 302:194-95. <http://jama.ama-assn.org/cgi/reprint/302/2/194>

4. (September 28): The Medical Device Sector: Policy Challenges and Opportunities

Guest speaker: Kristen Stewart, VP Medical Devices and Supplies, Credit Suisse

Readings:

K Stewart and C Hu. MedTech Boot Camp Primer, Edition 1. New York: Credit Suisse, March 23, 2009.

5. (October 5): Cost-Effectiveness Analysis

Readings:

JM Eisenberg. Clinical Economics: A Guide to the Economic Analysis of Clinical Practices. JAMA 1989; 262:2879-2886.

Tunis, SR. "Economic Analysis in Healthcare Decisions". The American Journal of Managed Care, May 2004; 10(5):301-304.

http://www.ajmc.com/files/articlefiles/AJMC04mayTunisEdtl_301_04.pdf

American College of Physicians. Position Paper. Information on Cost Effectiveness: An Essential Product of a National Comparative Effectiveness Program. Annals of Internal Medicine 2008; 12:148.

https://www.ecri.org/Documents/CERC/ACP_Annals_of_Internal_Medicine.pdf

Neumann, PJ. "Why Don't Americans Use Cost-Effectiveness Analysis?" The American Journal of Managed Care, May 2004; 10(5):308-

312.http://www.ajmc.com/files/articlefiles/AJMC04MayNeumann308_12.pdf

Steinbrook R. Saying No Isn't NICE: The Travails of Britain's National Institute for Health and Clinical Excellence. NEJM 2008; 359:1977-81.

<http://content.nejm.org/cgi/reprint/359/19/1977.pdf>

6. (October 12). Regulatory Authorization for Biosimilars

Readings:

H Grabowski, I Cockburn, and G Long. The Market for Follow-On Biologics: How Will It Evolve? Health Affairs 2006; 25:1291-1301.

<http://content.healthaffairs.org/cgi/reprint/25/5/1291>

Federal Trade Commission. Emerging Health Care Issues: Follow-on Biologic Competition (Executive Summary). June 2009.
<http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>

7. (October 19). Medicare, Medicaid, and Pharmaceuticals

Guest speaker: Adina Safer

Readings:

K Outterson and AS Kesselheim. How Medicare Could Get Better Prices on Prescription Drugs. Health Affairs 2009; 28(5):w832-841, (web exclusive July 30, 2009).
<http://content.healthaffairs.org/cgi/content/short/hlthaff.28.5.w832>

P Neuman and J Cubanski. Medicare Part D Update: Lessons Learned and Unfinished Business. New England Journal of Medicine 2009; 361(4):406-414.
<http://content.nejm.org/cgi/reprint/361/4/406.pdf>

8. (October 26). The Diffusion of Advanced Imaging Technologies

Readings:

LC Baker, SC Atlas, and CC Afendulis. Expanded Use of Imaging Technology and the Challenge of Measuring Value. Health Affairs 2008; 27:1467-78.
<http://content.healthaffairs.org/cgi/reprint/27/6/1467>

SD Pearson et al. Assessing the Comparative Effectiveness of a Diagnostic Technology: CT Colonoscopy. Health Affairs 2008; 27(6):1503-1514.
<http://content.healthaffairs.org/cgi/content/full/27/6/1503>

JR Iglehart. Health Insurers and Medical-Imaging Policy: A Work in Progress. NEJM 2009; 360:1030-37. <http://content.nejm.org/cgi/reprint/360/10/1030.pdf>

AHIP. Ensuring Quality through Appropriate Use of Diagnostic Imaging. Washington DC: America's Health Insurance Plans. July 2008.
<http://www.ahip.org/content/default.aspx?docid=24057>

J Appleby. The Case of CT Angiography: How Americans View and Embrace New Technology. Health Affairs 2008; 27:1515-1521.
<http://content.healthaffairs.org/cgi/reprint/27/6/1515>

RF Redberg and J Walsh. Pay Now, Benefits May Follow: The Case of Cardiac Computed Tomographic Angiography. NEJM 2008; 359:2309-11.
<http://content.nejm.org/cgi/reprint/359/22/2309.pdf>

TH Lee, TA Brennan. Direct-to-Consumer Marketing of High-Technology Screening Tests. NEJM 2002; 346(&):529-531. <http://content.nejm.org/cgi/content/full/346/7/529>

9. (November 2). Insurer Strategies for Managing Biologics

Readings:

JC Robinson. Insurers' Strategies for Managing the Use and Cost of Biopharmaceuticals. *Health Affairs* 2006; 25:1205-17.

<http://content.healthaffairs.org/cgi/reprint/25/5/1205.pdf>

WT McGivney and J Mullen. Cancer and Managed Care in the 21st Century. *American Journal of Managed Care* 2005; 11(17, supplement):S509-S521.

http://www.ajmc.com/media/pdf/A142_05decMcGivneyS509.pdf

TH Lee, EJ Emanuel. Tier 4 Drugs and the Fraying of the Social Compact. *NEJM* 2008; 359:333-335. <http://content.nejm.org/cgi/reprint/359/4/333.pdf>

Genentech, Inc. The Genentech Oncology Trend Report, 2008. (To be handed out in class)

10. (November 9). Health Care Reform: Potential Implications for Biomedical Technology

Guest speakers: Brian O'Shea and Evan Morris, Genentech

11. (November 16). Physician Conflicts of Interest over Drugs, Devices, and Imaging

Readings:

EG Campbell. Doctors and Drug Companies: Scrutinizing Influential Relationships. *NEJM* 2007; 357:1796-97. <http://content.nejm.org/cgi/reprint/357/18/1796.pdf>

Steinbrook R. Disclosure of Industry Payments to Physicians. *NEJM* 2008; 359:559-562. <http://nejm.highwire.org/cgi/reprint/359/6/559.pdf>

Steinbrook R. Controlling Conflict of Interest: Proposals from the Institute of Medicine. *NEJM* 2009; 360:2160-2165. <http://content.nejm.org/cgi/reprint/360/21/2160.pdf>

JM Mitchell. The Prevalence of Physician Self-Referral Arrangements after Stark II: Evidence from Advanced Diagnostic Imaging. *Health Affairs* 2007; 26:W415-424. <http://content.healthaffairs.org/cgi/reprint/26/3/w415>

12. (November 23). Price Transparency for Medical Devices

Readings:

JC Robinson and A Bridy. Confidentiality and Transparency for Medical Device Prices: Market Dynamics and Policy Alternatives. Report to the California Healthcare Foundation, 2009.

MV Pauly and LR Burns. Price Transparency for Medical Devices. *Health Affairs* 2008; 27(6):1544-53. <http://content.healthaffairs.org/cgi/reprint/27/6/1544.pdf>

RW Hahn, KB Klovers, and HJ Singer. The Need for Greater Price Transparency in the Medical Device Industry: An Economic Analysis. *Health Affairs* 2008; 27(6):1554-59. <http://content.healthaffairs.org/cgi/reprint/27/6/1554.pdf>

JC Lerner et al. The Consequence of Secret Prices: The Politics of Physician Preference Items. Health Affairs Health Affairs 2008; 27(6):1560-65.
<http://content.healthaffairs.org/cgi/reprint/27/6/1560.pdf>

13. (November 30). Physician/Hospital Gainsharing: Orthopedic and Cardiac Devices

Readings:

GR Wilensky, N Wolter, and MM Fisher. Gain-Sharing: A Good Concept Getting a Bad Name. Health Affairs 2006; 26:W58-71.

<http://content.healthaffairs.org/cgi/reprint/26/1/w58.pdf>

JD Ketcham and MF Furakawa. Hospital-Physician Gainsharing in Cardiology. Health Affairs 2008; 27(3):803-12. <http://content.healthaffairs.org/cgi/reprint/27/3/803.pdf>

HH Pham et al. Redesigning Care Delivery in Response to a High-Performance Network: The Virginia Mason Medical Center. Health Affairs 2007; 26(4):w532-44.

<http://content.healthaffairs.org/cgi/reprint/26/4/w532.pdf>

14. (December 7; last class). Student Presentations on Health Reform and Health Technology

Panelists: Weslie Kary (Integrated Healthcare Association), Brian O'Shea (Genentech), Adina Safer (CVS Caremark), Jill Yegian (California Healthcare Foundation)